

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 411, 424, 435, and 455

[HCFA-1809-P]

RIN 0938-AG80

Medicare and Medicaid Programs; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would incorporate into regulations the provisions of sections 1877 and 1903(s) of the Social Security Act. Under section 1877, if a physician or a member of a physician's immediate family has a financial relationship with a health care entity, the physician may not make referrals to that entity for the furnishing of designated health services under the Medicare program, unless certain exceptions apply. The following services are designated health services:

- Clinical laboratory services.
- Physical therapy services.
- Occupational therapy services.
- Radiology services, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services.
- Radiation therapy services and supplies.
- Durable medical equipment and supplies.
- Parenteral and enteral nutrients, equipment, and supplies.
- Prosthetics, orthotics, and prosthetic devices and supplies.
- Home health services.
- Outpatient prescription drugs.
- Inpatient and outpatient hospital services.

In addition, section 1877 provides that an entity may not present or cause to be presented a Medicare claim or bill to any individual, third party payer, or other entity for designated health services furnished under a prohibited referral, nor may the Secretary make payment for a designated health service furnished under a prohibited referral.

Section 1903(s) of the Social Security Act extended aspects of the referral prohibition to the Medicaid program. It denies payment under the Medicaid program to a State for certain expenditures for designated health services. Payment would be denied if the services are furnished to an individual on the basis of a physician

referral that would result in the denial of payment for the services under Medicare if Medicare covered the services to the same extent and under the same terms and conditions as under the State plan.

This proposed rule incorporates these statutory provisions into the Medicare and Medicaid regulations and interprets certain aspects of the law. The proposed rule is based on the provisions of section 1903(s) and section 1877 of the Social Security Act, as amended by section 13562 of the Omnibus Budget Reconciliation Act of 1993, and by section 152 of the Social Security Act Amendments of 1994.

DATES: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on March 10, 1998. We will also consider comments that we received in response to the final rule with comment period, "Physician Financial Relationships With, and Referrals to, Health Care Entities That Furnish Clinical Laboratory Services and Financial Relationship Reporting Requirements," which we published in the **Federal Register** on August 14, 1995 (60 FR 41914).

ADDRESSES: Mail written comments (1 original and 3 copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: HCFA-1809-P, 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 C5-09-26, 7500 Security Boulevard, Baltimore, MD 21244-1850.

Comments may also be submitted electronically to the following e-mail address: hcfa1809p.hcfa.gov. E-mail comments must include the full name and address of the sender and must be submitted to the referenced address in order to be considered. All comments must be incorporated in the e-mail message because we may not be able to access attachments. Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA-1809-P. 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).

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FOR FURTHER INFORMATION CONTACT: Joanne Sinsheimer (410) 786-4620.

SUPPLEMENTARY INFORMATION: To assist readers in referencing sections contained in this proposed rule, we are providing the following table of contents:

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I. Background

A. Problems Associated With Physician Self-referrals

When a patient seeks medical care, his or her physician has a major role in determining the kind and amount of health care services the patient will receive. Having a financial interest in an entity that furnishes these services can affect a physician's decision about what medical care to furnish a patient and who should furnish the care. In fact, numerous studies have raised serious concerns about the referral patterns of physicians who make self-referrals (referrals to entities with which they or their family members have financial relationships).

In June 1988, Congress mandated that the Office of Inspector General (OIG) of the Department of Health and Human Services conduct a study on physician ownership of and compensation from health care entities to which the physicians make referrals. The OIG reported that patients of referring physicians who owned or invested in independent clinical laboratories received 45 percent more laboratory services than all Medicare patients in general. The OIG found similar effects on utilization associated with the existence of compensation arrangements between laboratories and physicians. Patients of these physicians used 32 percent more laboratory services than all Medicare patients in general. ("Financial Arrangements Between Physicians and Health Care Businesses: Report to Congress," Office of Inspector

General, DHHS, pages 18 and 21 (May 1989)). Based in part on the results of this study, Congress enacted, in November of 1989, section 1877 of the Social Security Act (the Act). (Unless otherwise indicated, references to sections of the law below are to sections of the Act.) We discuss section 1877 in detail below.

Subsequent studies have supported the OIG findings on self-referrals. The studies indicate that other types of services are also associated with higher utilization and increased costs. For example, in 1991 the Florida Cost Containment Board (the Board) analyzed the effect of joint venture arrangements on the following aspects of health care: access, costs, charges, utilization, and quality. A joint venture was defined as any ownership or investment interest or compensation arrangement involving physicians (or any health care professionals who make referrals) and an entity providing health care goods or services.

The Board found that doctor-owned clinical laboratories, diagnostic imaging centers, and physical therapy and rehabilitation centers performed more procedures on a per-patient basis and charged higher prices than nondoctor-affiliated facilities. The Board concluded that there might be referral problems or the results did not allow clear conclusions for ambulatory surgical centers, durable medical equipment suppliers, home health agencies, and radiation therapy centers. The study revealed that little or no impact existed for acute care hospitals and nursing homes. ("Joint Ventures Among Health Care Providers in Florida," State of Florida Health Care Cost Containment Board (Sept. 1991)).

Additionally, in 1994, the General Accounting Office (GAO) released an analysis of 2.4 million diagnostic imaging services ordered by 17,900 physicians in the State of Florida. The GAO found that Florida physicians with a financial interest in joint venture imaging centers had higher referral rates for almost all types of imaging services than other Florida physicians. The differences in the referral rates were greatest for costly high-technology imaging services. For example, owners of joint ventures ordered 54 percent more magnetic resonance imaging scans for patients than did non-owners.

The GAO study also found that Florida physicians, group practices, or other practice affiliations with imaging facilities in their own offices ordered imaging tests more frequently than physicians who referred their patients to imaging facilities outside their practices. The in-practice imaging rates were

about 3 times higher for magnetic resonance imaging scans; about 2 times higher for computed tomograph scans; 4.5 to 5.1 times higher for ultrasound, echocardiography, and diagnostic nuclear medicine imaging; and about 2 times higher for complex and simple X-rays. (GAO Report, "Medicare: Referrals to Physician-owned Imaging Facilities Warrant HCFA's Scrutiny," No. B-253835; pages 2, 3, and 10, October 1994.)

Several other studies, appearing in the New England Journal of Medicine and the Journal of the American Medical Association, have found increased utilization for a variety of services when the physicians have a financial relationship with the entity to which they refer their patients. (See, for example, Bruce J. Hillman, M.D., and others, "Physicians' Utilization and Charges for Outpatient Diagnostic Imaging in a Medicare Population," Journal of the American Medical Association, Vol. 268, No. 15 (Oct. 21, 1992), pp. 2050-2054; Hemenway D., Killen A., and others, "Physicians' Responses to Financial Incentives—Evidence From a For-profit Ambulatory Care Center," New England Journal of Medicine, Vol. 322, No. 15 (April 12, 1990), pp. 1059-1063; Alex Swedlow and others, "Increased Costs and Rates of Use in the California Workers' Compensation System as a Result of Self Referral by Physicians," New England Journal of Medicine, Vol. 327, No. 21 (Nov. 19, 1992), pp. 1502-1506.)

B. Legislation Designed to Address Self-referrals and Similar Practices

1. Legislative History of Section 1877

Section 6204 of the Omnibus Budget Reconciliation Act of 1989 (OBRA '89), Public Law 101-239, enacted on December 19, 1989, added section 1877 to the Social Security Act. In general, section 1877 as it read under OBRA '89 provided that, if a physician (or an immediate family member of a physician) had a financial relationship with a clinical laboratory, that physician could not make a referral to the laboratory entity for the furnishing of clinical laboratory services for which Medicare might otherwise pay. (For the sake of brevity, whenever we refer to "immediate family member" or "family member," this means "a member of the physician's immediate family.") It also provided that the laboratory could not present or cause to be presented a Medicare claim or bill to any individual, third party payer, or other entity for clinical laboratory services furnished under the prohibited referral. Additionally, it required a refund of any

amount collected from an individual as a result of a billing for an item or service furnished under a prohibited referral.

The statute defined "financial relationship" as an ownership or investment interest in the entity or a compensation arrangement between the physician (or immediate family member) and the entity. The statute provided a number of exceptions to the prohibition. Some of these exceptions applied to both ownership/investment interests and compensation arrangements, while other exceptions applied to only one or the other of these. Additionally, the statute imposed reporting requirements and provided for sanctions.

Section 4207(e) of the Omnibus Budget Reconciliation Act of 1990 (OBRA '90), Public Law 101-508, enacted on November 5, 1990, 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.

Section 13562 of the Omnibus Budget Reconciliation Act of 1993 (OBRA '93), Public Law 103-66, enacted on August 10, 1993, extensively revised section 1877. It modified the prior law to apply to referrals for ten "designated health services" in addition to clinical laboratory services, modified some exceptions, and added new ones. Section 152 of the Social Security Act Amendments of 1994 (SSA '94), Public Law 103-432, enacted on October 31, 1994, amended the list of designated services, effective January 1, 1995. (Section II of this preamble contains a listing of the designated health services.) It also changed the reporting requirements in section 1877(f) and amended some of the effective dates of the OBRA '93 provisions.

Section 13624 of OBRA '93 extended aspects of the referral prohibition to the Medicaid program. It amended section 1903 of the Act by adding a new paragraph (s). This provision denies Federal financial participation (FFP) payment under the Medicaid program to a State for certain expenditures for designated health services. A State cannot receive FFP for designated health services furnished to an individual on the basis of a physician referral that would result in a denial of payment under the Medicare program if Medicare covered the services to the same extent and under the same terms and conditions as under the State Medicaid plan. Section 13624 also specified that the reporting requirements of section 1877(f) and the civil money penalty provision of section

1877(g)(5) (which relates to reporting) apply to a provider of a designated health service for which payment may be made under Medicaid in the same manner as they apply to a provider of a designated health service for which payment may be made under Medicare.

We describe the provisions of section 1877, as amended, in detail in part A of section II of this preamble. We discuss section 1903(s) in part B of section II.

2. Recent Provisions and How They Relate to Each Other

Congress has enacted into law several provisions governing financial relationships between entities furnishing health care services and those health care professionals who refer patients to them. For example, the "anti-kickback statute" provides criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit, or receive remuneration to induce the furnishing of items or services covered by Medicare or State health care programs (including Medicaid, and any State program receiving funds under titles V or XX of the Act). (This provision was originally enacted in 1972 as part of the Social Security Amendments of 1972, Public Law 92-603. It was revised in 1977 (in Public Law 95-142) to read as it does today. It was subsequently recodified by the Medicare and Medicaid Program Patient Protection Act of 1987 (Public Law 100-93). It currently appears at 42 U.S.C. 1320a-7b(b)(2) and section 1128B(b) of the Social Security Act.)

Both the anti-kickback statute and section 1877 address Congress' concern that health care decisionmaking can be unduly influenced by a profit motive. When physicians have a financial incentive to refer, this incentive can affect utilization, patient choice, and competition. Physicians can overutilize by ordering items and services for patients that, absent a profit motive, they would not have ordered. A patient's choice can be affected when physicians steer patients to less convenient, lower quality, or more expensive providers of health care, just because the physicians are sharing profits with, or receiving remuneration from, the providers. And lastly, where referrals are controlled by those sharing profits or receiving remuneration, the medical marketplace suffers since new competitors can no longer win business with superior quality, service, or price. Although the purposes behind the anti-kickback statute and section 1877 are similar, it is important to analyze them separately. In other words, to operate lawfully under Medicare and Medicaid, one must comply with both statutes.

Anti-kickback statute: The anti-kickback statute is a criminal statute that applies to those who *knowingly and willfully* offer, pay, solicit, or receive remuneration to induce the furnishing of items or services under Medicare or State health care programs (including Medicaid). The offense is classified as a felony and is punishable by fines of up to \$25,000 and imprisonment for up to 5 years. Violation of the statute is also a basis for exclusion from Medicare and Medicaid.

Since the statute on its face is very broad, a number of health care entities expressed concern after its enactment that many relatively innocuous, or even beneficial, commercial arrangements are technically covered by the statute and can therefore lead to criminal prosecution. Congress addressed this fact by enacting section 14 of the Medicare and Medicaid Patient and Program Protection Act of 1987. This provision requires the Department of Health and Human Services to issue "safe harbors," specifying those payment practices that will not be subject to criminal prosecution under the anti-kickback statute and will not provide a basis for an exclusion. The safe harbors are not mandatory in the sense that one is *required* to fit into a safe harbor. The safe harbors exist to provide absolute immunity to those arrangements.

Section 1877: Section 1877 prohibits physicians from referring Medicare patients to certain entities for designated health services if the physician (or an immediate family member) has a financial relationship with the entity, *unless* the relationship fits into an exception. Certain aspects of section 1877 also affect Medicaid referrals. While there are other remedies, section 1877 is primarily a payment ban that is effective *regardless of intent*. Many of the exceptions in section 1877 are similar to the safe harbors under the anti-kickback statute, such as exceptions for certain employees, personal service arrangements, and space and equipment rentals. The exceptions are different in the sense that, under section 1877, a physician is *required* to meet an exception if the physician wants to make an otherwise prohibited referral, while under the anti-kickback statute, a health care provider is not required to meet a safe harbor. That is, if a provider meets a safe harbor, it is automatically protected from prosecution. If a provider does not meet a safe harbor, it may still be in compliance with the anti-kickback statute and therefore be safe from prosecution, but that

determination would be based on a case-by-case assessment of the facts.

C. HCFA and OIG Regulations Relating to Section 1877

On December 3, 1991, we issued an interim final rule with comment period (56 FR 61374) setting forth the reporting requirements under section 1877(f). On March 11, 1992, we published a proposed rule (57 FR 8588) setting forth the self-referral prohibition and exceptions to the prohibition in section 1877, as these provisions were amended by OBRA '90, and as they relate to referrals for clinical laboratory services.

On October 20, 1993, the OIG published a proposed rule (58 FR 54096) that would set forth in regulations the penalty provisions specified in sections 1877(g)(3) and (g)(4). The final rule with comment period implementing the civil money penalty provisions was published on March 31, 1995 (60 FR 16580).

On August 14, 1995, we published a final rule with comment period in the **Federal Register** (60 FR 41914) that incorporated into regulations the provisions of section 1877 that relate to the prohibition on physician referrals for clinical laboratory services. The August 1995 final rule contains revisions to the March 11, 1992 proposal based on comments submitted by the public. Further, it incorporates the amendments and exceptions created by OBRA '93 and the amendments in SSA '94 that relate to referrals for clinical laboratory services.

The final rule addresses only those changes that had a retroactive effective date of January 1, 1992; it does not incorporate those modifications made to section 1877 that became effective for referrals made after December 31, 1994. (Even though the August 1995 final rule incorporates OBRA '93 and SSA '94 provisions, it generally only reiterates them without interpreting them. We interpreted the new provisions only in a few instances in which it was necessary to do so in order to implement the statute at all.) The final rule also responds to comments received on the December 1991 interim final rule covering the reporting requirements. In addition, it revises the regulations established by that rule to incorporate the amendments to section 1877(f) made by SSA '94, to apply to any future reporting that we require.

II. Sections 1877 and 1903(s) of the Act and the Provisions of This Proposed Rule

Many of the provisions covered below are discussed in detail in the preamble of either the March 1992 proposed rule

or the August 1995 final rule in the context of referrals for clinical laboratory services. We are proposing, as discussed below, to leave a number of these provisions unchanged except to apply them to the additional designated health services. Readers who desire more background information on these provisions are referred to the earlier documents.

We are also proposing to amend the provisions of the August 1995 final regulation to reflect other changes in section 1877 that were enacted in OBRA '93 or in SSA '94 and became effective on January 1, 1995. In part A of this section, we discuss how we have altered the final regulation to apply it to the additional designated health services, and to reflect the statutory changes in section 1877 that took effect on January 1, 1995. Part B of this section covers the changes made by section 13624 of OBRA '93 to the Medicaid program in section 1903(s) of the Act. Section 13624 applies aspects of the referral prohibition to the Medicaid program for referrals made on or after December 31, 1994. We discuss in part B how we propose to amend the Medicaid regulations to reflect the statutory changes.

In section III of this preamble we discuss in detail how we propose to interpret any provisions in sections 1877 and 1903(s) that we believe are ambiguous, incomplete, or that provide the Secretary with discretion. We also discuss policy changes or clarifications we propose to make to the August 1995 rule. In section IV, we present some of the most common questions concerning physician referrals that we received from the health care community. We include in section IV our interpretations of how the law applies in the situations described to us.

A. Reflecting the Statutory Changes in Section 1877

1. General Prohibition

With certain exceptions, section 1877(a)(1)(A) prohibits a physician from making a referral to an entity for the furnishing of designated health services, for which Medicare may otherwise pay, if the physician (or an immediate family member) has a financial relationship with that entity. This provision as it related to clinical laboratory services was incorporated into our regulations at § 411.353(a) by the August 1995 final rule. We would revise § 411.353(a) to apply the prohibition to referrals for designated health services.

Section 1877(a)(1)(B) prohibits an entity from presenting, or causing to be presented, either a Medicare claim or a

bill to any individual, third party payor, or other entity for designated health services furnished under a prohibited referral. This provision, with regard to clinical laboratory services, was incorporated into our regulations at § 411.353(b) by the August 1995 final rule. We would revise § 411.353(b) to apply it to claims or bills for any of the designated health services.

2. Definitions

For purposes of section 1877, the statute provides definitions of a number of terms. Because they are important to understanding the general prohibition set forth above, we discuss certain of these definitions immediately below. The statutory definitions of other terms are presented elsewhere in this preamble when relevant.

a. Referral, referring physician

As defined by section 1877(h)(5), a "referral" means the following:

- 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).
- The request or establishment of a plan of care by a physician that includes the furnishing of designated health services.

Section 1877(h)(5)(C), however, provides an exception to this definition in the case of a request by a pathologist for clinical diagnostic laboratory tests and pathological examination services, (and as added by OBRA '93) a request by a radiologist for diagnostic radiology services, and a request by a radiation oncologist for radiation therapy if the services are furnished by (or under the supervision of) the pathologist, radiologist, or radiation oncologist, respectively, as a result of a consultation requested by another physician.

The August 1995 final rule incorporated section 1877(h)(5), with regard to clinical laboratory services, into our regulations by defining "referral" at § 411.351. We interpreted a referral as the request by a physician for, or the ordering of, any item or service covered under Medicare Part B. We interpreted the referral for other items or services as 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. We also included the statutory exception for certain clinical diagnostic laboratory tests and pathological examination services requested by a pathologist.

This proposed rule would revise the definition of "referral" to apply it to referrals for designated health services. In accordance with section 1877(h)(5)(C), we would also add the exception to the definition described above relating to a request by a radiologist for diagnostic radiology services and a request by a radiation oncologist for radiation therapy. In addition, we would make a technical change in this section. We would remove the phrase "any item or service" and replace it with the phrase "any service." Because the term "services" is defined in our regulations (at § 400.202) to include "items," the phrase "any item or service" contains a redundancy. Hereinafter, unless we specifically state otherwise, we use the term "service(s)" as including "item(s)." We have also made several other changes to the definition that are discussed in section III of this preamble.

Also, in accordance with section 1877(h)(5), the August 1995 final rule at § 411.351 defined "referring physician" as a physician (or group practice) who makes a referral as defined in § 411.351. This proposed rule would retain this definition, but with one amendment that is described in section IV.A.5 of this preamble.

b. Designated health services

Section 1877(h)(6) defines "designated health services" as any of the following services:

- Clinical laboratory services.
- Physical therapy services.
- Occupational therapy services.
- Radiology services, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services.
- Radiation therapy services and supplies.
- Durable medical equipment and supplies.
- Parenteral and enteral nutrients, equipment, and supplies.
- Prosthetics, orthotics, and prosthetic devices and supplies.
- Home health services.
- Outpatient prescription drugs.
- Inpatient and outpatient hospital services.

This proposed rule would incorporate this definition of "designated health services" into our regulations at § 411.351, except that, for purposes of definition, we would combine radiology services and radiation therapy services and supplies. Also, we propose to define each of these designated health services in § 411.351. We explain our definitions and interpretations in section III of this preamble.

c. Financial relationship

Section 1877(a)(2) describes a financial relationship between a physician (or an immediate family member) 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. (We discuss compensation arrangements in the next section). The statute provides that an ownership or investment interest may be established through equity, debt, or other means. The statute further specifies that an ownership or investment interest includes an interest in an entity that holds an ownership or investment interest in any entity furnishing designated health services.

The August 1995 final rule incorporated this definition into our regulations, with regard to clinical laboratory services, at § 411.351. That section specifies that a financial relationship includes an interest in an entity that holds an ownership or investment interest in any entity providing laboratory services. This proposed rule would revise the definition to specify that a financial relationship includes an interest in an entity that holds an ownership or investment interest in any entity providing designated health services. We have also made certain other changes described in section III of this preamble.

d. Compensation arrangement, remuneration

Section 1877(h)(1)(A) defines a "compensation arrangement" as any arrangement involving any remuneration between a physician (or immediate family member) and an entity, other than an arrangement involving only remuneration described in section 1877(h)(1)(C). Section 1877(h)(1)(B) defines "remuneration" to include "any remuneration, directly or indirectly, overtly or covertly, in cash or in kind." Section 1877(h)(1)(C) provides 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 any other requirements the Secretary may impose by regulation as needed to protect against Medicare program or patient abuse.

The above definitions of a "compensation arrangement" and "remuneration" were incorporated into our regulations at § 411.351 by the August 1995 final rule. In the definition of "compensation arrangement," we clarified that such an arrangement could be either direct or indirect. This proposed rule would retain that definition. Also, because the statute defines "remuneration" only by referring to how the remuneration might be made (for example, in cash or in kind), we interpreted remuneration to mean any payment, discount, forgiveness of debt, or other benefit. This proposed rule would retain the definition of "remuneration," with one change. We will consider that payments made by an insurer to a physician are not "remuneration" if they meet the requirements in the statute, and if the amount of the payment does not take into account directly or indirectly other business generated between the parties. We explain this change in section III.E.3 of this preamble.

3. 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 interests and compensation arrangements.)

Because the first two of these exceptions apply to a "group practice," we begin with a discussion of "group practice" as defined in section 1877. A "group practice," as defined in section 1877(h)(4), is 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 under a billing number assigned to the group, and amounts so received are treated as receipts of the group (the "substantially all" test, which we discuss below). (The predecessor provision, that is, the provision as it read before January 1, 1995, required that the services be billed in the name of the group (not that they be billed under a billing number assigned to the group).)

- The overhead expenses of and the income from the practice are distributed in accordance with methods previously determined.

- Except for profits and productivity bonuses that meet the conditions described below, no physician member of the group directly or indirectly receives compensation based on the volume or value of referrals by the physician. (Added by OBRA '93 to be effective January 1, 1995.)

- Members of the group personally conduct at least 75 percent of the physician-patient encounters of the group practice. (Added by OBRA '93 to be effective January 1, 1995.)

- The group practice complies with all other standards established by the Secretary in regulations.

With regard to the above definition, section 1877(h)(4)(B) establishes the following "Special Rules":

- A physician in a group practice may be paid a share of the overall profits of the group, or a productivity bonus based on services personally performed or services incident to the personally performed services, so long as the share or bonus is not determined in any manner that is directly related to the volume or value of referrals by the physician. (Added by OBRA '93 to be effective for referrals made on or after January 1, 1995.)

- In the case of a faculty practice plan associated with a hospital, institution of higher education, or medical school 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.

Our August 1995 final rule established a definition of "group practice" at § 411.351 based on the statute as it read effective January 1, 1992. In implementing the statute, we interpreted the provision requiring that "substantially all" of the services of the physician members be furnished through the group as meaning 75 percent of the patient care services of the group practice. (We discuss additional requirements and definitions related to the "substantially all" test in section II.A.6. of this preamble.) As stated above, OBRA '93 made certain revisions to the definition of a group practice, effective January 1, 1995. This proposed rule would revise the definition of "group practice" at § 411.351 to conform with the changes made by OBRA '93. Therefore we would do the following:

- Remove the requirement that substantially all of the services must be billed in the name of the group. We would specify, instead, that substantially all of the services must be billed under a billing number assigned to the group.

- Add the above provisions restricting payments made to physicians based on volume or value of referrals, with the exception for profits and productivity bonuses.

- Add that members of the group must personally conduct at least 75 percent of the physician-patient encounters of the group practice.

In addition, for reasons explained in the August 1995 final rule, the definition would continue to provide that the "substantially all" test does not apply to any group practice that is located solely in a health professional shortage area (HPSA). Also, for group practices located outside of a HPSA, any time spent by group practice members providing services in a HPSA should not be used to calculate whether the group practice located outside the HPSA has met the "substantially all" test. We have also made several other changes to the definition of a group practice, which are discussed later in this preamble.

a. Exception—physician services

Section 1877(b)(1) specifies that the prohibition does not apply to services furnished on a referral basis if the services are physician services, as defined in section 1861(q), furnished personally by (or under the personal

supervision of) another physician in the same group practice as the referring physician. Our August 1995 final rule incorporated this provision at § 411.355(a), covering physician services as we have defined them at § 410.20(a). This proposed rule retains § 411.355(a).

b. Exception—in-office ancillary services

Section 1877(b)(2) specifies that the prohibition does not apply to referrals for certain in-office ancillary services. We consider in-office ancillary services to be all designated health services that can be provided in an in-office setting, except durable medical equipment (excluding infusion pumps) and parenteral and enteral nutrients, equipment, and supplies. (In other words, referrals for infusion pumps can qualify for the exception. However, the exception does not apply to referrals for the in-office provision of other durable medical equipment and parenteral and enteral nutrients, equipment, and supplies.) To qualify for the exception, an ownership or investment interest in the services must meet any requirements the Secretary sets forth in regulations to protect against Medicare program or patient abuse. Additionally, the ancillary services must meet the following requirements:

- The services must be furnished personally by the referring physician, a physician who is a member of the same group practice as the referring physician, or an individual who is directly supervised by the physician or by another physician in the group practice. Also, the services must 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 physician services unrelated to the furnishing of designated health services. (The predecessor provision read " * * * 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 either of the following:

- ++ Furnishing some or all of the group's clinical laboratory services.

- ++ The centralized provision of the group's designated health services (other than clinical laboratory services). (This provision, which was added by OBRA '93, became effective January 1, 1995.) Note that OBRA '93 also contains an undesignated paragraph following this provision 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, * * *." As discussed in the August 1995 final rule, it is our interpretation that this paragraph is intended to provide for the possibility of our liberalizing the conditions described in section 1877(b)(2)(A)(ii)(II); that is, the conditions concerning the provision of services in "another building" that is used by a group practice.

- The ancillary services must be billed by one of the following:
 - + The physician performing or supervising the services.
 - + A group practice of which the physician is a member under a billing number assigned to the group practice. (Prior to January 1, 1995, this provision did not require that the services be billed under a group practice's billing number.)
 - + An entity that is wholly owned by the physician or group practice.

The August 1995 final rule incorporated into our regulations an in-office ancillary services exception that was based on the statutory provision, as it was in effect on January 1, 1992, at § 411.355(b). This proposed rule would revise § 411.355(b) to conform it to the current statutory provision. That is, it would—

- Specify that the exception does not apply to durable medical equipment (other than infusion pumps) or to parenteral and enteral nutrients, equipment, and supplies; and
- Revise paragraph (b)(2) of § 411.355 to require that the services be furnished in one of the following locations:
 - + A building in which the referring physician (or another physician who is a member of the same group practice) furnishes physician services unrelated to the furnishing of designated health services.
 - + A building that is used by the group practice for the provision of some or all of the group's clinical laboratory services.
 - + A building that is used by the group practice for the centralized provision of the group's designated health services (other than clinical laboratory services).

- Indicate that when a group practice bills for ancillary services, the services must be billed under a billing number assigned to the group practice.

We have also made several other changes to the in-office ancillary services exception that we discuss in section III of this preamble.

For purposes of the in-office ancillary services exception, the August 1995 final rule also defined "direct supervision" at § 411.351. The rule defines this term as 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. This proposed rule would retain that definition, with several changes that are meant to clarify the meaning of the term "present in the office suite." We discuss these changes in section III of this preamble.

c. Exception—certain prepaid health plans

Section 1877(b)(3) specifies that the prohibition on referrals does not apply to services furnished by certain prepaid health plans. To qualify for the exception, the services must be furnished by a Federally-qualified health maintenance organization (within the meaning of section 1310(d) of the Public Health Services Act) to its enrollees or by a prepaid health care organization to its enrollees under a contract or agreement with Medicare under one of the following statutory authorities:

- Section 1876, which authorizes us to enter into contracts with health maintenance organizations and competitive medical plans to furnish covered items and services on a risk-sharing or reasonable cost basis.
- Section 1833(a)(1)(A), which authorizes payment for Medicare Part B services to prepaid health plans on a reasonable cost basis.
- Section 402(a) of the Social Security Amendments of 1967 or section 222(a) of the Social Security Amendments of 1972, both of which authorize us to conduct demonstration projects involving payments on a prepaid basis.

The August 1995 final rule incorporated section 1877(b)(3) into our regulations at § 411.355(c). We are proposing to set forth at § 435.1012(b) an exception for services provided by organizations analogous to those cited above to enrollees under the Medicaid program. We discuss this proposal in section III of this preamble.

d. Other exceptions

Effective January 1, 1995, section 1877(b)(4) authorizes the Secretary to provide in regulations for additional exceptions for financial relationships, beyond those specified in the statute, if she determines that they do not pose a risk of Medicare program or patient abuse. The Secretary determined, based on the rationale explained in the August 1995 final rule, that referrals for certain clinical laboratory services furnished in an ambulatory surgical center or end stage renal disease facility, or by a hospice do not pose a risk of Medicare program or patient abuse. The Secretary

found no risk of abuse when payments for these services are included in the ambulatory surgical center payment rate, the end stage renal disease composite payment rate, or as part of the hospice payment rate, respectively. Therefore, the August 1995 final rule incorporated an exception for those services into our regulations at § 411.355(d). This proposed rule would retain that provision, with a change discussed below. Because this proposed rule covers 10 additional designated health services, this exception would now apply to any of the designated health services provided in the same manner.

As we noted in the August 1995 final rule, we excepted the listed services because they are furnished as part of a composite rate that cannot vary in response to utilization. We are amending § 411.355(d) to allow the Secretary to except services furnished under other payment rates that the Secretary determines provide no financial incentive for either underutilization or overutilization, or any other risk of program or patient abuse. We are specifically soliciting comments on whether there are analogous composite rates under the Medicaid program that are similarly guaranteed not to result in program or patient abuse. Commenters who are interested in this issue should demonstrate why they believe a particular kind of service should qualify for the exception.

4. Exceptions That Apply Only to Certain Ownership or Investment Interests

The statute also provides 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

Under section 1877(c), the prohibition on referrals does not apply in the case of ownership by a physician (or immediate family member) of the following:

- 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 are—
- Securities listed 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

- Securities traded under an automated interdealer quotation system operated by the National Association of Securities Dealers, and

- In a corporation that had, at the end of the corporation's most recent fiscal year or on average during the previous 3 fiscal years, stockholder equity exceeding \$75 million. (OBRA '93 also included, until January 1, 1995, securities in a corporation that, at the end of the corporation's most recent fiscal year, had total assets exceeding \$100 million.)

- 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 the company's most recent fiscal year or on average during the previous 3 fiscal years, total assets exceeding \$75 million.

The August 1995 final rule incorporated the above provision into our regulations at §§ 411.356 (a) and (b). This proposed rule would remove from § 411.356(a) that portion of the provision that expired on January 1, 1995, and would make certain other changes described in section III of this preamble.

b. Exception—ownership or investment interest in certain health care facilities

Section 1877(d) provides additional exceptions to the prohibition on physician referrals for certain designated health services furnished by three types of facilities if the physician (or immediate family member) has an ownership or investment interest in the facilities:

- Designated health services furnished by a hospital located in Puerto Rico.

- Designated health services furnished in a rural area by an entity if substantially all of the designated health services furnished by the entity are furnished to individuals residing in a rural area. A "rural area" is defined in section 1886(d)(2)(D) as meaning an area outside of a Metropolitan Statistical Area. (Until January 1, 1995, this provision read as follows: "In the case of clinical laboratory services if the laboratory furnishing the services is in a rural area (as defined in section 1886(d)(2)(D)).")

- Designated health services furnished by 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).

The August 1995 final rule incorporated section 1877(d), as it

related to clinical laboratory services, into our regulations at § 411.356(c). In establishing the rural provider exception in the regulations, we required that referred laboratory testing be performed on the premises of the rural laboratory (if not performed on the premises, the laboratory performing the testing was required to bill the Medicare program directly). As described in the preamble to the proposed rule covering referrals for clinical laboratory services (57 FR 8598 (March 11, 1992)), we believe that Congress included this exception in order to benefit Medicare beneficiaries who live in rural areas where laboratories may not be available without the financial support of local physicians. We included the additional requirement to prevent situations in which physicians who own an urban laboratory set up a storefront or "shell" laboratory with a rural address in order to use the rural exception. In this scenario, the urban owner could make referrals to the rural laboratory, which would in turn refer the tests to the physician's urban laboratory. Alternatively, urban laboratories with physician owners could set up rural laboratories for the purpose of performing tests referred by the physician owners for their urban patients.

Because section 1877(d)(2) has been amended to apply only to designated health services that are actually furnished in a rural area (they cannot be transferred to an urban provider), and only by providers that provide designated health services to a predominantly rural population, we no longer believe that the extra requirement is necessary. We are therefore proposing to remove it from § 411.356(c).

The August 1995 final regulation adopted the OBRA '93 standard that substantially all of the designated health services furnished by the rural entity are furnished to individuals residing in a rural area. We interpreted "substantially all" as meaning at least 75 percent of the services. In addition, § 411.356(c) provided an exception, until January 1, 1995, for an ownership or investment interest in a hospital if the physician's ownership or investment interest does not relate (directly or indirectly) to the furnishing of clinical laboratory services. This exception was based on section 1877(b)(4) as it read under OBRA '90. OBRA '93, as amended by SSA '94, retained this provision only until January 1, 1995.

This proposed rule would revise § 411.356(c) to reflect the statutory provision as it became effective on January 1, 1995 and to apply § 411.356(c) to entities providing any of

the designated health services. We would change the requirement that a rural entity be located in a rural area to instead except referrals for designated health services furnished in a rural area by an entity that furnishes substantially all of its designated health services to individuals residing in a rural area. We would continue to interpret "substantially all" as being at least 75 percent of the services furnished by the entity. In addition, this proposed rule would remove the exception that expired on January 1, 1995.

5. Exceptions That Apply Only to Certain Compensation Arrangements

Section 1877(e) provides that certain compensation arrangements are not considered a "financial relationship" for purposes of the prohibition on physician referrals.

a. Exception—rental of office space

Section 1877(e)(1)(A) provides an exception for payments made by a lessee to a lessor for the use of premises if the following conditions are met:

- The lease is 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 rental or lease. Also, the space 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 under certain conditions. That is, acceptable payments for common areas cannot 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 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.

"Fair market value" is defined by section 1877(h)(3) as the value in arm's-length transactions, consistent with the general value market, and, with respect

to rentals or leases, the value of rental property for general commercial purposes (not taking into account its intended use) and, in the case of a lease of space by a lessor that is a potential source of patient referrals to the lessee, not adjusted to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor. (Meeting the fair market value standard is a requirement for several of the other compensation-related exceptions in the statute. We discuss these other exceptions later in this preamble.)

The August 1995 final rule incorporated the provisions of section 1877(e)(1)(A) into our regulations at § 411.357(a), without imposing any additional requirements. This proposed rule would retain § 411.357(a). In addition, the final rule incorporated the definition of "fair market value" in § 411.351. This proposed rule would retain the definition. Also, since the statute requires that fair market value be "consistent with the general market value," we have added to the definition an explanation of "general market value."

b. Exception—rental of equipment

Section 1877(e)(1)(B) provides an exception for payments made by a lessee of equipment to the lessor 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.

The August 1995 final rule incorporated this provision into our regulations at § 411.357(b), without imposing any additional requirements. This proposed rule would retain

§ 411.357(b), with minor editorial changes.

c. Exception—bona fide employment relationship

Under section 1877(e)(2), 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 a compensation arrangement for purposes of the prohibition if the following conditions 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 and (except for certain productivity bonuses) 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 made in accordance with an agreement that would be commercially reasonable even if no referrals were made to the employer.
- The employment meets any other requirements the Secretary may impose by regulation as needed to protect against Medicare program or patient abuse.

The statute provides that, under this exception, a productivity bonus that is based on services performed personally by the physician (or immediate family member) does not violate the "volume or value of referrals" standard.

"Employee" is defined in section 1877(h)(2) as an individual who would be considered to be an employee of the entity under the usual common law rules that apply in determining employer-employee relationships, as applied for purposes of section 3121(d)(2) of the Internal Revenue Code of 1986.

The August 1995 final rule incorporated the provisions of section 1877(e)(2) into our regulations at § 411.357(c), without imposing any additional requirements. This proposed rule would retain § 411.357(c), but with additional requirements that we describe in section III. The final rule also incorporated the definition of "employee" into our regulations at § 411.351. Again, this proposed rule would retain that definition.

d. Exception—personal service arrangements

Under section 1877(e)(3)(A), remuneration from an entity under an arrangement (including remuneration

for specific physician services furnished to a nonprofit blood center) does not constitute a compensation arrangement for purposes of 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) 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 State or Federal law.
- The arrangement meets any other requirements the Secretary may impose by regulation as needed to protect against program or patient abuse.

The August 1995 final rule incorporated section 1877(e)(3)(A) into our regulations at § 411.357(d)(1), without imposing any additional requirements. This proposed rule would retain § 411.357(d)(1), with several changes that we discuss in section III of this preamble.

Section 1877(e)(3)(B)(i) 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.

- 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 listed above.

(Note: Sections 1876(i)(8) and 1903(m)(2)(A) require that physician incentive plans be regulated. On March 27, 1996, we published, at 61 FR 13430, a final rule with comment period that implemented this legislation for purposes of both the Medicare and Medicaid programs by establishing requirements at § 417.479 (for Medicare) and at § 434.70 (for Medicaid). A final rule amending the final rule with comment was published on December 31, 1996 at 61 FR 69034.)

The August 1995 final rule incorporated section 1877(e)(3)(B)(i) into our regulations at § 411.357(d)(2). Because of the establishment at § 417.479 of requirements concerning incentive plans, this proposed rule would revise § 411.357(d)(2). It would replace the reference to requirements established by the Secretary under section 1876(i)(8)(A)(ii) of the Act with a reference to the requirements of § 417.479. We would also reverse the order of paragraphs (ii) and (iii) of § 411.357(d)(2) because we believe this order reflects a more logical progression. In addition, we would delete existing § 411.357(d)(3), which contains a time-sensitive provision related to personal services arrangements that, based on the statute, is now obsolete.

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. The August 1995 final rule incorporated this definition into our regulations at § 411.351. This proposed rule would retain that definition.

e. Exception—remuneration unrelated to the provision of designated health services

Prior to OBRA '93, section 1877(b)(4) provided an exception for any financial relationship with a hospital if the financial relationship does not relate to the provision of clinical laboratory services. OBRA '93 eliminated this provision, but SSA '94 reinstated it until January 1, 1995. OBRA '93 also added paragraph (e)(4) to section 1877, retroactive to January 1, 1992. Under

section 1877(e)(4), remuneration provided by a hospital to a physician that does not relate to the furnishing of designated health services does not constitute a compensation arrangement for purposes of the prohibition on referrals. Section 1877(e)(4) differs from the predecessor provision at section 1877(b)(4) in that it retains only the compensation aspect of the exception. In addition, it applies only to remuneration from a hospital to a physician (that is, it does not include remuneration from a physician to a hospital) if the remuneration does not relate to the furnishing of designated health services. Also, the exception does not apply to remuneration from a hospital to a member of a physician's immediate family.

The August 1995 final rule incorporated the provisions of sections 1877(b)(4) and (e)(4) as they were effective on January 1, 1992, and as they relate to compensation, into our regulations at § 411.357(g). This proposed rule would revise § 411.357(g) by removing that portion that was based on the predecessor provision of section 1877(b)(4), since that provision has expired. We would also revise that portion of § 411.357(g) that was based on section 1877(e)(4) by changing the reference to remuneration not related to the furnishing of clinical laboratory services to remuneration not related to the furnishing of designated health services. We have also made several other changes described in section III of this preamble.

f. Exception—physician recruitment

Section 1877(e)(5) provides that remuneration provided by 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 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 the Secretary may impose by regulation as needed to protect against program or patient abuse.

The August 1995 final rule incorporated the provisions of section 1877(e)(5) into our regulations at § 411.357(e), with additional requirements. Under our authority to impose additional requirements, we

specified that the arrangement and its terms must be in writing and signed by both parties. We also specified that the physician must not be precluded from establishing staff privileges at another hospital or referring business to another entity. This proposed rule would retain § 411.357(e), with a minor editorial change.

g. Exception—isolated transaction

Section 1877(e)(6) provides that an isolated transaction, such as a one-time sale of property or a practice, is not considered to be a compensation arrangement for purposes of the prohibition on referrals if the following conditions are met:

- The amount of remuneration for the transaction is consistent with fair market value and is not determined, directly or indirectly, in a manner that takes into account the volume or value of referrals by the physician.
- The remuneration is provided under an agreement that would be commercially reasonable even if no referrals were made to the entity.
- The arrangement meets any other requirements the Secretary may impose by regulation as needed to protect against Medicare program or patient abuse.

The August 1995 final rule incorporated the provisions of section 1877(e)(6) into our regulations at § 411.357(f), with additional requirements. Under our authority to impose additional requirements, we specified that there can be no additional transactions between the parties for 6 months after the isolated transaction, except for transactions that are specifically excepted under one of the other exceptions provided in the regulations. This proposed rule would retain § 411.357(f), with a minor editorial change. In addition, we established definitions of "transaction" and "isolated transaction" at § 411.351. We defined a "transaction" as an instance or process of two or more persons doing business. We defined an "isolated transaction" as one involving a single payment between two or more persons. We specified that a transaction that involves long-term or installment payments is not considered an isolated transaction. This proposed rule would retain those definitions, with the clarification that "transactions" can involve persons or entities.

h. Exception—certain group practice arrangements with a hospital

Section 1877(e)(7) provides that an arrangement between a hospital and group under which designated health 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 for 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 designated health services covered by the arrangement, substantially all of those 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.

The August 1995 final rule incorporated the provisions of section 1877(e)(7), as they relate to clinical laboratory services, into our regulations at § 411.357(h), without imposing any additional requirements. This proposed rule would revise § 411.357(h) to apply the provisions to the designated health services, and would make certain minor changes described in section III.

i. Exception—payments by a physician for items and services

Section 1877(e)(8) 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.

The August 1995 final rule incorporated the provisions of section 1877(e)(8) into our regulations at

§ 411.357(i). This proposed rule would retain § 411.357(i), but clarify that “services” as used in the provision means services of any kind (not just those defined as “services” for purposes of the Medicare program in § 400.202).

6. Requirements Related to the “Substantially All” Test

As mentioned earlier, the definition of “group practice” in section 1877(h)(4) contains a requirement that substantially all of the services of the physicians who are members of the group be furnished through the group. In the August 1995 final rule, we interpreted “substantially all” to mean at least 75 percent of the total patient care services of the group practice members. Further, we defined “members of the group,” at § 411.351, as 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. This proposed rule would revise the definition of “members of the group” to exclude independent contractors, to count physician owners other than partners, and to count physicians as members during the time they furnish “patient care services” to the group. We discuss these changes in section III of this preamble.

The August 1995 final rule defined “patient care services,” at § 411.351, as any tasks performed by a group practice member that address the medical needs of specific patients, regardless of whether they involve direct patient encounters. We included, as examples, the services of physicians who do not directly treat patients, time spent by a physician consulting with other physicians, and time spent reviewing laboratory tests. Under § 411.351, “patient care services” are measured by the total patient care time each member spends on these services.

This proposed rule would retain the definition of patient care services, but would broaden the definition to include tasks that benefit patients in general or the group practice. We are also proposing minor changes that we believe are necessary to clarify what tasks qualify under the definition. We describe these changes in section III of this preamble.

The August 1995 final rule also required, at § 411.360, that a group practice 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.

Section 411.360 also provides that 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 definition of a group practice as set forth at section 1877(h)(4) must—

- 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
- 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 to the group during the 12-month period that were conditioned on the group meeting the standard are overpayments.

In addition, § 411.360 specifies that—

- Once any group has chosen to use its fiscal year, the calendar year, or some other 12-month period, the group practice must adhere to this choice.
- 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.
- Any group that intends to meet the definition of a group practice in order to qualify for one of the exceptions provided in the regulations must submit the required attestation to its carrier by December 12, 1995.

The August 1995 final rule contains a discussion of the rationale for the above provisions. On December 11, 1995, we published in the **Federal Register**, at 60 FR 63438, a final rule that delays the date by which a group of physicians must file an attestation statement. The December final rule amended § 411.360 to require that a group that intends to meet the definition of a group practice must submit an attestation statement to its carrier no later than 60 days after the group receives attestation instructions from its carrier. The preamble to the December rule points out that a group can regard itself as a group practice in the interim period before it receives attestation instructions, provided the group believes that it meets the

definition of a group practice under § 411.351.

This proposed rule would retain § 411.360, as amended by the December 1995 final rule. We propose to make several minor changes to clarify that a group is only required to complete an attestation if it wishes to qualify as a group practice for purposes of meeting an exception that requires group status. We are also changing the provision to require that the attestation be signed by an authorized representative of the group practice who is knowledgeable about the group, and to contain a statement that the information furnished in the attestation is true and accurate to the best of the representative's knowledge and belief. The proposed provision also states that any person filing a false statement will be subject to applicable criminal and civil penalties.

7. Reporting Requirements

Prior to SSA '94, section 1877(f) included the requirement that each entity furnishing Medicare covered items or services must provide us with certain information concerning its ownership or investment arrangements. In our December 3, 1991 interim final rule with comment period, published in the **Federal Register** at 56 FR 61374, we extended the rule to include certain information concerning an entity's compensation arrangements for the reasons discussed in the preamble of that rule.

Section 1877(f) also gave the Secretary the option of waiving the reporting requirements, for certain entities that do not furnish clinical laboratory services, in all but 10 States. 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 10 States specified in the statute. In the 10 States, we were required to obtain data from at least six specific types of entities. We gathered data from these providers in the fall of 1991.

Section 152 of SSA '94 amended section 1877(f) extensively. It extended the reporting requirements to specifically cover information not only about an entity's ownership or investment interests, but about compensation arrangements 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 requirements continue to not apply to designated health services furnished outside of the United States. Section 1877(f) allows the Secretary to gather the information in such form, manner, and at such times as she specifies.

We discussed the provisions of section 1877(f), as they relate to clinical laboratories and as they read under OBRA '90, in detail in the December 1991 interim final rule. The August 1995 final rule adopted the provisions of the interim final rule with revisions that reflect the changes made by SSA '94. While the August 1995 final rule reflects the amendments made to section 1877(f), it did not interpret these amendments. This proposed rule retains the reporting requirements as they appear in the August 1995 final rule, subject to certain interpretations we have added in section III of this preamble. These requirements are set forth at existing § 411.361, and we would apply them to any future reporting we may require.

8. Sanctions

Prior to OBRA '93, section 1877(g)(1) required a denial of payment for a clinical laboratory service that was provided in violation of the referral prohibition. Paragraph (g)(2) of section 1877 required the timely refund of amounts collected in violation of the prohibition. OBRA '93 extended these provisions to apply to all of the designated health services, effective January 1, 1995. The August 1995 final rule incorporated these provisions as they relate to clinical laboratory services into our regulations at §§ 411.353(c) and (d), respectively. This proposed rule would revise §§ 411.353(c) and (d) to extend their application to the other designated health services.

Paragraph (g)(3) of section 1877 provides for the imposition of a civil money penalty of \$15,000 per service and exclusion from Medicare and any State health care program, including Medicaid, for any person who presents or causes to be presented a bill or claim the person knows or should know is for a service for which payment may not be made under § 1877(a). The same penalty applies for a service for which a person has not made a refund as described in paragraph (g)(2).

Paragraph (g)(4) provides for a \$100,000 civil money penalty and the same exclusion penalty for any physician or other entity that enters into a circumvention scheme that 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 made the referrals directly, would be in

violation of section 1877. A proposed rule published by the Office of Inspector General on October 20, 1993 (58 FR 54096) addresses sections 1877(g)(3) and (g)(4). That rule became final on March 31, 1995 (60 FR 16580).

Paragraph (g)(5) of section 1877 provides for possible exclusion and a civil money penalty of not more than \$10,000 per day for each day in which a person has failed to meet a reporting requirement in section 1877(f). The December 1991 interim final rule covering the reporting requirements incorporated this provision into our regulations at § 411.361(g), and the August 1995 final rule redesignated § 411.361(g) as § 411.361(f). This proposed rule would retain § 411.361(f).

9. Additional Definitions

In implementing provisions of section 1877 as they were effective on January 1, 1992, the August 1995 final rule established definitions of the following terms (which were not discussed above) at § 411.351:

a. *Clinical laboratory services* means the biological, microbiological, serological, chemical, immunohematological, 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.

b. *Entity* means a sole proprietorship, trust, corporation, partnership, foundation, not-for-profit corporation, or unincorporated association. For reasons discussed in section III of this preamble, this proposed rule would revise the definition of "entity" to include a physician's sole proprietorship and any practice of multiple physicians that provides for the furnishing of a designated health service.

c. *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. However, we have excluded from this definition entities that perform services for hospital patients "under arrangements" with the hospital. We propose to amend this definition to make it clear that "hospitals" include regular hospitals, psychiatric hospitals, and rural primary care hospitals.

d. *HPSA* means, for purposes of the August 1995 final rule, 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.

e. *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.

f. *Laboratory* means an entity furnishing biological, microbiological, serological, chemical, immuno-hematological, 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.

g. The August 1995 final rule defined a “plan of care” as 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. For reasons discussed earlier, this proposed rule would remove the words “items or” from this definition.

(We explain our rationale for some of these definitions in the March 1992 proposed rule, and we explain the remainder in the August 1995 final rule.) We would extend these definitions to apply to referrals involving any of the designated health services.

We have made some changes to the definitions in addition to those noted above. Any changes in definitions that

we have included in this proposed rule do not result from changes in the legislation, but reflect our most recent interpretations of the statute. In section III of this preamble, we discuss in detail how we propose to interpret provisions in section 1877 and in section 1903(s) that we have either not interpreted in the August 1995 final rule or that we believe we must reconsider in the context of the designated health services. In section III, we also define or interpret terms that are present in the statute (such as each of the designated health services) as well as include new definitions that we propose to add to the rule to enable us to implement other parts of the statute.

10. Conforming Changes

We propose to revise existing §§ 411.1(a) and 411.350(a), which set forth the statutory basis for the provisions in part 411, subpart A, and part 411, subpart J, respectively, by changing the reference to “clinical laboratory services” to “designated health services.”

11. Editorial Changes

In addition to the proposed changes discussed above, we would also make a number of editorial changes to subpart J of part 411. These changes would not affect the substance of the provisions. As an example of the type of change we would make, in § 411.355(a), we would add the words “of this chapter” after the reference to § 410.20(a).

B. Applying The Referral Prohibition to the Medicaid Program: Section 1903(s) of the Act and the Provisions of This Proposed Rule

Title XIX of the Act authorizes Federal grants to States to establish Medicaid programs to provide medical assistance to needy individuals. Medicaid programs are administered by the States in accordance with Federal laws and regulations. State Medicaid agencies operate their programs in accordance with a Medicaid State plan that is approved by us.

While Medicaid programs are administered by the States, they are jointly financed by the Federal and State governments. The Federal government pays its share of medical assistance expenditures to the State on a quarterly basis according to a formula described in sections 1903 and 1905(b). The amount of the Federal share for medical assistance is called Federal financial participation (FFP). Before the enactment of OBRA '93, there were no statutory or regulatory requirements concerning the availability of FFP for

Medicaid services resulting from physician referrals.

Section 13624 of OBRA '93, entitled “Application of Medicare Rules Limiting Certain Physician Referrals,” added a new paragraph (s) to section 1903 of the Act. This new provision extends aspects of the Medicare prohibition on physician referrals to Medicaid. Specifically, this provision restricts FFP for expenditures for medical assistance under the State plan consisting of designated health services, as defined under section 1877(h)(6), that are furnished to an individual on the basis of a physician referral that would result in the denial of payment under the Medicare program if Medicare covered the services to the same extent and under the same terms and conditions as under a State’s Medicaid plan.

This proposed rule would revise § 435.1002, “FFP for services,” to reflect section 1903(s). We would specify in § 435.1002(a) that the availability of FFP for expenditures for Medicaid services is subject to the limitations set forth in new § 435.1012. We would entitle § 435.1012 as “Limitation on FFP Related to Prohibited Referrals.” The proposed new provision states that we will deny FFP for designated health services (as defined in § 431.351) furnished under the State plan to an individual on the basis of a physician referral that would result in the denial of payment under the Medicare program if Medicare covered the services to the same extent and under the same terms and conditions as under the State plan. We believe that certain aspects of section 1903(s) require our interpretation, and we discuss these aspects in section III of this preamble.

Section 4314 of the Balanced Budget Act of 1997 established section 1877(g)(6) of the Act. It requires that the Secretary issue written advisory opinions to outside parties concerning whether the referral of a Medicare patient by a physician for designated health services (other than clinical laboratory services) is prohibited under the physician referral provisions in section 1877. Because the Medicare rules can affect whether a State will receive FFP for certain services, States, as well as individuals and entities that provide services under the Medicaid program, may be interested in the advisory opinion process. As a result, we have included in § 435.1012(c) a cross reference to the Medicare regulations that set forth the specific procedures we will use in issuing advisory opinions.

Section 1903(s) also specifies that the reporting requirements of section

1877(f) and the penalties for failing to report in section 1877(g)(5) apply to a provider of a designated health service for which payment may be made under Medicaid in the same manner as they apply to a provider that furnishes a designated health service for which payment may be made under Medicare.

This proposed rule would incorporate the provisions of sections 1877(f) and (g)(5) into our Medicaid regulations by adding new §§ 455.108 and 455.109 to part 455 ("Program Integrity: Medicaid"). These two provisions would appear under a new subpart C entitled "Disclosure of Information by Providers for Purposes of the Prohibition on Certain Physician Referrals." Section 455.108, "Purpose," would specify that subpart C implements section 1903(s) of the Act. Section 455.109, "Disclosure of ownership, investment, and compensation arrangements," would list the specific disclosure requirements, and the sanctions for failing to comply. We interpret these disclosure requirements, as we believe they apply to Medicaid providers, in section III of this preamble.

III. Interpretations of Sections 1877 and 1903(s) of the Act

In this section of the preamble, we discuss in detail how we propose to interpret provisions in section 1877 and in section 1903(s) that we either did not interpret in the August 1995 final rule or that we interpreted in the context of referrals for clinical laboratory services, but must reconsider in the context of the additional designated health services. We propose to define or interpret terms that are present in the statute (such as each of the designated health services) or to reinterpret or clarify certain statutory terms that we interpreted in the past. We also propose to add certain new terms and definitions to the rule that we believe are necessary for us to implement parts of the statute. This section is structured in the order we used to present the statutory provisions and our interpretations in the August 1995 final rule. We would like to point out that, in these proposed regulations, we intend to interpret only the provisions of section 1877 of the Act, and not the provisions of any other State or Federal laws, such as the antitrust laws, the anti-kickback statute, or the Internal Revenue Code.

A. Definitions

1. Designated Health Services

As we noted above, OBRA '93 expanded the physician referral prohibition to apply to ten designated

health services in addition to clinical laboratory services. Section 1877(h)(6) lists these services, but does not define them. Because the designated health services are not defined in section 1877, we would define them in § 411.351.

Designated health services as components of other services. We believe that a designated health service remains one, even if it is billed as something else or is subsumed within another service category by being bundled with other services for billing purposes. For example, most services provided by a skilled nursing facility (SNF) are considered SNF services, which are not themselves designated health services. Nonetheless, SNF services can encompass a variety of designated health services, such as physical therapy services or laboratory services.

Similarly under Medicaid, services provided by a clinic are considered "clinic services" under section 1905(a)(9) of the Act, but could encompass a variety of designated health services, such as occupational therapy, physical therapy, or radiology services.

We base our interpretation on the fact that Congress compiled its list of designated health services based on abuses or potential abuses it perceived in regard to a variety of specific kinds of services. The list in section 1877(h)(6), in fact, does not exactly track the service categories as they are defined under either Medicare or Medicaid. In short, we regard the services designated in section 1877 as subject to the requirements of that section regardless of the setting in which they are provided or the payment category under which they are billed.

On the other hand, we are also aware that designated health services are sometimes provided as merely peripheral parts of some other major service that a physician has prescribed. For example, physicians often employ echocardiography (to obtain ultrasound signals from the heart) as a mechanism to intraoperatively view the results of bypass surgery. We do not believe that a physician using echocardiography this way has made a specific referral for a designated health service; instead, we regard the physician as prescribing a physician service that happens to incidentally include echocardiography. In other words, it is our view that a physician is unlikely to over-prescribe bypass surgery in order to enhance his or her investment in an echocardiography machine. Because we believe that Congress meant to include under designated health services specific services that are or could be

subject to abuse, we are proposing to define those services accordingly. Thus, we propose to deviate from standard Medicare or Medicaid definitions of certain services in order to meet the intent of the statute.

How we define designated health services. We have chosen, in general, to base the definitions for the designated health services on existing definitions in the Medicare program. Except for inpatient hospital services and home health services, our definitions are based on how Medicare covers a service under Part B. As noted above, we have chosen to deviate from these definitions when we believe it is appropriate to fulfill the purpose of the statute.

These definitions would apply for purposes of physician referrals that are made for services covered under Medicare and for analogous services covered under the Medicaid program. However, section 1903(s) precludes FFP for medical assistance under a State plan consisting of a designated health service furnished to an individual on the basis of a referral that would result in a 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*. We believe that in enacting section 1903(s), Congress was clearly concerned that financial relationships of the kind that would prohibit a referral for services under Medicare may also lead to improper utilization of Medicaid services. However, because Medicaid has its own unique set of coverage requirements, a State can cover and reimburse designated health services very differently from the way these services are covered and reimbursed under the Medicare program. We believe that Congress was aware of these program differences and specifically meant to provide us with some flexibility in applying the Medicare physician referral rules in the Medicaid context. Therefore, we intend to apply this flexibility in the following manner, which we believe will further the goals of the statute:

When the definition of a designated health service is the same under both programs, we intend to use the same definition, as described in this preamble, for both programs. However, when the definition of a designated health service differs under a State's plan from the definition under Medicare, we will assume that the services under the State's plan take precedence, even if the definition will encompass services that are not covered by Medicare. However, we propose not to include Medicaid services as designated health services in situations

in which including those services appears to run counter to the underlying purpose of the legislation. Because Medicaid is administered by the States, we do not believe that we are in the best position to determine when including particular services will have this effect. As a result, we are specifically soliciting comments on how to implement our policy in a manner that will achieve the goals of the statute.

We have received a number of inquiries from individuals who were confused about whether a particular service falls under one of the designated service categories listed in section 1877(h)(6). In order to remedy this problem, we have included below general explanations of each of the designated health services, including explanations of how we interpret similar or parallel services under Medicare. In the text of the proposed regulation, however, we have defined designated health services whenever we could by simply cross-referencing existing definitions in the Medicare statute, regulations, or manuals or by including specific language whenever we believe the definitions should deviate from standard Medicare definitions.

a. Clinical laboratory services

We would retain the definition that was incorporated into our regulations at § 411.351 by the August 1995 rule.

b. Physical therapy services (including speech-language pathology services)

Physical therapy services. Sections 1861(s)(2)(D) and 1832 provide for coverage of outpatient physical therapy services under Part B, which are defined in section 1861(p). Under section 1861(p), outpatient physical therapy services may be furnished by a provider of services, a clinic, rehabilitation agency, or public health agency, or by others under arrangements with and under the supervision of one of these entities. The services must be furnished to an outpatient who is under the care of a doctor of medicine or osteopathy, or a doctor of podiatric medicine, under a plan of care established by one of these physicians or by a qualified physical therapist. The plan must be periodically reviewed by the physician and must include the type, amount, and duration of physical therapy services to be furnished. No service is included as outpatient physical therapy if it would not be included as an inpatient hospital service if furnished to an inpatient of a hospital. Outpatient physical therapy may be furnished by a provider to an individual as an inpatient of a hospital or extended care facility if the

individual has exhausted or is otherwise ineligible for benefit days under Medicare Part A.

Outpatient physical therapy services may be furnished by an independent physical therapist in his or her office or in an individual's home. The physical therapist must meet any standards created by the Secretary in regulations, including health and safety standards. Special provisions concerning services furnished by a physical therapist in independent practice are set forth at § 410.60(c).

Under section 1861(p), the term "outpatient physical therapy services" also includes speech-language pathology services. Medicare covers speech-language pathology services if furnished to an outpatient by a provider of services, a clinic, rehabilitation agency, or public health agency, or by others under arrangements with and under the supervision of one of these entities. However, the statute does not provide for coverage of services furnished by speech-language pathologists in independent practice.

Plan of treatment requirements for outpatient physical therapy and speech-language pathology services are set forth in § 410.61. Conditions for outpatient physical therapy services are set forth in § 410.60(a) and (b), and conditions and exclusions for outpatient speech-language pathology services are set forth in § 410.62.

Basically, covered outpatient physical therapy services include three types of services, which are best described in § 410.100(b) (which specifically concerns services provided by a comprehensive outpatient rehabilitation facility). Section 410.100(b) provides that the following are physical therapy services:

- Testing and measurement of the function or dysfunction of the neuromuscular, musculoskeletal, cardiovascular, and respiratory systems.
- Assessment and treatment related to dysfunction caused by illness or injury and aimed at preventing or reducing disability or pain and restoring lost function.
- The establishment of a maintenance therapy program for an individual whose restoration has been reached. (However, maintenance therapy itself is not covered as part of these services. Sections 3101.8 of the Medicare Intermediary Manual (HCFA Pub. 13, Part 3) and 2210 of the Medicare Carriers Manual provide guidelines for coverage of restorative therapy and maintenance programs.)

Speech-language pathology services. These services are defined in section 1861(l)(1) as such speech, language,

and related function assessment and rehabilitation services furnished by a qualified speech-language pathologist as this pathologist is legally authorized to perform under State law (or the State regulatory mechanism) as would otherwise be covered if furnished by a physician. Section 1877(l)(3) defines a "qualified speech-language pathologist."

Speech-language pathology services are briefly described in § 410.100(d) as those necessary for the diagnosis and treatment of speech and language disorders that create difficulties in communication. Section 2216 of the Medicare Carriers Manual provides that speech-language pathology services are also services necessary for the diagnosis and treatment of swallowing disorders (dysphagia), regardless of the presence of a communication disability. This section of the manual also discusses restorative therapy and maintenance programs and group speech pathology services under the two main categories of diagnostic or evaluation services and therapeutic services.

Services that are essentially the same as "outpatient physical therapy services" and "outpatient speech pathology services" are also covered by Medicare in other contexts and in different settings, and may be billed under different categories. For example, section 1861(b)(3) lists as "inpatient hospital services" other diagnostic or therapeutic items or services furnished by a hospital or by others under arrangements with the hospital, as are ordinarily furnished to inpatients. We have a longstanding policy of covering physical therapy and occupational therapy as diagnostic or therapeutic "inpatient hospital services." The Medicare regulations in § 482.56, in fact, include conditions of participation for hospitals that provide physical therapy, occupational therapy, or speech pathology services.

Similarly, these services can also be covered as SNF services. Section 1861(h)(3) includes as "extended care services" physical or occupational therapy or speech-language pathology services furnished by the SNF (or by others under arrangements made by the facility), to an inpatient of the facility. These services can also be furnished as "incident to" a physician's services under section 1861(b)(2)(A). This provision covers services and supplies furnished as an incident to a physician's professional service, of kinds that are commonly furnished in physicians' offices and are commonly either furnished without charge or included in the physicians' bills. Physical and occupational therapy can qualify as

“incident to” services, as reflected in section 2050.2 of the Carriers Manual, if the physician directly supervises auxiliary personnel who furnish these services and if these personnel are employed by the physician.

Section 1877(h)(6)(B) lists as a designated health service “physical therapy services,” rather than the more limited category of “outpatient physical therapy services.” Therefore, we believe that we can include within our definition of these services any physical therapy or speech-language pathology services that are covered under Medicare, regardless of where they are furnished and by whom, or how they are billed.

For purposes of section 1877, we would define “physical therapy services” as those outpatient physical therapy services (including speech-language pathology services) described at section 1861(p) of the Act and at § 410.100(b) and (d). Physical therapy services also include any other services with the characteristics described in § 410.100(b) and (d) that are covered under Medicare Part A or B, regardless of who provides them, the location in which they are provided, or how they are billed.

c. Occupational therapy services

Sections 1861(s)(2)(D) and 1832 of the Act provide for coverage of outpatient occupational therapy services under Part B. Section 1861(g) defines “outpatient occupational therapy services” by substituting the word “occupational” for the word “physical” each place that it appears in the definition of outpatient physical therapy services in section 1861(p).

Under section 1861(g), outpatient occupational therapy services may be furnished by a provider of services, a clinic, rehabilitation agency, or public health agency, or by others under arrangements with and under the supervision of one of these entities. The services must be furnished to an outpatient who is under the care of a doctor of medicine or osteopathy, or a doctor of podiatric medicine, under a plan of care established by one of these physicians or by a qualified occupational therapist. The plan must be periodically reviewed by the physician and must include the type, amount, and duration of occupational therapy services to be furnished. No service is included as outpatient occupational therapy if it would not be included as an inpatient hospital service if furnished to an inpatient of a hospital. Outpatient occupational therapy may be furnished by a provider to an individual as an inpatient of a hospital or extended

care facility if the individual has exhausted or is otherwise ineligible for benefit days under Medicare Part A.

Outpatient occupational therapy services may be furnished by an independent occupational therapist in his or her office or in an individual’s home. The occupational therapist must meet any standards created by the Secretary in regulations, including health and safety standards.

Coverage guidelines for occupational therapy services are set forth in sections 3101.9 of the Medicare Intermediary Manual (HCFA Pub. 13, Part 3) and 2217 of the Medicare Carriers Manual. The purpose of occupational therapy services is described generally in section 3101.9 of the Intermediary Manual as follows: “Occupational therapy is a medically prescribed treatment concerned with improving or restoring functions which have been impaired by illness or injury or, where function has been permanently lost or reduced by illness or injury, to improve the individual’s ability to perform those tasks required for independent functioning.”

Basically, covered outpatient occupational therapy services include the following types of services, which are best described in section 410.100(c), a section that specifically concerns services provided by a comprehensive outpatient rehabilitation facility. For purposes of section 1877, we would use the same services that are described in section 410.100(c). In § 411.351, occupational therapy services would include the following:

- Teaching of compensatory techniques to permit an individual with a physical impairment or limitation to engage in daily activities.
- Evaluation of an individual’s level of independent functioning.
- Selection and teaching of task-oriented therapeutic activities to restore sensory-integrative function.
- Assessment of an individual’s vocational potential, except when the assessment is related solely to vocational rehabilitation.

As we pointed out in the section covering physical therapy services, services that are essentially the same as “outpatient occupational therapy services” are also covered by Medicare in other contexts and in different settings, and may be billed under different categories. For example, they might be covered as “inpatient hospital services” under section 1861(b)(3) as “other diagnostic or therapeutic items or services” furnished by a hospital or by others under arrangements with the hospital; they might be covered as SNF services under section 1861(h)(3) as part

of a patient’s “extended care services”; or they might be furnished in a physician’s office as services “incident to” the physician’s services under section 1861(b)(2)(A).

Section 1877(h)(6)(C) lists as a designated health service “occupational therapy services,” rather than the more limited category of “outpatient occupational therapy services.” Therefore, we believe that we can include within our definition of these services any occupational therapy services which are covered under Medicare, regardless of where they are furnished and by whom, or how they are billed.

For purposes of section 1877, we would define “occupational therapy services” as those outpatient occupational therapy services described at section 1861(g) of the Act and at 42 CFR 410.100(c). Occupational therapy services also include any other services with the characteristics described in § 410.100(c) that are covered under Medicare Part A or B, regardless of who furnishes them, the location in which they are furnished, or how they are billed.

d. Radiology services, including magnetic resonance imaging, computerized axial tomography scans, ultrasound services, and radiation therapy services and supplies

Section 1877(h)(6)(D) identifies “radiology services, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound” as a designated health service. Section 1877(h)(6)(E) identifies “radiation therapy services and supplies” as a designated health service.

Sections 1861(s)(3) and 1832 establish that “diagnostic X-ray tests,” including diagnostic mammography services under certain conditions, are considered medical or other health services under Part B. Similarly, section 1861(s)(4) establishes that “X-ray, radium, and radioactive isotope therapy, including materials and services of technicians” are considered medical or other health services under Part B. Even though the statute does not define these terms, the payment provisions in section 1833(a)(2)(E) prescribe rules for paying for outpatient hospital radiology services. These include diagnostic and therapeutic radiology, nuclear medicine, computer assisted tomography (CAT scan) procedures, magnetic resonance imaging, and ultrasound and other imaging services (but excluding screening mammography). We cover these services under the conditions described in §§ 410.32(a) and 410.35 of the regulations and in the Coverage

Issues Manual (HCFA Pub. 6) and in other manuals.

Section 1861(s)(13) includes as medical or other health services screening mammography services, which are defined in section 1861(jj) as a "radiologic procedure" provided to a woman for the purpose of early detection of breast cancer. We believe that screening mammography could qualify as one of the "radiology services" listed in section 1877(h)(6)(D) as a designated health service. However, as we have stated elsewhere, we believe that Congress enacted the physician referral prohibition to limit the tendency for referring physicians to overutilize services because they have a financial incentive to do so. It is our view that screening mammography services cannot be subject to overutilization. We base this conclusion on the fact that the statute specifically limits the frequency with which the Medicare program will cover these services. That is, section 1834(c)(2) specifically prescribes how frequently the screenings will be covered for different age groups. In addition, we never consider the covered level of screenings to be unnecessary services—we believe that all women should receive the screenings that are covered for them under the statute. (We cover these screening services under the conditions described in § 410.34 and in the Coverage Issues Manual.)

We wish to make it clear that the only type of mammography that we would exclude from the definition of "radiology services" listed under section 1877(h)(6)(D) would be screening mammography as covered under section 1861(s)(13) and as defined in section 1861(jj). It is our view that "radiology services" does include diagnostic mammography, which is not subject to the same limits. (Diagnostic mammography services are defined in § 410.34(a) as mammography furnished to a symptomatic patient for the purpose of detecting breast disease, while screening mammography is furnished to asymptomatic patients.)

Although Congress did not set up section 1877(h)(6)(D) and (E) in a manner that parallels section 1861(s)(3) and (4), we believe that paragraphs (D) and (E) of section 1877(h)(6), taken together, cover the same services that are covered as Part B services under section 1861(s)(3) and (4). Therefore, throughout this document the terms "radiology" and "imaging" mean any diagnostic test or therapeutic procedure using X-rays, ultrasound and other imaging services, CT scans, MRIs, radiation, or nuclear medicine, including diagnostic mammography

services, except for the distinctions that follow.

The physician's professional component—Medicare has traditionally considered a physician's professional services related to radiology to in general be covered as physician services under section 1861(s)(1) rather than as radiology services under either paragraph (3) or (4) of section 1861(s). However, we believe that it is appropriate for purposes of section 1877 to consider radiology services as including these physician services. We are proposing to include the professional component because radiology always consists of a technical service combined with a physician's professional service. Whenever a technical radiological service is overutilized, it follows that a physician's radiological service will also be overutilized.

Several studies have found that nonradiologists with imaging facilities in their own offices order imaging tests far more frequently than physicians who refer their patients to imaging facilities outside their practices. We mentioned several of these studies in section I.A of this preamble in the general discussion concerning studies that have raised serious concerns about physicians who make self-referrals. For example, one GAO study found that Florida nonradiologists who were sole practitioners or in group practices or other practice affiliations with imaging facilities in their own offices, when compared to physicians who referred outside their practices, had imaging rates about 3 times higher for MRIs; about 2 times higher for CT scans; 4.5 to 5.1 times higher for ultrasound, echocardiography, and diagnostic nuclear medicine imaging; and about 2 times higher for complex and simple X-rays. (GAO Report, "Medicare: Referrals to Physician-owned Imaging Facilities Warrant HCFA's Scrutiny," No. B-253835, pages 2, 3, and 10 (October 1994).)

Similarly, a study appearing in the New England Journal of Medicine compared the frequency and costs of diagnostic imaging furnished by self-referring physicians to the frequency and costs of these same services when physicians refer patients to an unrelated radiologist. The study covered referrals for four medical conditions. The study determined that the self-referring physicians obtained imaging examinations 4.0 to 4.5 times more often than the physicians who referred to unrelated radiologists. In addition, with respect to three of the four medical conditions, the self-referring physicians charged significantly more than the

radiologists for imaging examinations of similar complexity. The combination of more frequent imaging and higher charges resulted in mean imaging charges per episode of care that were 4.4 to 7.5 times higher for the self-referring physicians. (Bruce J. Hillman, M.D., and others, "Frequency and Costs of Diagnostic Imaging In Office Practice—A Comparison of Self-Referring and Radiologist-Referring Physicians," The New England Journal of Medicine, Vol. 323, No. 23 (Dec. 6, 1990), pp. 1604–1608)

Exclusion for Invasive or Interventional Radiology

We would exclude from the meaning of radiology, for the purposes of section 1877, any "invasive" radiology (also commonly referred to as interventional radiology). Invasive radiology is any procedure in which the imaging modality is used to guide a needle, probe, or a catheter accurately. Examples include percutaneous transluminal angioplasty (PTA); the placement of catheters for therapeutic embolization of tumors, arteriovenous malformations, or bleeding sites; the placement of drainage catheters; removal of stones; balloon dilation of strictures; biopsies; arthrograms; and myelograms.

We are basing this exclusion on the theory that the radiology services in these procedures are merely incidental or secondary to another procedure that the physician has ordered. As we have stated earlier, we believe that Congress meant for the categories listed in the statute as designated health services to encompass services that tend to be subject to abuse. It is our view that physicians do not routinely refer patients for the main procedures listed in the last paragraph, such as angioplasty, in order to profit from unnecessary radiology services. As a result, we are proposing not to include these "secondary" radiology procedures as designated health services. We are also specifically soliciting comments on any other types of services that would qualify as designated health services, but which may actually be incidental to other procedures.

We would include the following definition at § 411.351:

Radiology services and radiation therapy and supplies means any diagnostic test or therapeutic procedure using X-rays, ultrasound or other imaging services, computerized axial tomography, magnetic resonance imaging, radiation, or nuclear medicine, and diagnostic mammography services, as covered under section 1861(s)(3) and (4) of the Act and §§ 410.32(a), 410.34, and 410.35, including the professional

component of these services, but excluding any invasive radiology procedure in which the imaging modality is used to guide a needle, probe, or a catheter accurately.

e. Durable medical equipment and supplies

Sections 1861(s)(6) and 1832 establish DME as one of the "medical or other health services" covered under Medicare Part B. Section 1861(n) defines DME as including iron lungs, oxygen tents, hospital beds, and wheelchairs (under certain conditions), used in a patient's home (including certain institutions that can qualify as the patient's home), whether furnished on a rental basis or purchased. The definition of DME is explained further in the Medicare regulations. Section 414.202 defines DME as equipment furnished by a supplier or a home health agency that meets the following conditions:

- Can withstand repeated use.
- Is primarily and customarily used to serve a medical purpose.
- Generally is not useful to an individual in the absence of an illness or injury.
- Is appropriate for use in the home.

Durable medical equipment includes equipment such as wheelchairs, hospital beds, nebulizers, and walkers. We also regard DME that is furnished to a patient under a home health plan under section 1861(m)(5) as DME for purposes of section 1877. The conditions under which we cover DME are described in § 410.38. For the purposes of this proposed rule, we would use the definition of DME set forth in section 1861(n) and in § 414.202.

We have received a number of inquiries concerning Medicare claims processed by the four Durable Medical Equipment Regional Carriers (DMERCs). Many people erroneously believe that all devices, items, or supplies processed by the DMERCs are items of DME. This is not so, because the DMERCs are also responsible for paying claims for other items, such as immunosuppressive drugs, orthotics, prosthetics, and prosthetic devices and related supplies.

We have received requests that we clearly identify in this regulation which items are considered DME and which are not. Because the number of items considered to be DME is so extensive, we cannot in this proposed rule identify each of them. However, in response to these requests, we have provided below the general categories of DME.

We have also listed below the types of supplies used with the DME. We are listing the supplies because when identifying DME as a designated health service, Congress also included the supplies necessary for the effective use of the DME as part of the designated health service. For example, supplies used with DME could include such items as test strips and lancets used with blood glucose monitoring equipment or drugs used with a nebulizer. In general, supplies are items that cannot be reused. We would also like to point out that, effective December 1, 1996, in order for drugs used in conjunction with DME to be covered by Medicare, the entity dispensing the drug must have a Medicare supplier number, must be licensed to dispense the drug in the State in which it will be dispensed, and must bill and receive payment in its own name.

An infusion pump may be covered as DME, in which case the supplies necessary for its effective use are covered as designated health services; these supplies include the drugs and biologicals that must be put directly into the infusion pump.

External infusion pumps—External infusion pumps may be covered as DME under Medicare if certain coverage requirements are met, including use in the home. The Medicare Coverage Issues Manual provides for the coverage of infusion pumps for certain indications and under certain circumstances, as described in sections 60–9 and 60–14. Other uses of external infusion pumps are covered if the DMERC's medical staff verifies the appropriateness of the therapy and of the prescribed pump for the individual patient. Payment may also be made for the drugs necessary for the effective use of an infusion pump as long as they are reasonable and necessary for the patient's treatment.

Section 1877(b)(2) provides an exception for in-office ancillary services "other than durable medical equipment (excluding infusion pumps) and parenteral and enteral nutrients, equipment, and supplies." Section 1877(b)(2) has the effect of specifically excepting infusion pumps from the prohibition on a physician referring durable medical equipment furnished in the physician's own office. External infusion pumps may be used in a physician's office to administer drug therapy, including chemotherapy. However, external infusion pumps (or other drug delivery systems *used in the physician's office* (and not in the patient's home) are covered by Medicare under section 1861(s)(2)(A) as a service incident to the physician's service and not as DME. In addition, we do not believe that the *in-office* ancillary exception applies to external infusion pumps used outside a physician's office. That is, we do not believe that Congress intended for the *in-office* exception to apply to infusion pumps that are only picked up at a physician's office to be used in the home, or that are delivered to the home.

Implantable infusion pumps—Implantable infusion pumps may also be covered as DME in accordance with the policy described in the Medicare Coverage Issues Manual when they are used for certain indications. Coverage for other uses of implantable infusion pumps is allowed if the carrier's medical staff verifies that the drug and the infusion pump are reasonable and necessary. (Implantable devices are not billed to the DMERC carriers; rather, they are billed to the local carrier.)

If an implantable infusion pump is implanted in the physician's office, but will be used at home and elsewhere, we believe that it qualifies as DME that has been furnished in the physician's office. Hence, the *in-office* ancillary services exception could apply, since section 1877(b)(2) specifically includes infusion pumps, but not other DME.

End-Stage Renal Disease equipment and supplies—Section 1861(s)(2)(F) includes as covered medical and other health services home dialysis supplies, equipment, and self-care home dialysis support services, as well

as institutional dialysis services and supplies provided to individuals with end-stage renal disease (ESRD). This ESRD benefit is separate from the DME benefit under section 1861(s)(6). Therefore, the equipment, services, and supplies covered under this section of the statute are not covered as DME under Medicare. Examples of home dialysis equipment and supplies include needles and syringes, blood pressure cuffs, dialysate solution, and intermittent peritoneal dialyzers.

Other items of equipment furnished in a physician's office—As mentioned above, Medicare does not cover equipment used in a physician's office as DME but may pay for the equipment under other provisions in the statute. For example, section 1861(s)(2)(A) covers services and supplies furnished incident to a physician's services, and can include the use of any equipment that is needed in order for a physician to provide a covered service.

In addition, we may cover diagnostic testing under the diagnostic services benefit under section 1861(s)(3), which would include equipment used in diagnostic testing irrespective of where the equipment is used. For example, dynamic electrocardiography (EKG), commonly known as Holter monitoring, is a diagnostic procedure that provides a continuous record of the electrocardiographic activity of a patient's heart while he or she is engaged in daily activities. Diagnostic services under section 1861(s)(3) are not themselves included as a designated health service and thus are not specifically covered by this rule.

General Categories of DME—Under certain circumstances (which include use in the patient's home), the following items may be covered as DME. (Readers should refer to section 60–9 of the Medicare Coverage Issues Manual for additional information.)

Alternating pressure pads and mattresses and miscellaneous support surfaces
 Bed pans
 Blood glucose monitors
 Canes/crutches and walkers
 Commodes
 Continuous positive airway pressure
 Cushion lift, power seat
 Decubitus care equipment
 Gel flotation pads and mattresses
 Heating pads
 Heat lamps
 Hospital beds and accessories
 Intermittent positive pressure breathing equipment
 Infusion pumps, supplies and drugs
 Lymphedema pumps
 Manual wheelchair base
 Motorized wheelchair/power wheel chair base
 Nebulizers
 Wheel chair options/accessories
 Oxygen and related respiratory equipment
 Pacemaker monitor
 Patient lifts
 Pneumatic compressor and appliances
 Power operated vehicles
 Restraints
 Roll about chairs
 Safety equipment
 Support surfaces

Suction pumps
Traction equipment
Transcutaneous electric nerve simulators and supplies
Trapeze equipment, fracture frame, and other orthopaedic devices
Ultraviolet cabinets

We would include the following definition at § 411.351:

Durable medical equipment has the meaning given in section 1861(n) of the Act and § 414.202.

f. Parenteral and enteral nutrients, equipment, and supplies

Coverage of enteral and parenteral therapy as a Medicare Part B benefit is provided under the prosthetic device benefit provision in section 1861(s)(8). The regulations cover prosthetic devices in § 410.36(a)(2). Details for enteral and parenteral therapy are set forth in the Medicare Coverage Issues Manual at section 65–10. When the coverage requirements for enteral or parenteral nutritional therapy are met, Medicare also covers related supplies, equipment and nutrients.

Enteral nutrients, equipment, and supplies—Enteral nutrition therapy provides nutrients to an individual with a functioning gastrointestinal tract who, due to pathology to or nonfunction of the structures that normally permit food to reach the digestive tract, cannot maintain weight and strength commensurate with his or her general condition. Enteral nutritional therapy may be administered by nasogastric, jejunostomy, or gastrostomy tubes. This benefit also includes supplies appropriate for the method of administration.

Therefore, at § 411.351, we would define “enteral nutrients, equipment, and supplies” as “items and supplies needed to provide enteral nutrition to a patient with a functioning gastrointestinal tract who, due to pathology to or nonfunction of the structures that normally permit food to reach the digestive tract, cannot maintain weight and strength commensurate with his or her general condition, as described in section 65–10 of the Medicare Coverage Issues Manual (HCFA Pub. 6).”

Parenteral nutrients, equipment, and supplies—Parenteral nutrition therapy provides nutrients to an individual with severe pathology of the alimentary tract that does not allow adequate absorption of sufficient nutrients to maintain weight and strength commensurate with the patient's general condition. Since the alimentary tract of such a patient does not function adequately, parenteral nutrition may be provided through an indwelling catheter placed percutaneously in the subclavian vein and then advanced into the superior vena cava. An example of a condition that may typically qualify for coverage is a massive small bowel resection resulting in a severe inability to absorb nutrition in spite of oral intake.

Parenteral nutritional therapy would include the equipment and supplies necessary to furnish the parenteral nutrition therapy. (Parenteral nutrients are commonly considered as prescription drugs. Effective

December 1, 1996, any entity dispensing drugs that are used in conjunction with a prosthetic device, including parenteral equipment, must meet certain conditions in order for the drugs to be covered under Medicare. These conditions are described in the section covering DME and the supplies used in conjunction with DME.)

At § 411.351, we would define “parenteral nutrients, equipment, and supplies” as “items and supplies needed to provide nutriment to a patient with permanent, severe pathology of the alimentary tract that does not allow absorption of sufficient nutrients to maintain strength commensurate with the patient's general condition, as described in section 65–10 of the Medicare Coverage Issues Manual (HCFA Pub. 6).”

We wish to point out that section 1877(b)(2) specifically excludes parenteral and enteral nutrients, equipment, and supplies as a service that can qualify for the in-office ancillary services exception.

g. Prosthetics, orthotics, and prosthetic devices

Prosthetics—Section 1861(s)(9) provides for inclusion as medical and other health services artificial legs, arms, and eyes, including replacements if required because of a change in a patient's physical condition. Prosthetics are covered in the regulations in §§ 410.36(a)(3) and 414.202. As described in section 2133 of the Medicare Carriers Manual, these appliances are covered when furnished under a physician's order. We also cover adjustments to artificial limbs or other appliances required by wear or by a change in the patient's condition when ordered by a physician.

We would define “prosthetics,” at § 411.351, as artificial legs, arms, and eyes, as described in section 1861(s)(9) of the Act.

Orthotics—Orthotics are included as a medical service under section 1861(s)(9) as leg, arm, back, and neck braces. The regulations at § 410.36(a)(3) allow payment for these services to include replacements if required because of a change in the individual's condition. We have interpreted the statute in section 2133 of the Medicare Carriers Manual to cover these items when used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body. In the Carriers Manual, orthotics are covered only when furnished under a physician's order.

Under section 2133D of the Medicare Carriers Manual, orthopedic footwear is covered under the orthotic benefit if the footwear is an integral part of a leg brace. Diabetic shoes are covered under section 1861(s)(12) of the Act in a separate benefit category. Splints, casts, and other devices used for the reduction of fractures and dislocations are covered under section 1861(s)(5). We do not consider diabetic shoes, casts, splints, or these other devices to be included under orthotics, prosthetics, or prosthetic devices.

At § 411.351, we would define “orthotics” as “leg, arm, back, and neck braces, as listed in section 1861(s)(9) of the Act.”

Prosthetic devices—Section 1861(s)(8) provides for inclusion as medical and other

health services “prosthetic devices (other than dental) which replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care), including replacement of such devices, and including one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens.” This definition is reflected in the regulations at §§ 410.36(a)(2) and 414.202. The statute specifically excludes dental devices from Medicare coverage as prosthetic devices. (In addition, renal dialysis machines are covered under the end stage renal disease benefit and are discussed elsewhere in this section.)

Under the prosthetic device benefit, Medicare also includes supplies that are necessary for the effective use of a prosthetic device, for example, tape to secure an indwelling catheter. Section 1877(h)(6)(H) includes prosthetic devices as a designated health service and also specifically includes the supplies associated with these devices. (Effective December 1, 1996, any entity dispensing drugs that are used in conjunction with a prosthetic device must meet certain conditions in order for the drugs to be covered under Medicare. These conditions are described in the section covering DME and drugs used in conjunction with DME.) Section 410.100(f)(2) provides that services necessary to design the device, select materials and components, measure, fit, and align the device, and instructions to the patient are also included in this benefit. Examples of prosthetic devices include cochlear implants, cardiac pacemakers, and incontinence control appliances.

We have received many questions concerning whether Medicare considers an intraocular lens to be a prosthetic device. The answer is yes. We have also been asked, for purposes of the designated health services listed in section 1877(h)(6), to define a prosthetic device to exclude any device that is implanted by a physician as part of a surgical procedure. The theory behind this exclusion is that such devices are only a small component of a central procedure, which is the surgery needed to implant them. Physicians would not unnecessarily subject patients to a surgical procedure just to boost profits on intraocular lenses or other implantable devices, and are thus not the kind of services Congress meant to cover. In addition, some physicians believe that it is critical in many cases that they have the freedom to prescribe their own choice of an implantable device because they have particularized the design or find the device better to work with than others.

On the other hand, we have also been advised that only a very small percentage of surgeons “customize” prosthetic devices by developing their own, or by modifying existing devices. In addition, it is not uncommon for physicians to receive compensation from companies that manufacture or supply these devices, sometimes in the form of “consulting fees,” perhaps in exchange for the physician's agreement to use that company's device exclusively. Physicians might also have an ownership interest in a supplier or manufacturer, thus realizing a profit every time the device is used.

It has also come to our attention that physicians who have some relationship with a manufacturer or supplier are in a position to manipulate a hospital's or an ASC's choice of a prosthetic device in exchange for the physicians' referrals. Although these practices might not lead to the overutilization of services, we believe that they can drive up the cost of certain services that are not subject to a fee schedule, which we would regard as a form of potential program abuse. Such an arrangement might also result in patient abuse, since a physician may choose a prosthetic device based on financial incentives rather than on the best interest of the patient. Because of the controversy surrounding surgically implanted devices, we have not excluded them from the definition of "prosthetic devices," but specifically solicit comments on this issue.

We would also like to point out that intraocular lenses that are implanted in an ambulatory surgical center (ASC) would be covered under the ASC payment rate. We have excluded any services covered under the ASC rate from the referral prohibition under an exception we created in § 411.355(d).

We have also been asked whether, if an ophthalmologist has an optical shop as part of his or her office, he or she can refer Medicare patients to the optical shop for eyeglasses. Medicare coverage of eyeglasses and contact lenses is very limited, covering only those that qualify as "prosthetic devices" used after intraocular lenses are implanted during cataract surgery. Thus, a physician would not be prohibited from referring a Medicare patient to the optical shop for any conventional eyewear that is not covered under the Medicare program. For eyeglasses that are covered by Medicare, the physician could prescribe and fill the eyeglass prescription if an exception applies. For example, the services might meet the in-office ancillary services exception if the optical shop is located in the physician's office suite. Alternatively, the optical shop might qualify as a rural provider so that the exception for rural ownership in section 1877(d)(2) of the Act could apply.

At § 411.351, we would define a "prosthetic device" as a device (other than a dental device) listed in section 1861(s)(8) that replaces all or part of an internal body organ, including colostomy bags and including one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens. We would define "prosthetic supplies" as "supplies that are necessary for the effective use of a prosthetic device (including supplies directly related to colostomy care)."

h. Home health services

How we will define home health services. Medicare-covered home health services are defined in section 1861(m), and requirements for payment for home health services furnished to eligible beneficiaries are set forth in part 409, subpart E ("Home Health Services Under Hospital Insurance") of our regulations. For purposes of the physician referral prohibition, "home health services" would have the same meaning as the appropriate provisions described in part 409,

subpart E. A brief explanation of the home health benefit follows:

Home health services are items and services furnished to an individual who is confined to the home, under the care of a physician, and in need of at least one of the following skilled services: intermittent skilled nursing services, physical therapy services, speech-language pathology services, or continuing occupational therapy services.

To receive covered home health services, a beneficiary must be under a plan of care established and periodically reviewed by a physician. Home health services are furnished by, or under arrangements made by, a participating home health agency. Home health services are furnished on a visiting basis in a place of residence used as an individual's home. (A patient may not receive home health services in a physician's office.) An individual's home is wherever the individual makes his or her home. This may be his or her own dwelling, an apartment, a relative's home, a home for the aged, or some other type of institution. However, an institution is not considered a patient's home if the institution meets the basic requirements in the definition of a hospital (as defined in section 1861(e)(1)), an SNF (as defined in section 1819(a)(1)), or a nursing facility (as defined in section 1919(a)(1)).

- The following services may be furnished under the home health services benefit if appropriate requirements are met:

- Part-time or intermittent nursing care furnished by or under the supervision of a registered professional nurse.
- Physical therapy, occupational therapy, and speech-language pathology services.
- Medical social services furnished under the direction of a physician.
- Part-time or intermittent services of a home health aide.
- Medical supplies (including catheters, catheter supplies, ostomy bags, and supplies related to ostomy care, and a covered osteoporosis drug, but excluding biologicals and other drugs), the use of durable medical equipment, and appliances suitable for home use.
- The medical services of an intern or resident in training under an approved hospital teaching program if a home health agency is affiliated with or under the common control of the hospital furnishing the medical services.

A beneficiary may also receive home health services on an outpatient basis at a hospital, SNF, or a rehabilitation center under arrangements made by the home health agency if equipment is required that cannot be made available at the beneficiary's home or the services are furnished while the beneficiary is at the facility to receive services requiring equipment that cannot be made available at the beneficiary's home. Home health services do not include transportation of the beneficiary to the facility for these home health services.

Existing § 409.49 identifies services that are excluded from payment under the Medicare home health benefit. Note that included among those services is any service that would not be covered as inpatient hospital services.

Also note that under the Medicare statute, home health services can be provided only

by an HHA. That is, under section 1814(a), payments for services furnished to an individual may be made only to providers of services that are eligible for that payment. To be eligible, an HHA must, among other things, have in effect its own provider agreement with Medicare, as described in section 1866, and meet the specific conditions of participation for HHAs, as described in section 1891. As a result, we regard home health services as services "provided by an HHA" and not as services provided by any other entity, even if the HHA is owned by the other entity or is otherwise financially related to it. (We regard hospital services the same way; that is, they can be provided only by an entity that meets the requirements for participation as a hospital.) Therefore, even if a hospital owns an HHA, the exception for hospital ownership in section 1877(d)(3), which applies to designated health services "provided by a hospital," would not apply to home health services provided by a hospital-based HHA.

At § 411.351, we would include the following definition: "Home health services" means the services described in section 1861(m) of the Act and part 409, subpart E of this chapter."

How We Propose to Reconcile Section 1877 and the Physician Certification Requirements for Home Health Services Under 42 CFR 424.22(d)

Section 903 of the Omnibus Reconciliation Act of 1980 amended sections 1814(a) and 1835(a) of the Act to prohibit the certification of need for home health services, and the establishment and review of a home health plan of care for those services, by a physician who has a significant ownership interest in, or a significant contractual or financial relationship with, the home health agency that provides those services. These amendments were incorporated into the regulations at 42 CFR 405.1633(d) (which was redesignated as section 424.22(d)), by an interim final rule with comment period that we published in the **Federal Register** on October 26, 1982, at 42 FR 47388, and that became effective on November 26, 1982.

On June 30, 1986, we published a final rule in the **Federal Register** at 51 FR 23541 that confirmed the provisions of the October 26, 1982 rule and clarified that under the term, "significant ownership interest in or a significant financial or contractual relationship with" the home health agency, we intended to include salaried employment. This clarification was made effective on August 29, 1986.

The only exceptions to the home health regulations were uncompensated officers or directors of an HHA, HHAs operated by Federal, State, or local governmental authority, and sole community HHAs. The home health certification restrictions of sections 1814(a) and 1835(a) and § 424.22(d) have not been significantly updated since 1986.

On November 5, 1997, we published a notice with comment period in the **Federal Register** (62 FR 59818) that announced our intention to reconcile the statutory prohibitions in sections 1814(a) and 1835(a) concerning physician certification for home health services with the related section 1877 prohibition. In that notice we stated that we had decided to reexamine appropriate provisions of section 1877 and the home health regulations as they pertain to indirect compensation arrangements involving physicians who are compensated by entities that own HHAs. We announced that, pending that evaluation, we had decided to withdraw certain recent interpretations of § 424.22(d), as it applies to certification and recertification or establishment and review of plans of care by physicians who are salaried employees of, or have a contractual arrangement to provide services to, an entity that also owns the HHA. In addition, we stated that we would address the issue of indirect compensation, applicable to the health services designated in section 1877, in this proposed rule.

We believe that sections 1814(a), 1835(a), and 1877 address the same behaviors and are identical in purpose: they each prohibit a physician who has a significant ownership interest in, or a significant financial relationship with, a home health agency from certifying or recertifying a patient's need for home health services. We have defined the concepts of "significant ownership interests and significant financial relationships" in the home health context in § 424.22(d)(1) through (d)(3), based on a fixed percentage of ownership and, for financial or contractual relationships, based on a specific dollar amount of compensation (or, if less, a percent of the agency's operating expenses).

Under section 1877, in contrast, any level of ownership or compensation amounts to a financial relationship unless the arrangement meets any of a number of exceptions. We believe that the provisions we are developing under section 1877 are more effective than the current provisions in § 424.22(d) in accommodating Congress' desire to discourage physicians from overutilizing certain services. Furthermore, section 1877 relates more specifically and in greater detail to the issue of referrals for home health services by physicians who have a financial relationship with the entity providing those services, and reflects Congress' most recent thoughts on that issue.

We believe that it is confusing to have in effect two provisions that address prohibited referrals, each of which includes different criteria, and can lead to different results.

We are therefore proposing to use the section 1877 definition of a "financial relationship," and our interpretations of this definition, for the concept of a "significant ownership interest in, or a significant financial or contractual relationship with, a home health agency" in sections 1814(a) and 1835(a). In order to do this, we are proposing to amend § 424.22(d) to state that a physician cannot certify or recertify a patient's need to receive home health

services from an agency if the physician has a "financial relationship" with that agency, as defined in § 411.351, unless the financial relationship meets one of the exceptions in §§ 411.355 through 411.357. In addition, we will list sections 1814(a) and 1835(a) in § 411.1 as part of the statutory basis for this proposed regulation.

Section 424.22, paragraphs (d)(4), (e), (f), and (g) relate to certain specific exceptions to the prohibition on certification in sections 1814(a) and 1835(a). These paragraphs except physicians who serve as uncompensated officers or directors of an HHA, HHAs that are operated by a Federal, State, or local governmental authority, or HHAs that are classified as sole community HHAs in accordance with our regulations. Even if a physician and an HHA are involved in an arrangement that meets one of these exceptions, the arrangement simultaneously remains subject to the requirements in section 1877. That is, if an exception in § 424.22 is subsumed within the exceptions in section 1877, a physician will be able to refer; if it is not, the arrangement will disqualify the physician from referring in spite of § 424.22. Thus, we believe the exceptions listed in § 424.22 have been superseded by section 1877 and should not be separately listed; we are therefore proposing to eliminate them. We are particularly interested in hearing from the public about these proposed changes.

i. Outpatient prescription drugs

Medicare does not cover a category of services called "outpatient prescription drugs." Without additional direction from Congress on what constitutes "outpatient prescription drugs" for the purposes of section 1877, we believe that it is reasonable to assume that Congress intended to include only drugs furnished to individuals under the Medicare Part B benefit and to exclude drugs furnished by providers under Medicare Part A. We also propose to limit "outpatient prescription drugs" to drugs that a patient would be able to obtain from a pharmacy with a prescription. We consider that this category includes any drugs that a patient could get with a prescription, even if patients generally do not do so. For example, we would include such drugs as oncology drugs that are routinely furnished in a physician's office, under the physician's direct supervision, provided the drugs could be obtained by prescription from a pharmacy.

Coverage for prescription drugs furnished outside of a provider setting is very limited under Medicare Part B. "Drugs and biologicals" are defined in the Medicare statute in section 1861(t) and the coverage of drugs and biologicals is explained in part 410 of our regulations. We consider a "biological" to be a drug product that is derived from a living organism or its products, including, but not limited to, serums, vaccines, antigens, and antitoxins. We apply to biologicals the same rules that we apply to any drugs. Therefore, for purposes of section 1877, we propose to define outpatient prescription drugs to include biologicals.

An explanation of the drug and biological benefit is set forth in section 2049 of the Medicare Carriers Manual. This section of the manual provides general requirements for drugs and biologicals that are covered under Medicare Part B. (These requirements do not apply to certain kinds of drugs that are covered under specific provisions of the statute. We discuss these other provisions below, following the general requirements.) In general, drugs are covered only if all of the following requirements are met:

- The drug or biological is included, or approved for inclusion, in the latest official edition of the *United States Pharmacopoeia*, the *National Formulary*, or the *United States Homeopathic Pharmacopoeia*, unless unfavorably evaluated in *AMA Drug Evaluations* or *Accepted Dental Therapeutics*.

- The drug or biological is furnished incident to a physician's services.

- The drug or biological is reasonable and necessary for the diagnosis or treatment of the illness for which it is administered according to accepted standards of medical practice.

- The drug or biological is not excluded as a preventive immunization.

- The drug or biological has not been determined by the Food and Drug Administration (FDA) to be less than effective. Drugs or biologicals must be approved for marketing by the FDA to be considered safe and effective, for purposes of the Medicare program, when used for indications specified on the labeling.

- Based on the usual method of administration of the form of a drug or biological as furnished by a physician, the drug or biological is of a type that cannot be self-administered.

Drugs and biologicals that are specifically covered under Part B would include those furnished in a physician's office incident to the physician's professional services under section 1861(s)(2)(A); as part of outpatient hospital services under section 1861(s)(2)(B); and, even though they are preventive immunizations, pneumococcal vaccine, influenza vaccine, and hepatitis B vaccine under section 1861(s)(10); and antigens under section 1861(s)(2)(G).

Drugs that are or can be self-administered, such as those in pill form or in a self-injectable form, are not covered by Medicare Part B unless the statute specifically provides this coverage. The statute currently provides for the coverage of the following self-administered drugs under limited conditions: blood clotting factors under section 1861(s)(2)(I), drugs used in

immunosuppressive therapy under section 1861(s)(2)(J), erythropoietin (EPO) for dialysis patients under section 1861(s)(2)(O), and certain oral cancer drugs under section 1861(s)(2)(Q). (The statute provides under section 1861(m) for the coverage of certain osteoporosis drugs, defined in section 1861(kk), that can be self-administered but are furnished to a home health patient who is unable to self-administer the drugs. However, these drugs are covered under section 1861(m) as part of the Medicare Part A home health services benefit.)

After much consideration, we believe it would be inappropriate to include as outpatient prescription drugs, for purposes of section 1877, EPO and other drugs furnished as part of dialysis treatment for ESRD patients who dialyze at home or in a dialysis center, even though these drugs are not included in the end stage renal disease composite payment rate, but are billed separately. We base this policy on our perception that what the patient is primarily receiving is the dialysis treatment. EPO and several other drugs are a relatively minor (although important) part of a much larger and more complicated treatment and are inextricably linked to the dialysis service. That is, it would not be possible to provide dialysis safely and effectively without these drugs because they are critical to the overall effectiveness of the treatment and well-being of the patient. In addition, although many dialysis patients self-administer EPO, we believe that the opportunity for program abuse involving EPO is extremely unlikely. That is because section 1881(b)(11)(B)(ii)(I) establishes the payment rate for EPO, regardless of whether the beneficiary purchases the drug for self-administration or it is administered by the dialysis facility. Also, we have recently implemented a claims processing mechanism to ensure that payment is not made for excessive administration. That is, payment will not be made for EPO when a patient's hematocrit reading over a 3-month average exceeds 36.5, the upper limit of the drug labeling indication.

We would define "outpatient prescription drugs" at § 411.351 as "those drugs (including biologicals) defined or listed under section 1861(t) and (s) of the Act and part 410 of this chapter, that a patient can obtain from a pharmacy with a prescription (even if patients can only receive the drug under medical supervision), and that are furnished to an individual under Medicare Part B, but excluding EPO and other drugs furnished as part of a dialysis treatment for an individual who dialyzes at home or in a facility."

j. Inpatient hospital services

Services generally regarded as inpatient hospital services. Inpatient hospital services are a Part A benefit defined under section 1861(b). The definition of these services in section 1861(b) is reflected in § 409.10(a) of our regulations. As defined at § 409.10(a), inpatient hospital services include the following services when furnished to an inpatient of a participating hospital or, in the case of emergency services or services in foreign hospitals, to an inpatient of a qualified hospital (as described below).

- Bed and board.
- Nursing services and other related services.
- Use of hospital facilities.
- Medical social services.
- Drugs, biologicals, supplies, appliances, and equipment.
- Certain other diagnostic or therapeutic services.
- Medical or surgical services provided by certain interns or residents-in-training.

We propose to use the definition in section 1861(b) and § 409.10(a). As a clarification, we would state in the definition that inpatient hospital services include services that a hospital provides for its patients that are furnished either by the hospital or by others under arrangements with the hospital; that is, the hospital bills for these services on behalf of its patients. We would specify that the definition does not encompass the services of other physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse midwives, and certified registered nurse anesthetists and qualified psychologists who bill independently. Also, we would refer to existing § 409.10(b), which states that "inpatient hospital services" do not include SNF-type care furnished by a hospital or an RPCH that has a swing-bed approval, or any nursing facility-type care that may be furnished as a Medicaid service.

Psychiatric hospital and RPCH services. We propose to also include as inpatient hospital services inpatient psychiatric hospital services, which are defined in section 1861(c). These services are defined as "inpatient hospital services" furnished to an inpatient of a psychiatric hospital (defined in section 1861(ff)), which means that they are essentially the same services as those furnished to an inpatient of a regular hospital. In addition, we believe that a psychiatric hospital qualifies as a hospital, for all practical purposes, except that it is primarily engaged in providing

psychiatric services for the diagnosis and treatment of mentally ill persons rather than the more general care and treatment that a regular hospital provides to injured, disabled, or sick persons. Also, a psychiatric hospital must meet all of the nine basic requirements that a regular hospital must meet in order to qualify as a hospital, except that for two of the requirements, it must meet analogous standards that relate particularly to psychiatric care.

We also propose to regard as "inpatient hospital services," for purposes of section 1877, inpatient services provided by a participating rural primary care hospital (RPCH). This term refers to facilities designated as RPCHs by the Secretary under section 1820(i)(2). "Inpatient rural primary care hospital services" are defined in section 1861(mm)(2) as items and services, furnished to an inpatient of an RPCH by such a hospital, that would be inpatient hospital services if furnished to an inpatient of a hospital by a hospital.

Section 1861(e) of the Act states that "the term 'hospital' does not include, unless the context otherwise requires, a rural primary care hospital * * *." While it seems clear from this provision that RPCHs are not to be considered hospitals under the Medicare law for most purposes, we also believe the reference to context in this provision indicates that RPCHs may be classified as hospitals where, in specific contexts, it is consistent with the purpose of the legislation to do so. We base the policy to include inpatient RPCH services as "inpatient hospital services" on our belief that a physician who has a financial relationship with an RPCH is in as much of a position to profit from overutilizing referrals to the RPCH as he or she would be if the financial relationship were with an ordinary hospital. In addition, the RPCH provides services that are very similar to inpatient hospital services.

Because we propose to consider RPCH and psychiatric hospital services as inpatient hospital services, the exception for hospital services included in section 1877(d)(3) could apply. This exception applies to services furnished by a hospital if a physician refers to a hospital in which he or she is authorized to perform services and if the physician has an ownership or investment interest in the hospital as a whole, and not in a subdivision of the hospital.

Emergency hospital services. We propose to not include within the definition of "inpatient hospital services" emergency inpatient services provided by a hospital located outside

the United States and covered under the authority in section 1814(f)(2) of the Act and part 424, subpart H. We also propose to exclude inpatient hospital services provided by a nonparticipating hospital within the United States under emergency conditions, as authorized by section 1814(d) and described in part 424, subpart G. We are excluding these services because Medicare covers them infrequently and only when they result from an emergency situation.

The regulations define "emergency services" in § 424.101 as only those services necessary to prevent death or serious impairment of health and, because of the danger to life or health, require use of the most accessible hospital available and equipped to furnish the services. In order to receive payment, a physician or the hospital must submit medical information that describes the nature of the emergency and specifies why it required that the beneficiary be treated in the most accessible hospital. Because Medicare covers these services only if they involve a documented emergency situation, we do not believe that physicians have the opportunity or incentive to overutilize them.

For the reasons cited above, we are also proposing to exclude from the definition of "designated health services" any physician services that otherwise qualify as designated health services but are furnished to an individual in conjunction with emergency inpatient hospital services furnished outside of the United States. These physician services are covered by Medicare under the authority in section 1862(a)(4), which permits coverage of inpatient hospital services, accompanying physician services, and ambulance services (which are not designated health services) furnished outside of the United States under certain limited conditions. To reflect this proposal, we are defining "designated health services" for purposes of the referral prohibition to exclude emergency physician services furnished outside of the United States.

Certain dialysis services. We are aware that there are situations in which a physician might own a dialysis machine, rent it to a hospital, and provide the hospital with a technician to run the machine. This arrangement might fail to meet an exception if the physician refers patients for dialysis services, and also receives rental payments based on the volume or value of those referrals. The physician might also fail to meet an exception if he or she owns a part of the dialysis unit in the hospital (rather than owning part of the hospital as a whole, as required

under the "hospital exception" in section 1877(d)(3)).

We believe there are certain unique situations involving dialysis in which there would be no risk of overutilization. We intend to exclude from the definition of "inpatient hospital services" dialysis furnished by a hospital that is not certified to provide end stage renal dialysis (ESRD) services under subpart U of 42 CFR 405. In these circumstances, we do not believe there would be a risk of program or patient abuse because dialysis would be provided only under the following emergency circumstances, when there is no other appropriate treatment:

- A non-ESRD patient needs dialysis because of renal dysfunction or for augmenting clearance of toxins. For example, a patient with acute tubular necrosis or a patient with theophylline overdose requires dialysis.
- The primary reason for a hospital admission for an ESRD patient is not maintenance dialysis. For example, an ESRD patient needs surgery unrelated to his or her kidney condition, and the surgeon has operating privileges only at a participating Medicare, but non-ESRD, certified hospital and the individual receives maintenance dialysis while he or she is an inpatient.

Certain lithotripsy services. We have been asked to consider excluding from the definition of "inpatient hospital services" services involving certain lithotriptors. Specifically, we are referring to services involving lithotriptors that employ extracorporeal shock wave lithotripsy (ESWL) when used to break up upper urinary tract kidney stones. ESWL focuses shock waves generated outside of the body specifically on stones under X-ray visualization, pulverizing them by repeated shocks. (The use of lithotripsy for breaking up kidney stones is discussed in section 35–81 of the Medicare Coverage Issues Manual.)

The theory behind excluding from "inpatient hospital services" services involving ESWL is that there is no risk of overutilization of these services. In general, severe obstruction, infection, intractable pain, or serious bleeding are indications of the need for surgical removal of a stone. Only when a patient requires surgical treatment would a physician prescribe ESWL. When a patient needs additional treatment, there is no alternative available that is less invasive or less expensive than ESWL. In addition, the procedure itself apparently documents the medical necessity to prescribe it. As we understand ESWL, the kidney stone is located, identified, and the progress of

the therapy is recorded as part of the visualization process.

While we agree that it might be unlikely that physicians would overutilize ESWL, we wish to raise some of the same concerns that we raised under our discussion on surgically-implanted prosthetic devices. That is, we believe that these arrangements can potentially lead to patient abuse, with physicians requiring the use of certain equipment based on financial incentives, rather than on the best interests of the patient. Because of the controversial nature of lithotripsy, we have not excluded it from the definition, but specifically solicit comments on this issue.

Inpatient hospital services and the definition of a "hospital." Note that our proposed definition of "inpatient hospital services" would affect in only a limited way the definition of the term "hospital" that we included in the August 1995 final rule. We included the definition of a "hospital" in § 411.351 solely for the purpose of determining ownership of a hospital as an entity, and we did not include as part of the hospital any entities furnishing services under arrangements. However, we would amend the definition of a hospital to make it clear that the entities covered by that definition are those that qualify as a "hospital" under section 1861(e), as a "psychiatric hospital" under section 1861(f), or as a "rural primary care hospital" under section 1861(mm)(1).

We would include the following definition at § 411.351: "Inpatient hospital services" are those services defined in section 1861(b) of the Act and § 409.10(a) and (b) and include inpatient psychiatric hospital services listed in section 1861(c) of the Act and inpatient rural primary care hospital services, as defined in section 1861(mm)(2). "Inpatient hospital services" do not include emergency inpatient services provided by a hospital located outside the United States and covered under the authority in section 1814(f)(2) and 42 CFR part 424, subpart H and emergency inpatient services provided by a nonparticipating hospital within the United States, as authorized by section 1814(d) and described in 42 CFR part 424, subpart G. These services also do not include dialysis furnished by a hospital that is not certified to provide end stage renal dialysis (ESRD) services under subpart U of 42 CFR 405.

Inpatient hospital services include services that a hospital provides for its patients that are furnished either by the hospital or by others under arrangements with the hospital. They do

not encompass the services of other physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse midwives, and certified registered nurse anesthetists and qualified psychologists who bill independently.

k. Outpatient hospital services

Sections 1861(s)(2)(B) and (C) and 1832 provide for coverage of outpatient hospital services under Part B. Section 1861(s)(2)(B) provides for coverage of hospital services (including drugs and biologicals that cannot, as determined in accordance with regulations, be self-administered) incident to physician services furnished to outpatients (we consider these "therapeutic services") and partial hospitalization services incident to these services. Section 1861(s)(2)(C) provides for coverage of "diagnostic services which are—(i) furnished to an individual as an outpatient by a hospital or by others under arrangements with them made by a hospital; and (ii) ordinarily furnished by such hospital (or by others under such arrangements) to its outpatients for the purpose of diagnostic study." We describe below the coverage provisions concerning outpatient hospital services under the categories of therapeutic and diagnostic services, and partial hospitalization services. We also discuss briefly the special rules for physical therapy, occupational therapy, and speech pathology services furnished to a hospital outpatient.

We would consider all covered services (either diagnostic or therapeutic) performed on hospital outpatients that are billed by the hospital to Medicare (including arranged for services) as outpatient hospital services. In addition, it should be noted that outpatient hospital emergency services may be therapeutic (furnished incident to a physician's service) or may be diagnostic in nature. Unlike other outpatient hospital services, emergency services may be covered in nonparticipating hospitals subject to the conditions described in section 1835(b) and 42 CFR part 424, subpart G. We propose to exclude these emergency services from the definition of "outpatient hospital services" for the same reasons that we cited above in excluding them from the definition of "inpatient hospital services."

We have also been asked to exclude services involving lithotriptors that employ ESWL when used to break up upper urinary tract kidney stones. We have the same concerns in the outpatient context about the potential for patient abuse that we raised in our discussion about excluding these

services from the definition of "inpatient hospital services." In addition, we have learned of situations in which urologists in a particular geographic area invest in lithotriptors, then require that outpatient departments use the physicians' equipment if they want to receive any urology referrals. Because this kind of manipulation can lead to increases in the cost of services, we regard it as creating the potential for program abuse. Because of the controversial nature of lithotripsy, we have not excluded it as an outpatient hospital service, but specifically solicit comments on this issue.

However, we are proposing to include under the definition of "outpatient hospital services" outpatient services furnished by a psychiatric hospital (as defined in section 1861(f)) and RCH services, which are included under Medicare Part B by section 1832(a)(2)(H). "Outpatient rural primary care hospital services" are defined in section 1861(mm)(3) as medical and other health services furnished by an RCH. We are including both of these kinds of services as "outpatient hospital services" for the same reasons that we have included them as "inpatient hospital services," as described in the section above covering inpatient hospital services.

Outpatient hospital services incident to physician services (therapeutic services)—Under sections 1861(s)(2)(B) of the Act and 42 CFR 410.27, these "incident to" services specifically include drugs and biologicals that cannot be self-administered. "Incident to" services must be furnished by or under arrangements made by a participating hospital and as an integral though incidental part of a physician's services. We consider these services as therapeutic services that aid the physician in the treatment of the patient. Under section 230.4 of the Medicare Hospital Manual (HCFA Pub. 10), therapeutic services that hospitals furnish on an outpatient basis are those services and supplies (including the use of hospital facilities) that are incident to the services of physicians in the treatment of patients. These services include clinic services and emergency room services. To be covered as "incident to" a physician's services, the services and supplies must be furnished on a physician's order by hospital personnel under hospital medical staff supervision in the hospital or, if outside the hospital, by hospital-affiliated personnel who are under the direct personal supervision of a physician who is treating the patient.

Diagnostic outpatient hospital services—Under § 410.28, diagnostic

services furnished in a hospital to outpatients, including certain drugs and biologicals required to perform the services (even if those drugs or biologicals are self-administered), are covered if the services meet the following conditions:

- They are furnished by or under arrangements made by a participating hospital.
- They are ordinarily furnished by, or under arrangements made by, the hospital to its outpatients for the purpose of diagnostic study.
- They would be covered as inpatient hospital services if furnished to an inpatient.
- If furnished under arrangements, they are furnished in the hospital or in other facilities operated by or under the supervision of the hospital or its organized medical staff.

Section 230.3 of the Medicare Hospital Manual explains that a service is diagnostic if it is an examination or procedure to which the patient is subjected, or which is performed on materials derived from a hospital outpatient, to obtain information to aid in the assessment of a medical condition or the identification of a disease. Among these examinations and tests are diagnostic laboratory services such as hematology and chemistry; diagnostic x-rays; isotope studies; EKGs; pulmonary function tests; and other tests given to determine the nature and severity of an ailment or injury. Hospital personnel may furnish diagnostic services outside the hospital premises without the direct personal supervision of a physician.

Partial hospitalization services—Partial hospitalization services are included as "medical or other health services" covered by Medicare Part B under section 1861(s)(2)(B) and must be provided "incident to" a physician's services. Partial hospitalization services are defined in section 1861(ff). This definition is reflected in §§ 410.27(d) and 410.43, which provide that partial hospitalization services consist of a variety of outpatient psychiatric services. These services must be prescribed by a physician, who certifies and recertifies the need for the services, and the services must be furnished under a plan of treatment, all in accordance with provisions in subpart B of part 424. Section 424.24(e)(1) requires that a physician certify that an individual would require inpatient psychiatric care if the partial hospitalization services were not provided.

Section 230.5 of the Medicare Hospital Manual further explains the partial hospitalization services benefit. It points out that there is a wide range

of services and programs that a hospital may provide to its outpatients who need psychiatric care, ranging from a few individual services to comprehensive, full-day programs. However, payment may be made only for services meeting the requirements of the outpatient hospital benefit. That is, the services must be incident to a physician's service and be reasonable and necessary for the diagnosis or treatment of the patient's condition. This means the services must be for the purpose of diagnostic study or the services must reasonably be expected to improve the patient's condition.

Special rules that apply to physical therapy, occupational therapy, and speech pathology services furnished to a hospital outpatient covered under Part B—The rules for these services appear in sections 241 and 242 of the Medicare Hospital Manual. Sections 210.8, 210.9, and 210.11 of the Medicare Hospital Manual describe these therapies (which do not require direct physician supervision) and set forth the conditions that must be met for the services to be covered as outpatient hospital services.

We would include the following definition at § 411.351: "Outpatient hospital services" means the therapeutic, diagnostic, and partial hospitalization services listed under section 1861(s)(2)(B) and (C); outpatient services furnished by a psychiatric hospital, as defined in section 1861(f); and outpatient rural primary care hospital services, as defined in section 1861(mm)(3); but excluding emergency services covered in nonparticipating hospitals under the conditions described in section 1835(b) and 42 CFR part 424, subpart G.

2. Direct Supervision

Section 1877(b)(2) provides an exception for in-office ancillary services. To qualify as in-office ancillary services, the services must, among other things, be furnished personally by a referring physician or another physician in the same group practice, or be furnished by individuals who are "directly supervised" by one of these physicians.

In the August 1995 final rule, we defined "direct supervision" as supervision by a physician who is present in the office suite and immediately available to provide assistance and direction throughout the time that clinical laboratory services are being performed. We are proposing to apply this definition to referrals for any of the other designated health services that can be excepted under section 1877(b)(2). We also propose to revise this definition to make it clear that

"present in the office suite" means the physician must be present in the office suite in which the services are being furnished, at the time they are being furnished. We believe this clarification is necessary for situations in which a physician might be working in more than one suite in a building, such as when he or she provides services other than designated health services in one suite, while the designated health services are furnished in a separate suite in the same building.

We also wish to clarify that we believe the supervision requirement is meant to establish the services as those that are integral to the physician's own practice, and that are conducted within his or her own sphere of activity: hence the title *in-office ancillary* services. It is our view that Congress did not intend to except referrals made by a physician to a separate, profit-making enterprise in which the physician has invested or from which he or she receives payments. Hence, we do not believe the in-office ancillary exception applies to services that are performed in a location that is separate and distinct from one in which the physician conducts his or her own everyday activities.

Consistent with our interpretation that Congress intended this exception to apply to services that are closely attached to the activities of the referring physician, we used the definition of "direct supervision" that appears in section 2050 of the Medicare Carriers Manual, Part 3—Claims Processing, which describes services that are "incident to" a physician's professional services under section 1861(s)(2)(A). This provision requires that the physician be present in the office suite and immediately available to provide assistance and direction throughout the time the aide or technician is performing services. The very same definition appears in the regulations at § 410.32(a), which states, in general, that diagnostic x-ray tests are covered only if performed under the "direct supervision" of certain physicians or by certain radiology departments. As we stated in the preamble to the August 1995 final rule, we believe Congress was adopting and ratifying the Secretary's longstanding definition of this term.

Nonetheless, since the publication of the August 1995 final rule, we have become aware that many of the ancillary services that physicians and physician groups provide are subject to a range of supervision requirements for coverage purposes, some of which are more stringent than the current "incident to" supervision requirements, and some of which are less stringent. (The requirements for diagnostic services, for

example, currently appear in § 410.32 of the regulations, in various places in the Medicare Carriers Manual, and as part of certain CPT codes. The requirements for physician supervision of diagnostic tests in all settings in which the technical component is payable under the physician fee schedule have been consolidated in a proposed regulation that was published on June 18, 1997 at 62 FR 33158.)

We recognize, in examining supervision requirements that include a physician's presence, that they each have some of the same and some separate purposes. The "incident to" rule is intended to ensure that the physician is at hand when the services are furnished because the law only covers them when they are "incident to a physician's professional services," making the physician's presence essential, for both quality control and billing purposes, as a condition of coverage. In the case of the diagnostic services, the service is explicitly related to a medical need for the personal supervision or involvement of a physician in performing or monitoring the tests. These two sets of coverage-based "supervision" tests have their particular purposes and both remain a condition of coverage and payment for Medicare, in addition to any supervision requirements that appear in the section 1877 referral provisions.

The "direct supervision" requirement in the in-office ancillary services exception appears to us to share with the "incident to" test the need to tie the services directly to the activities of the physician, to ensure that they are part of his or her own medical practice. We continue to believe that Congress intended in including "direct supervision" in the law the concept of "direct supervision" that appears as part of the "incident to" requirements. However, in the context of physician referrals, we believe the physician's presence is necessary for "management" purposes (that is, to demonstrate that the physician is there, actively running the practice), rather than for coverage purposes. Thus, the requirement that the physician be on the premises the entire time that a designated health service is being furnished can have absurd and impractical results, preventing a physician from leaving the office suite for even brief periods when there may be no health and safety standards requiring his presence.

Accordingly, we propose to depart from our interpretation that the definition of "direct supervision" for purposes of the referral prohibition is identical to the definition in the "incident to" context. That is, we

propose to continue to require that the services in general be performed by aides or technicians only when the physician is present in the office suite so that they are tied to his or her activities, but allow very limited absences from the office. We propose to amend the definition as follows:

Direct supervision means supervision by a physician who is present in the office suite in which the services are being furnished, throughout the time they are being furnished, and immediately available to provide assistance and direction. "Present in the office suite" means that the physician is actually physically present. However, the physician is still considered "present" during brief unexpected absences as well as during routine absences of a short duration (such as during a lunch break), provided the absences occur during time periods in which the physician is otherwise scheduled and ordinarily expected to be present and the absences do not conflict with any other requirements in the Medicare program for a particular level of physician supervision.

Under this definition, a physician must actually be physically present in the office suite at the time designated health services are being furnished, or be absent only under the limited conditions described in the definition. We anticipate that the question of when an absence qualifies as "brief and unexpected" or as a "routine absence of a short duration" will be a determination that only the local carrier can make, based on individual circumstances.

A service will not qualify as an in-office ancillary service during any time period in which the physician is scheduled to be in the office, but in reality is specifically or routinely expected to be somewhere else or during any time period in which the physician is scheduled to be somewhere else. Therefore, laboratory services or other designated health services performed by technicians or aides would not qualify as in-office ancillary services if they are performed during time periods that occur before or after the physician's regularly scheduled office hours. (Aides or technicians can perform other tasks in the absence of the physician, such as setting up equipment or cleaning up, as long as the tasks are not components of designated health services provided to Medicare or Medicaid patients.) Also, a physician's absences to perform medical services outside the office would not be permissible under "direct supervision," such as absences to do hospital rounds or provide care in an outpatient clinic. However, we would allow absences for unexpected medical emergencies.

While this definition for referral purposes would allow a physician to

occasionally be absent for short periods, specific coverage requirements for services furnished and billed as "incident to" a physician's services, for diagnostic services, or for any other services with separate supervision requirements would continue to operate to determine whether a specific service is covered. We recognize that this approach will require a physician to pay close attention to the specific coverage requirements that apply to individual services, as well as the supervision requirement in section 1877(b). Nonetheless, most of the coverage rules have been in effect for many years, so physicians have had experience in complying with them. In coordinating the separate supervision requirements with the requirement in section 1877, physicians must only comply with the separate coverage requirement if it is more stringent than the requirement in section 1877, as interpreted in this proposed rule.

We believe that our proposed amendment to the definition of "direct supervision" addresses the concerns of physicians who feel that, as a practical matter, they cannot be in the office every single minute of every day. The amendment will allow physicians who must be called away briefly to avoid the sanctions that could arise from section 1877 if they are not present at the moment when a medical service is furnished, provided there are no health and safety reasons for them to be on the premises.

In line with the "incident to" manual provision, we are also proposing that a physician is directly supervising an individual outside the office suite (such as in an SNF) if the physician is in the room with the technician when the technician is performing services. (We derive this rule from section 2050, which states that direct supervision does not exist if a physician is only available by phone or is only physically present somewhere in the building.) Section 45-15 of the Coverage Issues Manual discusses situations in which a physician establishes an office within an SNF or other institution. Under this provision, a physician's office within an institution must be confined to a separately identified part of the facility that is used solely as the physician's office and cannot be construed to extend throughout the entire institution. (However, to qualify for the in-office ancillary exception in either of these "out of office" situations, the services must meet the additional statutory requirements for location and billing described in section 1877(b)(2).)

We are not proposing that there must be any particular configuration of rooms

for an office to qualify as one office "suite." However, direct supervision means that a physician must be in the office suite and immediately available to provide assistance and direction. Thus, a group of contiguous rooms should in most cases satisfy this requirement. We have been asked whether it would be possible for a physician to directly supervise a service furnished on a different floor. We think the answer would depend upon individual circumstances that demonstrate that the physician is close at hand. The question of physician proximity for physician referral purposes, as well as for incident to purposes, is a decision that only the local carrier could make based on the layout of each group of offices. For example, a carrier might decide that in certain circumstances it is appropriate for one room of an office suite to be located on a different floor, such as when a physician practices on two floors of a townhouse.

3. Entity

In-office referrals are referrals to an "entity." Section 1877(a)(1) prohibits a physician from referring Medicare patients for the furnishing of designated health services to an entity with which the physician (or an immediate family member) has a financial relationship, unless an exception applies. The statute encompasses *any* entity that provides designated health services, without qualifications or limits. We attempted to reflect the breadth of the concept in the August 1995 final rule at § 411.351, where we defined an "entity" as a sole proprietorship, trust, corporation, partnership, foundation, not-for-profit corporation, or unincorporated association.

We wish to clarify that we regard an individual physician or group of physicians as referring to an "entity" when they refer to themselves, or among themselves. The concept of a "referral" under section 1877(h)(5)(A) and (B) covers the request by a physician for an item or service under Part B, or the request or establishment of a plan of care by a physician that includes the provision of a designated health service. This statutory definition does not exclude in-office referrals, nor does it specify that a referral occurs only when a physician refers to an outside entity.

In addition, the in-office ancillary services exception in section 1877(b)(2) would not be necessary if in-office referrals were free from the prohibition. Section 1877(b)(2) makes it clear that designated health services that are furnished personally by the referring physician who is a solo practitioner or, in the case of a group practice, by

another member of the physician's group practice, or by other individuals who are directly supervised by these physicians, are subject to the referral prohibition. Physicians who refer to or among themselves are excepted from the prohibition only if they meet the criteria specified in section 1877(b)(2).

Similarly, physician services provided personally by (or under the personal supervision of) another physician in the same group practice as the referring physician are specifically excepted under section 1877(b)(1). To clarify our position on in-office referrals, we propose revising the definition of an "entity" in § 411.351 to include any physician's solo practice or any practice of multiple physicians that provides for the furnishing of a designated health service.

4. Fair Market Value

The term "fair market value" appears in most of the compensation related exceptions. These exceptions, among other things, require that compensation between physicians (or family members) and entities be based on the fair market value of the particular items or services that these parties are exchanging. We defined this term in the August 1995 final rule by using the definition in section 1877(h)(3). This provision defines fair market value as the value in arm's-length transactions, consistent with the general market value, with other specific terms for rentals or leases.

We have previously defined the term fair market value in our regulations in part 413, in the context of reasonable cost reimbursement in payments for end stage renal disease services. Section 413.134(b)(2) explains the circumstances under which an appropriate allowance for depreciation on buildings and equipment used in furnishing patient care can be an allowable cost. This provision defines "fair market value" for purposes of determining the costs incurred by a present owner in acquiring an asset. "Fair market value" is defined as "the price that the asset would bring by bona fide bargaining between well-informed buyers and sellers at the date of acquisition. Usually the fair market price is the price that bona fide sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition."

To be consistent, we are incorporating this definition of what constitutes "fair market value" into this proposed rule to explain, for purposes of those exceptions that involve compensation paid for assets, what we believe constitutes a value that is "consistent

with the general market value."

However, we are modifying the definition as follows so that it also applies to any arrangements involving items or services, including employment relationships, personal services arrangements, and rental agreements:

General market value is the price that an asset would bring, as the result of bona fide bargaining between well-informed buyers and sellers, or the compensation that would be included in a service agreement, as the result of bona fide bargaining between well-informed parties to the agreement, on the date of acquisition of the asset or at the time of the service agreement. Usually the fair market price is the price at which bona fide sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition, or the compensation that has been included in bona fide service agreements with comparable terms at the time of the agreement.

The definition of "fair market value" will continue to include the additional requirements in section 1877(h)(3) for rentals or leases. Among other things, the statute defines the fair market value of rental property as its value for general commercial purposes, not taking into account its intended use.

5. Financial Relationship

A referral alone is not a financial relationship. We wish to clarify that when a physician simply refers patients to an outside entity, he or she does not have a financial relationship with that entity. A financial relationship consists of an ownership or investment interest in the entity or a compensation arrangement with the entity. If the physician does not own any portion of the entity, and does not pay the entity or receive any kind of payment from the entity for the referral or for anything else, there is no financial relationship.

A financial relationship can involve more than the Medicare or Medicaid programs. In § 411.351 we defined a financial relationship as a direct or indirect relationship in which a physician or immediate family member has an ownership or investment interest in an entity or a compensation arrangement with the entity. We would like to emphasize that a financial relationship can exist between a physician and an entity even if that relationship does not involve designated health services or the Medicare or Medicaid programs. For example, a compensation arrangement is defined in § 411.351 as, in general, any arrangement involving any remuneration between a physician (or family member) and an entity. This remuneration can involve payments for anything, such as payments for rent,

payments for nonmedical types of items or services, or for housing or travel expenses.

Ownership interests can be indirect. The statute and the August 1995 final regulation specify that an ownership or investment interest in an entity can exist through equity, debt, or other means and includes an interest in an entity that holds an ownership or investment interest in any entity providing designated health services. We do not regard the last part of this provision as a limiting factor, but rather as an indication that Congress wished to include, in the concept of "ownership," an interest that is at least one level removed from direct ownership. We propose to interpret this provision to apply to interests that are removed by an unlimited number of levels.

This interpretation would cover situations involving multiple levels, such as when a physician has an interest in an entity that has an interest in another entity that in turn holds the ownership interest in the entity that provides designated health services. We believe that this interpretation fulfills the intent of the statute, which was meant to prevent physicians from evading the prohibition by establishing their ownership interests indirectly in "holding companies" rather than in the entities that furnish designated health services. It is our view that the number of layers of ownership is irrelevant, as long as a physician or family member has established an indirect interest. To reflect this interpretation, we would revise the description of ownership in § 411.351 (as part of the definition of "financial relationship") as follows: "An ownership or investment interest in an entity that exists in the entity through equity, debt, or other means and includes any indirect ownership or investment interest, no matter how many levels removed from a direct interest; for example, ownership includes situations in which a physician or immediate family member has an interest in any entity that holds an ownership or investment interest in any entity providing designated health services."

Payments that result from an ownership or investment interest are not compensation. We would like to emphasize a point that we discussed at length in the preamble to the August 1995 final regulation. We explained there that when a physician or family member has an ownership or investment interest in an entity, we will not count as compensation any returns on that investment. For example, if a physician has an investment interest in an entity in the form of stock or

securities, we will not count any of the dividends or other payments that derive from that ownership or investment interest as a compensation arrangement between the physician and the entity. (However, a physician or family member can receive an ownership interest from an entity in a manner than could constitute a compensation arrangement, such as when a physician receives stock as part of a salary payment or in exchange for the sale of his or her practice.)

6. Group Practice

The value of group practice status under the law. When a group of physicians qualifies as a "group practice" as defined under section 1877(h)(4), the group may qualify for several exceptions in the law that are specifically designed to accommodate groups. For example, section 1877(b)(1) excepts from the referral prohibition physician services provided personally by (or under the personal supervision of) another physician in the same group practice as the referring physician. Similarly, section 1877(b)(2) excepts in-office ancillary services that are furnished personally by or are directly supervised by either the referring physician or by another physician who is a member of the same group practice as the referring physician. However, a group of physicians does not have to meet the definition of a group practice in order to qualify for other exceptions under the law that are based on characteristics other than the referring physician's group practice status.

We wish to also point out that the definition of a group practice in section 1877(h)(4) is particular to the referral rules. That is, it was designed to allow physicians in specific kinds of groups to continue to refer patients for designated health services under certain circumstances. Therefore, the definition may have little or no bearing on which physicians qualify as a group practice for purposes of other Medicare or Medicaid provisions.

Who can organize and control a group practice. The statute defines a "group practice" as a group of two or more physicians legally organized into a partnership, professional corporation, foundation, not-for-profit corporation, faculty practice plan, or similar association. The statute requires that a group practice consist of a legal entity. Thus, a group that is not legally organized, but is instead only holding itself out as a group, would not qualify as a group practice under the statutory definition. Moreover, we believe that the statute specifically requires that a partnership consist of two or more

physicians who are partners and that a professional corporation consist of two or more physicians who are incorporated together.

We believe that more complex business configurations may be involved when two or more physicians are "legally organized" into a foundation, not-for-profit corporation, or a faculty practice plan. As we pointed out in the preamble to the August 1995 final rule, the statute is silent about who must actually legally organize these kinds of associations. As a result, we interpreted this provision in the final rule to allow any individuals or entities to set up legal structures for these kinds of associations, provided two or more physicians have a role in providing services and the physicians meet all of the other specific requirements in section 1877(h)(4). In addition, the statute is silent about who must operate any of the group practice associations. We have interpreted the statute, in the August 1995 final rule, to allow any individuals or entities to do this. For example, a hospital could own and operate a group practice, provided there are no State laws to prevent this.

A group practice as one legal entity. In the August 1995 final rule we took the position that the statute contemplates a group practice that is composed of one single group of physicians who are organized into one legal entity. We stated that a group practice could not consist of two or more groups of physicians, each organized as separate legal entities, although we believed that a single group practice (that is, one single group of physicians) could own other legal entities (such as a billing entity) for the purpose of providing services to the group practice. We based this conclusion on the fact that section 1877(h)(4)(A) defines a group practice as a group of two or more physicians who are legally organized as a partnership, professional corporation, etc. However, we continue to receive numerous inquiries about whether a group can consist of several legal entities that are, in turn, legally organized into the one group.

We believe that Congress meant that a group must be one legal entity, and that it regarded this characteristic as a mark of a true group practice. It is our view that any other interpretation could pose the risk of multiple groups of physicians remaining in many ways separate, but joining together for the sole purpose of taking advantage of the exceptions in section 1877 that apply to group practices. Therefore, we propose to continue to require that a group consist of just one legal entity.

Nonetheless, we would like to clarify that we believe that a group practice is still "one legal entity" even if it is composed of owners who are actually individual professional corporations or is owned by physicians who are individually incorporated. It is our understanding that a group can contain physicians who are individually incorporated as professional corporations, and who provide services to group patients. This kind of configuration is apparently common in group situations and generally results when an individual physician wishes to qualify for certain tax and pension advantages. The physician is employed by the professional corporation, which in turn contracts with the group. We believe that such a group is not a conglomeration of multiple physician groups, but may instead be a true group practice, provided all the other criteria in section 1877(h)(4) are met.

We have also considered the issue of whether individuals who are separately incorporated as individual professional corporations and who contract with the group practice qualify as "members" of the group. We are proposing (in this section under the heading "The requirement for physician-patient encounters") to, in general, eliminate contractors from qualifying as "members" of a group practice, a proposal that a major group practice association asserted would be highly important to its membership. The association believes that many group practices would have difficulty meeting the "substantially all" requirement in the group practice definition if the groups have to consider as members the many specialists with whom they contract to furnish services through the group practice on a part-time basis. Thus, we are proposing to include only owner and employee physicians as "members" of a group practice. However, we are also proposing to consider as owner "members" physicians who belong to individual professional corporations that, in turn, own the group practice.

The "full range of services" test. A "group practice" is defined in some detail in section 1877(h)(4) of the statute. One of the criteria in the statutory definition is that each physician who is a member of the group must furnish substantially the full range of 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. We defined the term "group practice" in § 411.351 of the August 1995 final rule by using the statutory

definition and by adding certain interpretations. In one of these, we required physician members to furnish the full range of "patient care services" that they routinely furnish, rather than just "services." Elsewhere in § 411.351, we defined "patient care services" as any tasks performed by a member that address the medical needs of specific patients, regardless of whether they involve direct patient encounters.

On considering this issue further, we propose revising the definition of "patient care services" to apply to any of a physician's tasks that address the medical needs of specific patients or patients in general, or that benefit the practice.

We believe that the "full range of services" provision, along with most of the other criteria in the group practice definition, was designed to ensure that, as part of the group, a physician is actually practicing medicine as he or she ordinarily would and has not simply joined the group in name only. We realize, however, that a physician member can legitimately furnish other kinds of services to the group, beyond services that benefit only specific patients. For example, a physician member might spend time training staff members, arranging for equipment, or performing administrative or management tasks. As long as these tasks actually benefit the operation of the group practice, we believe they should be counted as part of the test for gauging "substantially the full range of" a physician's services.

The "substantially all" test and the group billing number requirement. The "Substantially All" Test—Effective January 1, 1995, substantially all of the services of the group members must be furnished through the group and be billed under a billing number assigned to the group (the "substantially all" test). We discussed the substantially all test, as it was effective on January 1, 1992, at great length in the August 1995 final rule. We wish to clarify certain aspects of the test, which appears as part of the definition of a group practice in § 411.351.

Section 411.351 requires that substantially all of the "patient care services" of the physicians who are group members (at least 75 percent of the total patient care services of the members) be furnished through the group. The change we have described above in the section on the "full range of services" test, concerning our definition of "patient care services," would affect this test as well. As a result, a group would count any of a physician's tasks that address the medical needs of specific group patients

or group patients in general or that benefit the group practice. The group would not consider in the calculation any time during a physician's week that he or she spent on nonpatient care services, such as teaching in a medical school or doing outside research. For example, if a physician spends 3 days a week furnishing patient care services as part of a group practice and 2 days a week doing research outside the practice, the physician is providing 100 percent of his or her patient care services through the group practice.

The definition in § 411.351 also requires that patient care services be measured in terms of total patient care time that each member spends on patient care services. We wish to clarify that we expect a group practice to look at a physician's total patient care time during a week, furnished both inside and outside of the group practice, to determine what percentage of this time is furnished through the one group. For example, if a physician provides patient care services to a group practice 4 days a week and patient care services in an unrelated clinic 1 day a week, the physician is providing 80 percent of his or her patient care services through the group practice.

Some group practices have informed us that patient care time is not a common measurement of how groups keep track of a physician's contributions to the group. The time standard in the regulation, they claim, will create a whole separate, burdensome administrative process. In light of these comments, we explored alternative options that were suggested to us. These included counting a percentage of the physician's personal income, counting physician-patient encounters, or counting resource-based Relative Value Units (RVUs), a method of assigning resources to CPT codes ([Physicians'] Current Procedural Terminology, 4th edition, 1993 (copyrighted by the American Medical Association)). We found that there is no perfect measure; each of these methods has advantages and disadvantages.

The income option would require that a group determine what percentage of the physician's overall practice income is derived from the group practice. While this would be perhaps the easiest calculation to make, many physicians might consider the data involved to be intensely private. In addition, to the extent that a physician's billing practices differ among settings, an equivalent amount of income derived from within the practice may not account for the same amount of patient care activity that occurs outside the practice. For example, a physician who

works at a clinic for low income patients while outside the group could receive considerably less income for patient care than he or she would receive for equivalent services furnished through the group practice.

We also explored the possibility of counting the number of a physician's patient encounters. However, encounters do not capture the level of intensity involved in any task. For example, a physician might complete one encounter in an entire day, if it involves complex surgery. Another physician could have 30 encounters in the same day, each of which took 15 minutes to complete. In addition, a group would need to gather information about the number of a physician's encounters outside of the group practice to determine the percentage of encounters furnished through the group. One problem with counting the number of patient care encounters and also with counting RVUs, which is discussed immediately below, is that neither method can take into account work that benefits the group in general but is not a service furnished to a patient, for example, time a physician spends training technical personnel.

We next explored the possibility of counting RVUs to determine the share of a physician's efforts furnished through a group practice, since RVUs capture the intensity level of different services. For Medicare purposes, a physician is paid based on the CPT code that is billed for a particular service. Each CPT code has assigned to it a certain intensity level (based on the content of the service and the time the physician has spent), and each intensity level translates into a specified number of RVUs. It is this associated RVU amount that determines a physician's payment for a service. The Medicare billing system can reveal all of the procedures for which a physician has billed, based on the CPT codes, and the value of all of the associated RVUs. There are thousands of CPT codes, many of which can be modified (for instance, to state that a physician acted as an assistant at surgery or co-surgeon, rather than as the surgeon). There is software available that can assign RVUs based on the CPT code and modifiers.

To use this method, it would be necessary for a group to collect all CPT and modifier billing data for the physician both inside and outside the practice, assign RVUs, and compare the totals. There is no "full-time" equivalent RVU amount that a group could use as a proxy to measure the inside RVUs against; therefore, the group would have to collect detailed data about outside practice time. We believe that the RVU method could

impose a burden on groups because of the high volume of codes that physicians are likely to submit, especially in large group practices. This method is further complicated by the fact that it is not clear that all insurers use CPT codes in all cases. For example, some HMOs provide a given payment for a particular kind of service and may not collect data on individual office visits or tests.

As a result of our assessment, we believe that measuring a physician's activities by using time spent doing work for the group, as required in the August 1995 final rule, may be the most straightforward and least burdensome method for measuring a physician's efforts, especially because we do not intend to require that physicians keep detailed time sheets to verify their time. Practices should already be able to track the amount of time spent by each member in activities related to the practice. While this data may not be present in billing records, it should be present in appointment databases, personal schedules, and other easily accessible sources. To simplify matters, a group can assume a physician works a standard 40 hour week unless he or she can present evidence of a shorter or longer work week. A practice should be able to maintain records in the form of general schedules that are sufficient to demonstrate its calculations in the event of an audit. Finally, we consulted several group practice associations about their preference for measuring the standard. They informed us that they favor using time in calculating the standard.

As a result of our investigation, we are therefore proposing to use the measure of physician time as the "default" standard. We believe that our carriers can evaluate the "substantially all" test only if we have one, or perhaps a few, standards. Therefore, we are soliciting comments on other possible methods that groups might use, provided these methods will provide verifiable data that demonstrates that a group meets the "substantially all" criteria. We will review all alternative methods, but only include those in the final rule that we believe are both verifiable and administratively feasible.

The Billing Number Requirement—We are interpreting the new billing number requirement in the "substantially all" test to mean that a single group can have more than one billing number, as long as the group bills under a billing number that has been assigned to the group. We do not believe there is anything in the statute to preclude a group practice from having more than one number. This

interpretation will accommodate situations in which one group practice has multiple numbers because it has many locations or operates in more than one State.

It has also come to our attention that there are an increasing number of situations in which a group has another entity (not a wholly-owned entity) bill for it, such as a management services organization (MSO) or billing agent. We propose to allow a group to meet the requirement that services have been "billed under a billing number assigned to the group" if an agent bills for the group, under the group's name, using the group's billing number, provided the arrangement meets the requirements in § 424.80(b)(6). However, because of the specific terms of the statute, we do not believe a group can receive payments for its services through a separate entity (one that is not wholly owned) that bills in its own right, under its own billing number, even if the payments ultimately constitute group revenues.

The requirement for physician-patient encounters and the definition of group "members". Effective January 1, 1995, the group practice definition in section 1877(h)(4)(A)(v) requires that members of the group must personally conduct no less than 75 percent of the physician-patient encounters of the group practice. We believe this provision may have been designed to differentiate between legitimate group practices and those with "member" owners or investors who are members in name, but who treat few, if any, patients. In such a scenario, nonmember physician contractors could be hired to treat most of the group's patients. This arrangement would allow the nonpracticing "outside" physician owners to refer to the "group" for the furnishing of laboratory services or other ancillary types of services that are designated health services.

In § 411.351 of the August 1995 final rule, we defined "members" of a group practice broadly as 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. This definition would cover all of the physicians who are involved, in some capacity, in a group practice arrangement, while they are furnishing services to group patients. As a result, all group practice patients who have an encounter in the group setting with a physician would be treated by a member of the group practice. Our interpretation would thus render the encounter requirement in section 1877(h)(4)(A)(v) superfluous.

It has come to our attention that group practices generally do not regard independent contractors as members of the group. In addition, when a group practice contracts with a number of independent contractors, the group can experience difficulties in meeting the "substantially all" requirement, especially if the contractors work for the group only on a part-time basis. In order to remedy this problem, and to give meaning to the encounter requirement in section 1877(h)(4)(A)(v), we propose a change in the definition of a member of a group practice. We propose to exclude independent contractors from the definition. In addition, we propose to redefine "members of the group" to include not just physician partners, but physicians with any other form of ownership in the practice (including physicians whose ownership is held by their individual professional corporations). We also propose to count any of the physicians listed under the definition as "members" during the time they furnish "patient care services" to the group rather than just during the time they furnish services to patients of the group that are furnished through the group and are billed in the name of the group. This change reflects our belief that a physician can legitimately be participating as a group member while providing services to the group for which the practice cannot directly bill, such as certain administrative services. We are also proposing to extend this definition to group practices in the context of the additional designated health services.

Group practices should note that under the revised definition of a group "member," independent contractors cannot supervise the provision of designated health services under the in-office ancillary services exception. Under section 1877(b)(2), services must be furnished personally by the referring physician, personally by a physician who is a member of the same group practice, or by individuals who are directly supervised by the referring physician or another physician in the group practice. We will no longer consider independent contractors as physicians who are "in the group practice." An independent contractor may be able to refer to the group practice for the provision of designated health services, provided the physician qualifies for the personal services exception in section 1877(e)(3) of the Act, or the new general compensation exception in § 411.357. We would also like to point out that the definition of who qualifies as a "member of a group practice" in § 411.351 applies only in

the context of the referral provisions in section 1877 of the Act. The concept of group membership may be different for purposes of other provisions of the Medicare or Medicaid statutes.

As a result of our change in who constitutes a group practice member, at least 75 percent of all physician-patient encounters must occur between owner or employee physicians and patients. We regard an "encounter" as any appointment during which a group practice patient is actually examined or treated by a physician.

Methods for distributing group costs and revenues. The statute requires that a group distribute its income and overhead in accordance with methods that are "previously determined." We regard this provision as ambiguous, since it is not clear prior to what event these methods must be in place. A method will always be in place just prior to a distribution, since a distribution can occur only if there is some method in place to carry it out.

It is our view that this provision was meant to require that a group have an established plan for its distributions, rather than making ad hoc decisions about distributions just before making them. Congress may have feared that ad hoc disbursements would be more likely to reflect a physician's referrals. To give meaning to this provision, we propose to interpret it so that a group must have in place methods for distribution determined prior to the time period the group has earned the income or incurred the costs. We believe these methods can be determined by any party, and not just members of the group practice. For example, if a hospital has established a group practice to run a hospital affiliated clinic, the hospital might be the party that determines how clinic income will be distributed.

We are also proposing that the overhead expenses of and the income from the practice be distributed according to methods that indicate that the practice is a unified business. That is, the methods must reflect centralized decision making, a pooling of expenses and revenues, and a distribution system that is not based on each satellite office operating as if it were a separate enterprise. We would impose this additional standard under our authority under section 1877(h)(4)(A)(vi) to add standards by regulation to the definition of a group practice.

Volume or value of referrals cannot be reflected in a physician member's compensation. Beginning on January 1, 1995, physicians who are group practice members cannot directly or indirectly receive compensation based on the volume or value of their own referrals.

However, the statute qualifies this rule by allowing physicians to be paid a share of over-all profits of the group, or a productivity bonus, as described under the next two subheadings. (Groups should take note that the following discussion only describes what is appropriate under section 1877. You should be aware of and comply with other applicable statutes, including the anti-kickback statute, when entering into arrangements.)

We believe that the "volume or value" standard precludes a group practice from paying physician members for each referral they personally make or based on the value of the referred services. This standard applies to any of a physician's actions that constitute "referrals," as these are defined in section 1877(h)(5)(A) and (B) of the Act. We include here a brief discussion of what constitutes a "referral" for purposes of the "volume or value" standard:

Section 1877(h)(5)(A) states that referrals include, subject to an exception for certain specialized services, the request by a physician for an item or service for which payment may be made under Part B, including the 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). We are interpreting this provision to apply not to a physician's requests for any Part B items or services, but only to a physician's requests for designated health services covered under Part B. We explain our rationale for this position in the next section, which discusses the definition of a "referral."

The second part of the statutory definition of "referral" in section 1877(h)(5)(B) covers (subject to an exception for certain specific services) the request or establishment of a plan of care by a physician that includes the provision of a designated health service. Although this second part is not drafted in Medicare-specific terms and could be interpreted to cover situations involving any designated health service, we are interpreting it as applying only to those designated health services covered under Medicare. We discuss this position, and our interpretation of referrals for Medicaid covered services, in more detail in the section dealing with what constitutes a "referral."

Because of our interpretation of what constitutes a "referral," an entity wishing to be considered a group practice in order to use the in-office ancillary services exception cannot compensate its members based on the volume or value of referrals for designated health services for Medicare

or Medicaid patients but could do so in the case of other patients. However, the most straightforward way for a group to demonstrate that it is meeting the requirements for the exception would be for the group to avoid a link between physician compensation and the volume or value of any referrals, regardless of whether the referrals involve Medicare or Medicaid patients. Alternatively, a group that wants to compensate its members on the basis of non-Medicare and non-Medicaid referrals would be required to separately account for revenues and distributions relating to referrals for designated health services for Medicare and Medicaid patients. If a group purports to be making payments to its physicians for nonprogram referrals, but these appear to us to be inordinately high or otherwise inconsistent with the fair market value of those referrals, we could determine that the physicians' compensation does not meet the fair market value standard, and thus may actually reflect additional compensation for Medicare or Medicaid referrals.

A physician member's compensation can reflect over-all profits. Although physician members cannot be compensated directly or indirectly based on their own referrals, under section 1877(h)(4)(A)(iv) and (B)(i), a physician can be paid a share of over-all profits of the group, as long as the share is not determined in a manner that is *directly* related to the volume or value of that physician's own referrals.

In the case of over-all profits, we are interpreting the statute as follows: First, we are taking the position that the statute does not affect a physician's compensation for services other than designated health services. Thus, for purposes of section 1877, a group practice can distribute profits from services other than designated health services in any way it sees fit. For example, a group can distribute profits from the physicians' own nondesignated health services under an even split, based on referrals, or according to the amount of a physician's investment in the group, seniority, hours spent devoted to the practice, or the number or difficulty of services the physician has furnished. The practice can also offer different types of sharing of profits or other kinds of compensation arrangements, or combinations of arrangements, to different physicians or groups of physicians. (Groups should be careful to comply with other statutes, including the anti-kickback statute, when creating compensation arrangements.)

However, when a physician makes a referral for a designated health service

for a Medicare or Medicaid patient (for example, orders a laboratory test or occupational therapy), we believe the statute requires a different scheme. That is, the referring physician can receive a portion of the group's overall pooled revenues from these services as long as the group does not share these profits in a manner that relates directly to who made the referrals for them. We believe, for example, that these profits can be shared according to most of the principles described above, such as an even split, a physician's investment in the group, the number of hours a physician in general devotes to the group, or the difficulty of a physician's work. However, each physician's personal compensation cannot include payments based directly on the number or value of the referrals he or she has made.

Since self-referrals are referrals under section 1877, profits should not be pooled and divided between group members so that they relate directly to the number of designated health services for Medicare or Medicaid patients physicians referred to themselves or the value of those self-referrals (such as a value based on the complexity of the service). Thus, a physician should not receive extra, specific compensation from the pooled profits for performing a designated health service he or she has self-referred. We believe that rewarding a physician each time he or she self-refers for a designated health service can constitute an incentive to overutilize services. Nor should a physician's compensation relate directly to the number of referrals for designated health services he or she has made to other group physicians, to the group's nonphysician staff, or to any other entity or individual.

We regard "over-all profits of the group" to mean all of the profits or revenues a group can distribute in any form to group members, even if the group is located in two different States or has many different locations within one State. We would not interpret the concept of "overall profits" as the profits that belong only to a particular specialty or subspecialty group. We believe that the narrower the pooling, the more likely it will be that a physician will receive compensation for his or her own referrals (for example, a subspecialty group or location could contain only one or two physicians).

A physician member's compensation can reflect productivity bonuses. Under section 1877(h)(4)(A)(iv) and (B)(i), a physician's compensation cannot directly or indirectly reflect the volume or value of his or her referrals, except

that the physician can receive a productivity bonus, as long as the bonus is not determined in a manner that is *directly* related to the volume or value of that physician's own referrals. A productivity bonus must be based on services that are personally performed by a physician or incident to personally performed services.

As we have noted above for sharing of profits, we have interpreted section 1877 as imposing no restrictions on productivity bonuses based on revenues that have nothing to do with a physician's referrals for designated health services under Medicare or Medicaid. Thus, for all nondesignated health services, a physician can be compensated under any productivity scheme that a group derives. We understand that group practices use many different measures of a physician's productivity, such as counting patient encounters, charges or collections attributable to the physician, or hours of patient care services, or factoring in the degree of difficulty of a physician's procedures, ways in which the physician has improved his or her professional qualifications, or the amount of time the physician is willing to be on-call. In addition, a group can pay physicians based on a percentage of profits, straight salary, or any combination of base and incentive payments.

In terms of designated health services that a physician refers for Medicare or Medicaid patients, a physician's productivity bonus can only indirectly reflect those services that he or she personally performed or that are incident to those personally performed services. We regard services as "personally performed" by a physician when he or she participates directly in the delivery of the service. As we have noted elsewhere, we believe that a physician has made a "referral" if the physician refers a patient for a designated health service to him or herself, to other physicians in the group, or to the physician's own or the group practice's employees or contractors or to any other entity or individual. Unlike the over-all profit situation, in which amounts can be aggregated, the productivity bonus by its very nature will be based on a physician's individual referrals and performance, and will fluctuate accordingly. However, the statute precludes a productivity bonus for a physician that directly reflects the volume or value of that physician's own referrals.

Thus, we believe a physician's compensation can reflect a bonus for designated health services the physician personally performs or "incident to"

services the physician directly supervises, provided the services result from the referral of a physician other than the one performing or supervising the service. A physician in this situation is not being compensated based on the volume or value of his or her own referrals. A physician can receive compensation for his or her own referrals for designated health services only through the aggregation that occurs as part of over-all sharing of profits.

We regard the reference in section 1877(h)(4)(B)(i) to services performed "incident to a physician's personally performed services" as a reference to the services defined in section 1861(s)(2)(A) of the Act. Here they are listed under "Medical and Other Health Services" as services and supplies (including drugs and biologicals that cannot, as determined in accordance with regulations, be self-administered) furnished as an incident to a physician's professional service, of kinds that are commonly furnished in physicians' offices and are commonly either furnished without charge or included in the physicians' bills.

Our longstanding interpretation of this provision appears in section 2050 of the Medicare Carriers Manual, Part 3—Claims Processing. This provision states that "incident to" services are those that are furnished as an integral, although incidental part, of the physician's personal professional services in the course of diagnosis or treatment of an illness or injury. The services of nonphysicians must be furnished under the physician's direct supervision by employees of the physician.

Because the provision in section 1877(h)(4)(B)(i) on productivity bonuses is a difficult one, and because physicians are now compensated in many ways, we directly solicit comments on our interpretation of this provision.

7. Referral

We have received a number of inquiries about what constitutes a "referral" for purposes of section 1877. The concept of a referral appears in several places: physicians are prohibited from making certain referrals and a number of the compensation-related exceptions require that any payment passing between a physician and an entity not reflect the volume or value of the physician's referrals. We believe that the concept of a "referral" in the statute is a broad one, and that prohibited referrals are a subset of these. Below we discuss our interpretation of what constitutes a "referral."

Under section 1877(h)(5)(A), referrals include, subject to an exception for

certain specialized services, the request by a physician for an item or service for which payment may be made under Part B, including the 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).

We believe that "an item or service for which payment may be made under Part B" means a Part B item or service that ordinarily "may be" covered under Medicare (that is, that could be a covered service under Medicare at the present time in the community in which the service has been furnished) for a Medicare-eligible individual, regardless of whether Medicare would actually pay for this particular service, at the time, for the particular eligible individual who has been referred. (For example, Medicare might not pay for a service if the individual has not yet met his or her deductible.)

The second part of the statutory definition of "referral" in section 1877(h)(5)(B) covers (subject to an exception for certain specialized services) the request or establishment of a plan of care by a physician that includes the provision of a designated health service. Although this second part is not drafted in Medicare-specific terms and could be interpreted to cover situations involving any designated health service, we are interpreting it as applying only to those designated health services that "may be" covered under Medicare. We base this position on the fact that the referral prohibition in section 1877(a)(1) applies only to designated health services covered under Medicare.

We are not aware of any rationale for the distinction between the definition for Part B services, in which a physician's request for any Part B item or service constitutes a referral, and the definition for other items or services, in which a referral consists of a physician's request for, or a plan of care providing for, only a designated health service. The broader definition for Part B services has no ramifications in terms of the actual referral prohibition, which encompasses only referrals for designated health services. However, it is significant in terms of the standard that appears in the "group practice" definition and in a number of the compensation-related exceptions that precludes compensation between parties that reflects the volume or value of a physician's referrals.

It is our understanding that section 1877 was designed to prevent physicians from overutilizing the specific health care services designated in the statute, a list Congress derived

based on its sense of which services tend to be subject to abuse. We do not believe the statute was meant to preclude physicians from being compensated for their referrals for totally different Part B services. Thus, we are taking the position that, since the prohibition relates only to referrals for designated health services, the concept of a referral for a Part B service under section 1877(h)(5)(A) should be limited to just referrals for designated health services.

As we explained in the discussion on the definition of an "entity," we believe that the concept of a "referral" covers situations in which physicians refer to themselves or among themselves. (As we noted in that discussion, a physician could be prohibited from referring to him or herself or to other group practice members if the services do not meet the in-office ancillary services exception in section 1877(b)(2) or the physician services exception in section 1877(b)(1) of the Act or some other exception.) We believe that a physician has made a referral under section 1877(h)(5) when he or she requests any designated health service covered under Part A or Part B or establishes a plan of care that includes a designated health service covered under Part A or B, even if the physician furnishes the service personally. We interpret this language to cover a physician's certifying or recertifying a patient's need for a designated health service. For Part B services, a referral can also include a consultation with another physician.

We are interpreting a physician's "request" for an item or service, or the establishment of a plan of care, as a step that occurs after a physician has initially examined a patient or furnished physician services that are not designated health services, or otherwise concluded that the patient needs a designated health service. (We describe our rationale for this interpretation in more detail in section III.C.2 of this preamble, where we discuss the in-office ancillary services exception.)

We are interpreting a "request" as occurring whenever a physician asks for a service in any way or indicates that he or she believes the service is necessary (for example, by verbally stating that the service is necessary, by entering description of the service into the patient's records or onto a medical chart or by writing a prescription).

What constitutes a "referral" for a Medicaid service. Section 1903(s) of the Act applies aspects of the referral prohibition to the Medicaid program for referrals that would result in a denial of payment for the service under Medicare, if Medicare covered the service to the

same extent and under the same terms and conditions as under the State plan. We interpret this provision to mean that a State should apply the Medicare rules in section 1877 to a referral for a Medicaid service, even if the service is not covered under Medicare.

However, the definition of a referral in section 1877(h)(5)(A) and (B) is cast specifically in terms of a request for certain Part B Medicare services and for "other items," which in the Medicare context we have interpreted to mean Part A services. Since Medicaid services are not categorized this way, we propose to interpret this provision by establishing an analogous definition. That is, (subject to an exception for certain specialized services, which we describe below) a physician has made a referral if he or she has requested a Medicaid covered designated health service that is comparable to a service covered under Part B of Medicare (including a request for a consultation with another physician). A physician has also made a referral for any other Medicaid covered item or service if the service is a designated health service and the physician has requested it or has established a plan of care that includes it.

We are also translating a "referral" from the Medicare context to mean a physician's requests for, or plan of care including, a designated health service that ordinarily "may be" covered under the particular State Medicaid program for an individual in the patient's eligibility category, regardless of whether the State Medicaid agency would actually pay for this particular service, at the time, for the particular Medicaid-eligible individual who has been referred.

Prohibited referrals only involve designated health services. It is important to keep in mind that the only referrals that are prohibited under section 1877 of the Act are those that involve the furnishing of a designated health service listed in section 1877(h)(6). As we note in section IV.A.5 of this preamble in our discussion on referrals to immediate family members, a physician is free to make a referral for a service that is not a designated health service (or a service that does not include a designated health service), such as certain physician services. For example, a physician can refer a patient to an obstetrician for general prenatal care. If the obstetrician prescribes ultrasound as part of this prenatal care, it is the obstetrician who has made a referral for a designated health service, and not the original physician.

The statutory exception to the definition of a "referral." Before OBRA

'93, the definition of a "referral" under section 1877(h)(5)(A) was qualified by an exception in section 1877(h)(5)(C) for a request by a pathologist for certain clinical diagnostic laboratory tests and pathological examination services. These services had to be furnished by (or under the supervision of) the pathologist, as the result of a consultation requested by another physician. We incorporated this provision into the August 1995 final rule in § 411.351.

We are also proposing to interpret the level of supervision that a pathologist must provide if another individual, such as a technician, actually furnishes the services. The statute requires "supervision," rather than the "direct supervision" that appears as part of the in-office ancillary services exception. We are interpreting "supervision" to mean the level of supervision ordinarily required under Medicare coverage and payment rules or, when they apply, the health and safety standards, for the particular services at issue in the particular locations in which the services will be furnished.

As the result of OBRA '93, beginning on January 1, 1995, the exception to what constitutes a "referral" in section 1877(h)(5)(C) was expanded to include a request by a radiologist for diagnostic radiology services and a request by a radiation oncologist for radiation therapy, if the services are furnished by (or under the supervision of) the radiologist or radiation oncologist as the result of a consultation requested by another physician. We are incorporating this amendment into the definition of a "referral" in § 411.351. Diagnostic radiology services and radiation therapy are also defined in § 411.351, where we have presented our proposed definitions of the different designated health services.

When a physician has requested a "consultation." The services that are excepted from the "referral definition" under section 1877(h)(5)(C) must result from a consultation requested by a physician other than the pathologist, radiologist, or radiation oncologist who actually performs or supervises the performance of the services listed above. We discussed the concept of a consultation briefly in the preamble to the proposed rule covering referrals for clinical laboratory services at 57 FR 8595. We said that, for purposes of Medicare coverage, a "consultation" is—

a professional service furnished to a patient by a physician (the consultant) at the request of the patient's attending physician. A consultation includes the history and examination of the patient as well as a

written report that is transmitted to the attending physician for inclusion in the patient's permanent record ***. Other referrals, such as sending a patient to a specialist who assumes responsibility for furnishing the appropriate treatment, or providing a list of referrals for a second opinion, are not "consultations" or "referrals" that would trigger the laboratory services use prohibition.

We would like to clarify that a consultation occurs whenever a physician requests that a patient see another physician, such as a particular specialist, but the original physician retains control over the care of the patient, including any care related to the condition that prompted the consultation. Section 1877(h)(5)(A) implies that a "consultation" is still a consultation even if the consultant physician takes the initiative to order, perform, or supervise the performance of, tests for the patient. The consultant physician, as we noted in the preamble of the August 1995 rule, must provide the original physician with a report. Nonetheless, we regard this as a consultation as long as it is the original physician who gathers information from the consultant physician about his or her examination of the patient and any test results and then makes a decision about how to proceed with the patient's care.

Conversely, the original physician has not arranged for a consultation, but instead has made a referral, in situations in which the specialist takes over the patient's care for purposes of the condition that prompted the referral. For example, a physician might send a patient to a specific cardiologist, who examines the patient thoroughly, sends a report to the attending physician but is the only one who sees the patient thereafter for the purpose of treating a heart problem.

8. Remuneration

Remuneration that does not result in a compensation arrangement. A compensation arrangement is defined in section 1877(h)(1) as any arrangement involving any remuneration between a physician (or family member) and an entity, *other than* an arrangement involving only remuneration described in section 1877(h)(1)(C). Section 1877(h)(1)(C) lists certain specific kinds of remuneration that do not result in a compensation arrangement, such as the forgiveness of amounts owed for inaccurate tests, mistakenly performed tests, or for the correction of minor billing errors.

We believe there is some ambiguity in section 1877(h)(1) concerning the requirement that excepted remuneration

must result *from an arrangement involving only* the remuneration described in section 1877(h)(1)(C). This provision could be read to mean that the items in section 1877(h)(1)(C) are excepted when the arrangement that exists between the physician and entity involves nothing but the excepted forms of payment. As a practical matter, we realize that the kinds of remuneration listed in section 1877(h)(1)(C) seldom occur as isolated transactions, but are often subsets or components of other arrangements. For example, the forgiveness of minor billing errors suggests that the parties transact and exchange services or items for payment when there are no billing errors; those transactions that contain billing errors may be only a small fraction of the parties' overall business dealings.

To clarify this provision, we are interpreting it to mean that the portion of a business arrangement that consists of the remuneration listed in section 1877(h)(1)(C) alone does not constitute a compensation arrangement. Any other forms of remuneration that might accompany these payments are not excepted and could constitute a compensation arrangement, provided they do not otherwise meet one of the other exceptions in this proposed regulation.

Section 1877(h)(1)(C)(ii) excepts from the definition of "remuneration" 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. We believe that some pathology laboratories have been furnishing physicians with materials ranging from basic collection items and storage items (for example, jars for urine samples and vials for blood samples) to more specialized or sophisticated items, devices, or equipment (snare used to remove gastrointestinal polyps, needles used for biopsies or to draw bone marrow or samples of amniotic fluid for amniocentesis, and computers or fax machines used to transmit results).

In order for these items and devices to meet the statutory requirement, they must be used *solely* to collect, transport, process, or store specimens for the laboratory or other entity that provided the items and devices. We interpret "solely" in this context to mean that these items are used solely for the purposes listed in the statute, such as cups used for urine collection or vials used to hold and transport blood to the entity that supplied the items or devices.

We do not believe that an item or device meets this requirement if it is used for any purposes besides these. For example, we do not regard specialized equipment such as disposable or reusable aspiration and injection needles and snares as solely collection or storage devices. Instead, these items are also surgical tools that are routinely used as part of a surgical or medical procedure. For example, the Food and Drug Administration (FDA) regulations in 21 CFR 878.4800(a) define a "manual surgical instrument for general use" as a "non-powered, hand-held, or hand-manipulated device, either reusable or disposable, intended to be used in various general surgical procedures." Surgical instruments listed in the regulation include disposable or reusable aspiration and injection needles, snares, and other similar devices. Snares are also listed in these regulations as components of various specialized surgical devices, such as ear, nose, and throat manual surgical instruments, endoscopic electrosurgical units, and manual gastroenterology-urology surgical instruments and accessories.

In addition, to ensure that items or devices that could qualify for this exception are used solely for the entity that supplied them, the number or amount of these items should be consistent with the number or amount that is used for specimens that are actually sent to this entity for processing. That is, if a physician tends to annually perform 400 blood tests that are sent to a particular laboratory for analysis, we would not expect the physician to accept from that laboratory items, devices, or supplies in excess of an amount that is reasonable for the projected tests. In determining the amount of goods that are reasonable, we would consider not just quantity, but such facts as whether the laboratory packages together a set of items to be used for just *one* tissue collection or one use, or whether an item can be used multiple times, for multiple entities.

If, on the other hand, a physician keeps a particular item or device and uses it repeatedly or could use it repeatedly for any patients or for other uses, we would presume that the item or device is not one that meets the requirement, unless the physician can demonstrate otherwise. For example, if computer equipment or fax machines can be used for a number of purposes in addition to ordering or receiving results from an entity, we would presume that the "solely" requirement is not met, unless the physician can demonstrate that the equipment is integral to, and used exclusively for,

performing the outside entity's work. Detailed records concerning the use of the machine would be necessary to overcome this presumption.

Section 1877(h)(1)(C)(iii) "excepts" from a compensation arrangement situations involving certain payments made by an insurer or a self-insured plan to a physician. The payments must be those that 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. The payments must meet certain specified conditions.

We believe that this provision was designed for situations in which an insurer is involved in the delivery of health care services. If the insurer owns a health care facility, a physician might otherwise be precluded from referring to that facility just because the physician receives compensation from the insurer in the form of payments that satisfy claims the physician has submitted. If the physician is seeking fee-for-service payments from an insurer, he or she may not have an arrangement with the insurer that could qualify as a personal services arrangement, or otherwise qualify under any of the other statutory exceptions.

Discounts can be a form of remuneration for some of the designated health services. In the August 1995 final rule, we defined remuneration to include discounts. In the preamble to that rule, we explained that we believe that, for most items or services that a physician might purchase, the statute dictates this result. Section 1877(e)(8)(B) excepts from a compensation arrangement 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. As a result, any amounts that a physician pays for items or services that do not reflect fair market value, such as certain discounted items or services, would not meet the exception.

We may have implied in the August 1995 final rule that all discounts would fail to meet the fair market value standard. We wish to clarify here that we believe a discount does meet the fair market value standard if it is an arm's-length transaction; an entity offers it to all similarly situated individuals, regardless of whether they make referrals to the entity; the discount does not reflect the volume or value of any referrals the physician has made or will make to the entity; and the discount is passed on to Medicare or other insurers. We are aware of situations in which discounts enure to the benefit of

referring physicians. For example, physicians will sometimes purchase oncology drugs from manufacturers at a discount, yet mark the drugs up to eliminate the discount when billing Medicare. Such arrangements would not meet the standard.

We are also creating a new exception under our authority in section 1877(b)(4), which allows us to except any other financial relationship that we determine does not pose a risk of program or patient abuse. The new exception would allow physicians to receive a discount based on the volume of their referrals to an entity, provided the discount is passed on in full to the patients or their insurers (including Medicare), and does not enure to the benefit of the physicians in any way.

The statute provides a different exception for laboratory services. Section 1877(e)(8)(A) states that there is no compensation arrangement when a physician makes payments to a laboratory in exchange for the laboratory providing clinical laboratory services. This exception does not include a fair market value standard. Congress may not have included this standard based on its belief that, under the Medicare program, physicians cannot purchase laboratory services at a discount, and then bill the Medicare program for them at a marked up rate.

We agree that physicians are precluded from purchasing and marking up laboratory services covered under Medicare under section 1833(h)(5)(A) of the Act. This provision states that, in general, 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. In addition, payment for laboratory tests is made on the basis of a fee schedule.

B. General Prohibition on Referrals

Which designated health services are covered by the prohibition. Section 1877(a)(1)(A) prohibits referrals to an entity for the furnishing of designated health services "for which payment otherwise may be made under [Medicare], * * *." We believe that this means any designated health service that ordinarily "may be" covered under Medicare (that is, that could be a covered service under Medicare in the community in which the service has been provided) for a Medicare-eligible individual, regardless of whether Medicare would actually pay for this particular service, at the time, for that particular individual (for example, the individual may not have met his or her deductible).

We believe that the same principles apply for designated health services under the Medicaid program. Section 1903(s) says that the Secretary cannot make Federal financial participation payments to a State for designated health services, as they are defined under section 1877(h)(6), furnished to an individual on the basis of a referral that would result in a denial of payment under Medicare, if Medicare covered the services to the same extent and under the same terms and conditions as under the State plan. We interpret this provision to mean that the Medicare rules in section 1877 apply to Medicaid services, as if Medicare covered the same items and services as a State's Medicaid program.

As a result, a referral could affect a State's FFP if the designated health service is one "for which payment otherwise may be made" under a State's Medicaid program, regardless of whether a State agency would actually pay for this particular service, at the time, for that particular individual. Therefore, if a State plan could cover the service for a Medicaid eligible individual in the individual's eligibility group, we believe it is a service that is covered by the referral prohibition.

Limitations on billing and refunds on a timely basis. As part of the prohibition on referrals in section 1877(a), the statute also provides that an entity may not present or cause to be presented a Medicare claim or a bill to any individual, third party payor, or other entity for designated health services furnished under a prohibited referral. In the August 1995 final rule, we included in § 411.353(d) the requirement that 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. We are proposing to apply this provision to such amounts collected for any of the designated health services. We are also proposing to define "timely basis" by cross referring to § 1003.101 in the OIG civil money penalty regulations. While § 1003.101 currently defines this term as "the 60-day period from the time the prohibited amounts are collected by the individual or entity," the OIG is planning to issue shortly revised final regulations that will amend this term. Under the amended version, the 60-day timeframe for a refund will begin when the individual or entity knew or should have known that the amount collected was related to a prohibited referral. We plan to adopt this revised definition as well.

C. General Exceptions That Apply to Ownership or Investment Interests and to Compensation Arrangements

1. Exception for Physician Services

The statute provides that the referral prohibition does not apply in cases involving physician services (as defined in section 1861(q)) provided personally by (or under the personal supervision of) another physician in the same group practice as the referring physician. Physician services are generally defined in section 1861(q) as professional services *performed* by physicians, including surgery, consultation, and home, office, and institutional calls. The Medicare regulations have interpreted this provision in § 410.20(a) to include diagnosis, therapy, surgery, consultations, and home, office, and institutional calls, provided the services are furnished by one of the types of doctors listed in § 410.20(b).

Note that this exception applies to physician services that constitute designated health services, as we would define designated health services in § 411.351. The exception in the Medicare context does not cover services that are performed by nonphysicians but are furnished under a physician's supervision, such as ancillary or "incident-to" services. Under Medicare, physician services can only be performed by a physician. Thus, we believe the exception applies only to services that are provided personally by a physician who is a member of the same group practice as the referring physician or that are provided by a nonmember physician who is personally supervised by a group practice physician. We would interpret "personal supervision" to mean that the group practice physician is legally responsible for monitoring the results of any test or other designated health service and is available to assist the individual who is furnishing the service, even though the member physician need not be present while the service is being furnished.

2. Exception for In-office Ancillary Services

This exception applies to services other than parenteral and enteral nutrients, equipment and supplies and durable medical equipment (although it does apply to infusion pumps) that are referred by a solo practitioner or group practice member within his or her own practice. The exception requires that the services be performed by the referring physician or group practice member, or by another member of the same group practice as the referring physician, or be directly supervised by one of these

physicians (we discussed the direct supervision requirement in section III.A.2 of this preamble), that the services be furnished in certain locations, and that the services be billed in a particular way. We discuss these last two requirements below.

a. The site requirement

Where a service is actually "furnished." Section 1877(b)(2)(A)(ii)(I) requires, for a solo or group practice, that the services be furnished in a building in which the referring physician or another member of the group practice furnishes physician services unrelated to the furnishing of designated health services. It is our view that a service is furnished wherever a procedure is actually performed upon a patient or in the location in which a patient receives and begins using an item.

For example, if a patient receives an MRI (magnetic resonance image) in a physician's office, the service has been furnished there. If a patient is fitted for and receives a brace in the physician's office, the brace has been furnished there. The same rule would apply to a prosthetic device that is implanted in a physician's office. However, any item that is given to a patient but is meant to be used at home or outside the physician's office, or any item that is delivered to the patient's home, has not been "furnished" in the physician's office.

What constitutes the "same building" in which the physician is practicing. We are interpreting "the same building" to mean one physical structure, with one address, and not multiple structures that are connected by tunnels or walkways. In addition, we believe "the building" consists of parts of the physical structure that are used as office or other commercial space. For example, a mobile X-ray van that is pulled into the garage of a building would not be part of that building.

When a physician is furnishing physician services "unrelated to the furnishing of designated health services." To meet this criterion, we believe that a physician must be providing in the same building any amount of physician services (as defined in § 410.20(a)) other than those listed as designated health services as we have defined them in § 411.351. Thus, we would regard as "unrelated to designated health services" a physician's examination of a patient and diagnosis, even if these lead to the physician requesting a designated health service, such as an X-ray or laboratory test.

The location test for group practices. In the case of a group practice, the group has the option of meeting a location test other than the one requiring that the designated health services be provided in the same building in which a group member provides physician services. The group can provide clinical laboratory services in any other building that is used by the group for the provision of some or all of the group's clinical laboratory services.

A group can furnish the other designated health services in another building that is used by the group for the centralized provision of the group's designated health services. We believe that a location meets this "centralized" requirement if it services more than one of a group's offices, and if it furnishes one or any combination of designated health services. It is also our view that a group can have more than one of these centralized locations. To meet the in-office ancillary exception, a group would be required to have a physician member present in the "centralized" location to perform or directly supervise the performance of designated health services, but the physician would not be required to perform physician services that are unrelated to the designated health services in this location.

b. The billing requirement

Section 1877(b)(2)(B) requires that in-office ancillary services be billed by the physician performing or supervising the services, by the referring or supervising physician's group practice under a billing number assigned to the group, or by an entity that is wholly owned by the physician or group practice. For a group practice that bills, we discussed a similar requirement for a group billing number in section III.A.6 of this preamble, where we covered the definition of a group practice. There, as here, we are interpreting this provision to allow a single group to bill under any billing number that has been assigned to the group in situations in which a group has more than one number, and to allow an agent to bill for the group in the group's name, using the group's number, provided the arrangement meets the requirements in § 424.80(b)(6).

In situations in which a "wholly-owned" entity bills for a group, we do not believe the statute requires that the service be billed under the group number, if the wholly owned entity can bill under its own provider number. Also, we are interpreting "a wholly-owned" entity that bills to cover an entity that provides billing or administrative services to a physician or group practice. Alternatively, this entity

can be a wholly-owned provider of designated health services, such as a laboratory or radiology facility that is wholly owned by a physician or group, but bills for its own services. However, because the provision refers to an entity that is "wholly owned," we do not believe that it covers billing entities that are owned jointly by a physician or group practice with any other individuals or entities.

We also believe that a group practice member cannot use the in-office ancillary services exception to refer to other group practice members for services he or she intends to bill independently. Section 1877(b)(2)(B) states that the services must be billed *by the physician performing or supervising the services* or by a group practice of which the physician is a member, or by entities wholly owned by the physician or the group. Nonetheless, under the definition of who qualifies as a "member" of a group practice in § 411.351, a group practice physician billing under his or her own provider status would be considered a solo practicing physician for purposes of the in-office ancillary exception.

In § 411.351, we defined who can qualify as a "member" of a group practice broadly in order to accommodate the many part-time and contract physicians who often participate in one or more group practices. The definition of a "member" covered physician partners and full and part-time physician contractors and employees. Physicians under the definition qualify as "members" only *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*. Therefore, whenever a physician bills separately for a lab service the physician has personally performed or supervised, he or she is functioning as a solo practitioner and not as a group member. (We are currently proposing to amend the definition of a "member" to exclude independent contractors and to regard a physician as a member during the time he or she furnishes "patient care services" to the group. These changes would not affect our interpretation.)

If a physician bills for a service independently, other group members cannot directly supervise those services for the referring physician. In addition, if a group member bills for too many services independently, the group practice may fail to meet the "substantially all" test under the definition of a group practice in section 1877(h)(4)(A)(ii). That provision requires that substantially all of the services provided by group members be

billed under a billing number assigned to the group.

c. Designated health services that do not trigger the in-office exception

The location requirements for this exception specify that designated health services must be provided in a building in which a solo practitioner or a group practice physician also provides physician services unrelated to the furnishing of designated health services or, for group practices, in a building that serves as a centralized location in which a group provides designated health services. Thus, this exception would not cover services provided elsewhere, such as home health services.

If services are furnished in a hospital or skilled nursing facility, we believe they can be covered under this exception if these locations serve as a centralized location in which a group provides designated health services or if the referring physician or a member of the same group practice furnishes unrelated physician services in the building, and the physicians can meet the requirement for direct supervision and billing.

3. Exception for Services Provided Under Prepaid Health Plans

We are aware that the health care world is evolving rapidly, consisting of a broad spectrum that ranges from traditional practices using fee-for-service billing all the way to fully capitated managed care systems, many of which are excepted under the "prepaid" provision in the statute. In between these extremes exist a host of "hybrid" systems that display a mixture of fee-for-service and managed care characteristics. Section 1877 addresses some of these systems directly; most others we believe can continue to function by meeting the exceptions in the statute and in this proposed regulation. We specifically solicit comments on whether our assessment is accurate.

In this section we describe how we propose to interpret the law in a manner that we believe will help to safeguard the Medicare and Medicaid programs from abuse, while facilitating the evolution of integrated delivery and other health care delivery systems. We also discuss how we believe the law affects referrals for designated health services provided under demonstration projects and waivers.

a. Physicians, suppliers, and providers that contract with prepaid organizations

The "prepaid plan" exception covers services furnished by certain specified organizations to their enrollees. Under

section 1877(b)(3), these include health maintenance organizations and competitive medical plans that have a contract with Medicare, certain prepaid organizations functioning under a demonstration project, and Federally qualified health maintenance organizations. We have incorporated this exception into the regulations at § 411.355(c). We are aware that a number of these organizations do not furnish services directly but often contract with outside physicians, providers, or suppliers to furnish items or services to their enrollees, for which the organizations bill. The outside physicians, providers, or suppliers may, in turn, contract with other physicians or entities for certain supplies or services. In order to accommodate these situations, we are interpreting this exception broadly to cover not only services furnished by the organizations themselves, but also those furnished to the organization's enrollees by outside physicians, providers, or suppliers under contract with these organizations. The exception would also cover services furnished to enrollees by those with whom the outside physicians, providers, or suppliers have contracted.

b. Managed care organizations under the Medicaid program

We propose to add to the regulation a new exception in § 435.1012(b) for designated health services provided by managed care entities analogous to those listed in section 1877(b)(3) that provide services to Medicaid eligible enrollees under contracts with State Medicaid agencies. We are basing this addition on our analysis of section 1903(s) of the Act. Under section 1903(s), a State can receive no FFP for expenditures for medical assistance under the State plan consisting of a designated health service furnished to an individual on the basis of a referral that would result in a denial of payment for the service under Medicare if Medicare covered the service to the same extent and under the same terms and conditions as under the State plan. We read this provision to mean that the Medicare-based rules in section 1877 must be applied to services furnished under a State's Medicaid program to determine when a referral is a "prohibited" one.

Section 1877(b)(3) excepts from the referral prohibition services furnished to enrollees of certain "prepaid" plans; however, all of the entities listed in that exception provide services to Medicare patients. As a result, the exception for prepaid arrangements has no meaning for physicians who wish to refer in the context of the Medicaid program. In

order to give some meaning to this provision in the Medicaid context, when it is read in conjunction with section 1903(s), we are adding an exception for services furnished by the Medicaid counterparts of the Medicare managed care contracts expressly referenced in section 1877(b).

In section 1877(b)(3), Congress exempted all types of Medicare contracts with prepaid managed care health plans. We propose to extend this exemption to the categories of Medicaid-contracting managed care plans analogous to those exempted for Medicare in section 1877(b)(3). Like the section 1876 Medicare contracts exempted under section 1877(b)(3)(A), section 1903(m) governs Medicaid HMO contracts (specifically, comprehensive risk contracts), and requires that contracting HMOs comply with the physician incentive plan requirements in section 1876(i)(8).

The type of Medicare prepaid health plan exempted under section 1877(b)(3)(B) is an entity with a less than comprehensive contract (involving only Part B, or outpatient, services) under section 1833(a)(1)(A) of the Act and regulations at 42 CFR Part 417, Subpart U. These entities are known as "health care prepayment plans" (HCPPs). The Medicaid equivalent of a Medicare HCPP is a "prepaid health plan," or PHP. Like an HCPP, PHPs generally contract for less than a comprehensive range of services (a PHP can also be a nonrisk comprehensive contract, since section 1903(m) only governs comprehensive risk contracts). Like HCPPs, PHPs are not subject to the full range of requirements that HMOs must satisfy under section 1876 or section 1903(m).

Section 1877(b)(3)(C) exempts entities receiving payment on a prepaid basis under a demonstration project under section 402(a) of the Social Security Amendments of 1967 or section 222(a) of the Social Security Amendments of 1972. The Medicaid counterpart of section 402(a) is section 1115(a) of the Social Security Act. Indeed, several demonstration projects under section 402(a) involving Medicaid-eligible Medicare beneficiaries also involve Medicaid capitation payments under the authority in section 1115(a). We accordingly are proposing to exempt entities receiving payments on a prepaid capitation basis under a demonstration project under section 1115(a) of the Act.

Finally, in order to cover the full range of Medicaid managed care contractors paid on a prepaid basis, as Congress did for Medicare, it is also necessary to exempt "Health Insuring Organizations" (HIOs) if they furnish or

arrange for services as a managed care contractor. We are accordingly proposing to exempt these entities as well.

c. Evolving structures of integrated delivery and other health care delivery systems

As described above, the statute directly excepts from the referral prohibition all of the services provided by "prepaid" entities described in section 1877(b)(3) to the entities' enrollees. We realize that a host of organizations and integrated systems are not specifically excepted under the statute, so the services they provide to Medicare and Medicaid patients may be subject to the referral prohibition. For example, Medicare may provide secondary coverage to patients who participate in employer group health plans and are treated by HMOs that do not have contracts with Medicare or are not Federally qualified. Also, there are nontraditional systems that use both fee-for-service and capitated billing and are not specifically excepted under the law. We can find no grounds to create a blanket exception for these arrangements; we see no guarantee that these "hybrid" structures will all be free from any risk of patient or program abuse.

It is our view that a large percentage of the new and evolving structures will continue to thrive by meeting the exceptions in the statute and in this proposed regulation. For example, entities such as preferred provider organizations (PPOs) and physician hospital organizations (PHOs) that are not excepted under section 1877(b)(3) normally contract with physicians to provide services to the organization's patients, including Medicare or Medicaid patients. These physicians can continue to refer Medicare and Medicaid patients to the organization for designated health services, provided the physicians' arrangements with the organization qualify for the personal services exception in section 1877(e)(3) (and in § 411.357(d) of this proposed regulation).

This exception provides, among other things, that the arrangement must be for at least 1 year, the physician's compensation must be based on fair market value and cannot reflect the volume or value of the physician's referrals, except as allowed under certain physician incentive plans. We have defined "fair market value" in § 411.351 to allow payment that is consistent with the general market value of the services; that is, the compensation that would be included in a comparable service agreement, as the result of bona

fide bargaining between well-informed parties, at the time the agreement takes place.

If a physician has contracted with an organization for less than 1 year, the arrangement could meet the new general exception for compensation arrangements that we have added in § 411.357(l). We have added this new exception to accommodate the many complex arrangements that we believe exist between physicians and entities, as described below in section II.E.1. Also, as described in section II.E.3, we have interpreted the "volume or value of referrals" standard (one of the standards in the personal services exception and in many of the compensation-related exceptions) in a manner that we believe will not obstruct physicians who are required to refer for certain services within a network when the entity furnishing the services is at substantial financial risk for their cost. In section IV, in which we answer questions about the law, we present a discussion about physicians who have contracted with HMOs or other prepaid organizations, but who wish to refer fee-for-service patients to the HMO or to other physicians or providers who are affiliated with the HMO.

d. Designated health services furnished under a demonstration project or waiver

We propose to interpret section 1877 in a manner that we believe will allow most Medicare or Medicaid patients to continue to receive designated health services under demonstration projects or waivers. Our analysis of this issue depends upon whether the organization is paid on a prepaid basis under section 1115(a) of the Social Security Act or under one of the demonstration authorities specified in section 1877(b)(3)(C).

Prepaid demonstration contracts. Entities receiving payment on a prepaid basis under section 402(a) of the Social Security Amendments of 1967 or section 222 of the Social Security Amendments of 1972, have been exempted from the referral prohibition by section 1877(b)(3)(C). Entities receiving payment on a prepaid basis under a Medicaid demonstration project under section 1115(a) of the Social Security Act would be exempt under the proposed Medicaid analogue, as discussed earlier in this section.

We would note that the exemption for Medicare prepaid demonstration contractors extends not only to demonstration projects initiated by the Secretary under her discretionary authority in sections 402(a) and 222, but to all demonstrations that incorporate or rely upon section 402 authority,

including such congressionally-mandated demonstrations as the PACE ("Program for All-inclusive Care for the Elderly") demonstration projects, under which a public or non-profit entity contracts to provide comprehensive care to frail elderly Medicare beneficiaries, including dual eligibles who have been certified for skilled nursing facility level care, and the "Social HMO" (SHMO) demonstration projects, including the ESRD SHMO demonstration.

Demonstration projects that are not prepaid. If a demonstration project does not involve an organization receiving payments on a prepaid basis, the Medicare "prepaid" exception in section 1877(b)(3)(C) and the Medicaid analogue we are proposing in this rule would not apply.

We believe that the referral prohibition applies to services furnished under a demonstration project or waiver that does not qualify under section 1877(b)(3)(C) or the Medicaid prepaid demonstration exception proposed in this rule; however, the Secretary can exercise authority to waive or otherwise alter the requirements in sections 1877 or 1903(s). For example, section 402(a) of the Social Security Amendments of 1967 permits the Secretary to conduct demonstrations for a variety of purposes specified in section 402(a)(1)(A) through (K) (for example, to test whether changes in methods of reimbursement and payment for services, or covering additional services, would have the effect of increasing efficiency and economy without adversely affecting quality). Section 402(b) of these amendments permits the Secretary to waive compliance with the requirements of the Medicare statute for such research, insofar as these requirements are related to reimbursement or payment. We have determined that the requirements in section 1877 constitute requirements related to reimbursement and payment and thus may be waived for the kind of demonstration project described above, when there are no prepaid payments.

In the Medicaid context, where a demonstration project does not fall within the general exception proposed in this rule, the Secretary has the authority under section 1115(a)(2) to consider as expenditures under the State plan costs of the demonstration project that would not otherwise be included as expenditures under section 1903, to the extent and for the period prescribed by the Secretary. Hence, section 1115 could allow the Secretary to provide to a State the FFP that would otherwise be precluded under section 1903(s).

D. Exceptions That Apply Only to Ownership or Investment Interests

1. Exception for Ownership in Publicly Traded Securities

To qualify for the securities exception under section 1877(c)(1), the statute originally required that a physician's or family member's investment had to be in securities "which were purchased on terms generally available to the public * * *" (Emphasis added.) OBRA '93 amended this provision to require that the securities be those "which may be purchased on terms generally available to the public." (Emphasis added.) This amendment went into effect retroactively to January 1, 1992, and is reflected in the August 1995 final rule. We did not, however, interpret this change in the final rule.

We believe the purpose of this exception is to allow physicians or family members to acquire stock in large companies if the transaction does not particularly favor the physicians over other purchasers. In keeping with this purpose, we propose to interpret "may be purchased" to mean that, at the time the physician or family member obtained the securities, they *could* be purchased on the open market, even if the physician or family member did not actually purchase the securities on those terms. For example, the physician or family member may have inherited the securities or otherwise acquired them without actually purchasing them. We have reflected this interpretation in § 411.356(a).

Section 1877(c)(1) also requires that the securities be in a corporation that had, at the end of the corporation's most recent fiscal year, or on average during the previous 3 fiscal years, stockholder equity exceeding \$75,000,000. In proposed 411.356(a)(2), we define stockholder equity as the difference in value between a corporation's total assets and total liabilities.

2. Exception for Hospital Ownership

Section 1877(d)(3) excepts designated health services "provided by a hospital" (other than a hospital located in 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). We believe that this exception applies only to designated health services that are furnished by a hospital, and not to services furnished by any other health care providers the hospital owns, such as a hospital-owned home health agency or SNF. It is our view that services "provided by a hospital" corresponds only to those

services provided by an entity that qualifies as a "hospital" under the Medicare conditions of participation. We further believe that section 1877(d)(3) covers any "designated health services" provided by a hospital, rather than just "inpatient or outpatient hospital services," because hospitals can provide services to individuals who are neither inpatients nor outpatients (for example, they provide laboratory services to outside patients).

E. Exceptions That Apply Only to Compensation Arrangements

1. A new exception for all compensation arrangements that meet certain standards

Section 1877 of the Act contains a number of exceptions to the referral prohibition that apply only to compensation arrangements. Section 1877(e) contains eight exceptions to the referral prohibition based specifically on various kinds of compensation arrangements, and these are reflected in § 411.357 of the August 1995 final rule. If a physician's (or family member's) arrangement with an entity falls within one of the categories covered by these exceptions, and the arrangement meets the specific criteria listed for that category, the physician is not prohibited from making referrals to the entity.

It has come to our attention that the statutory categories, because of their specificity, do not encompass some compensation arrangements even though they may be common in the provider community, are based on fair market value or are otherwise commercially reasonable, and do not reflect the volume or value of a physician's referrals. For example, a physician can continue to make referrals to an entity under section 1877(e)(8)(B) even if the physician purchases items from the entity, provided the items are furnished at fair market value. On the other hand, the law does not exempt from the referral prohibition situations in which entities purchase items from a physician, even if the purchase price is comparably fair.

In light of the increase in recent years of integrated delivery systems, and the complex nature of financial arrangements between physicians and entities, it is our view that any compensation arrangements that are based on fair value, and that meet certain other criteria, should be excepted. Therefore, we are proposing to establish a new paragraph (l) in § 411.357 to provide an additional exception for compensation arrangements under the authority of section 1877(b)(4). This provision

allows the Secretary to establish exceptions for any other financial relationship that she determines, and specifies in regulations, does not pose a risk of program or patient abuse. To meet this requirement, we are proposing an exception for any compensation arrangement between a physician (or immediate family member), or any group of physicians (even if the group does not qualify as a group practice) and an entity, provided the arrangement meets the following criteria, which we believe by their terms will prevent program or patient abuse. The arrangement must—

- Be in writing, be signed by the parties, and cover only identifiable items or services, all of which are specified in the agreement;
- Cover all of the items and services to be provided by the physician or immediate family member to the entity or, alternatively, cross refer to any other agreements for items or services between any of these parties.
- Specify the timeframe for the arrangement, which can be for any period of time and contain a termination clause, provided the parties enter into only one arrangement covering the same items or services during the course of a year. An arrangement made for less than 1 year may be renewed any number of times if the terms of the arrangement and the compensation for the same items or services do not change;
- Specify the compensation that will be provided under the arrangement, which has been set in advance. The compensation must be consistent with fair market value and not be determined in a manner that takes into account the volume or value of any referrals (as defined in § 411.351), payments for referrals for medical services that are not covered under Medicare or Medicaid, or other business generated between the parties;
- Involve a transaction that is commercially reasonable and furthers the legitimate business purposes of the parties; and
- Meet a safe harbor under the anti-kickback statute or otherwise be in compliance with the anti-kickback provisions in section 1128B(b) of the Act.

We would advise the parties involved in a compensation arrangement to use this exception if they have any doubts about whether they meet the requirements in the other exceptions listed in § 411.357.

2. A new exception for certain forms of "de minimis" compensation

We are aware that there are a number of situations in which physicians or

their immediate family members receive compensation in the form of incidental benefits that are not part of a formal, written agreement. For example, a physician might receive free samples of certain drugs or chemicals from a laboratory, training sessions for his or her staff before entering into an agreement with a facility that furnishes a designated health service, or training sessions that are not considered part of the agreement. Also, a provider might furnish a physician with free coffee mugs or note pads. We are exercising our authority under section 1877(b)(4) to create a new exception that we believe will allow physicians or their family members to receive de minimis amounts of compensation, without a risk that the compensation will result in any Medicare program or patient abuse.

We have drafted the exception, which would appear at § 411.357(k), to apply to noncash items or services. Items cannot include cash equivalents, such as gift certificates, stocks or bonds, or airline frequent flier miles. We propose to limit the exception to a value of \$50 per gift, with a \$300 per year aggregate. This exception would apply only in situations in which the entity providing the compensation makes it available to all similarly situated individuals, regardless of whether these individuals refer patients to the entity for services. In addition, any compensation a physician or family member receives from an entity cannot be based in any way on the volume or value of the physician's referrals. We believe the criteria for this exception, by their terms, will prevent patient or program abuse.

3. The "volume or value of referrals" standard

Most of the exceptions in the law covering specific kinds of compensation arrangements state that the compensation involved cannot reflect the volume or value of any referrals. (We have included a similar standard in the two new compensation exceptions described above.) We are applying our interpretation of that standard as it appears in section III.A.6 under our discussion of the criteria a group of physicians must meet to qualify as a "group practice." In that section, we describe what constitutes a "referral" for purposes of the "volume or value" standard.

The volume or value of referrals standard appears in the exceptions for the rental of space or equipment, bona fide employment relationships, personal services arrangements, physician recruitment, isolated transactions, and group practice arrangements with a

hospital. It also appears in the definition of "remuneration," which excepts certain payments made by an insurer or self-insured plan to a physician to satisfy a claim, and in the definition of a group practice. The exceptions for the rental of office space, rental of equipment, personal service arrangements, and group practice arrangements with a hospital also state that the compensation cannot reflect, directly or indirectly, the volume or value of referrals or any other business generated between the parties.

It is our view that Congress intended to except arrangements in which a physician or family member receives fair market compensation for providing a particular item or service. We believe Congress may not have wished to except arrangements that include additional compensation for other business dealings. We also believe that it would be administratively difficult for us to sort out, from a particular business arrangement, different strands of payment that are meant to compensate an individual for things other than the items or services that qualify for the exception. In sum, we believe that the "or other business generated between the parties" merely clarifies this concept.

As a result of this analysis, we are proposing to interpret the "volume or value" standard that appears in the compensation exceptions and elsewhere as a standard that uniformly is meant to cover (and thus exclude from an exception) other business generated between the parties. We are doing so under our authority, in each of the compensation exceptions and under the definitions, to add other requirements that we may impose by regulation as needed to protect against patient and program abuse. If a party's compensation contains payment for other business generated between the parties, we would expect the parties to separately determine if this extra payment falls within one of the exceptions.

The volume or value standard also varies from exception to exception in terms of simply precluding compensation that takes into account the volume or value of referrals, as opposed to not taking into account, *directly or indirectly*, the volume or value of referrals. We regard these provisions as essentially equivalent, since we believe not accounting for referrals can be interpreted as not accounting for them in any way.

We have been asked whether an arrangement fails to meet the "volume or value" of referrals standard only in situations in which a physician's

payments from an entity fluctuate in a manner that reflects referrals. It is our view that an arrangement can also fail to meet this standard in some cases when a physician's payments from an entity are stable, but predicated, either expressly or otherwise, on the physician making referrals to a particular provider. For example, a hospital might include as a condition of a physician's employment the requirement that the physician refer only within the hospital's own network of ancillary service providers, such as to the hospital's own home health agency. We believe that in these situations, a physician's compensation reflects the volume or value of his or her referrals in the sense that the physician will receive no future compensation if he or she fails to refer as required.

However, we do not intend to include, in this interpretation, situations in which physicians are not required to refer within the entity's network, but choose to on their own. Nor do we believe the volume or value standard is violated in those situations in which physicians refer patients within a network at the patients' own request, rather than under an entity's mandate, even if the entity has encouraged patients to remain within the network through various incentives.

In addition, we do not believe that an arrangement affects the volume or value standard for any designated health services a physician is required to refer within a network, provided the entity itself is, through a risk sharing arrangement, at substantial financial risk for the cost or utilization of items or services that the entity is obligated to provide. In these situations, we believe the requirement that a physician refer within the network addresses the issue of where a physician must refer, rather than whether the physician is encouraged or discouraged from making a referral (resulting in under or overutilization).

4. The commercial reasonableness standard

A number of the compensation-related exceptions in section 1877(e) include the requirement that remuneration provided under an agreement "would be commercially reasonable" even if no referrals were made between the parties. We are interpreting "commercially reasonable" to mean that an arrangement appears to be a sensible, prudent business agreement, from the perspective of the particular parties involved, even in the absence of any potential referrals.

5. The Secretary's authority to create additional requirements

Several of the statutory exceptions (particularly the compensation-related exceptions) permit the Secretary to impose additional conditions if the conditions are needed to protect against program or patient abuse. In promulgating these regulations, the Secretary has taken into account the fact that many of the excepted arrangements are also subject to the Medicare and Medicaid anti-kickback statute. The Secretary believes that the proposed regulatory exceptions, in conjunction with the independent requirements of the anti-kickback statute, are such that in most cases no additional conditions are necessary at this time to protect against program or patient abuse (we have included in this proposed regulation several specific new requirements that we believe are necessary). However, with respect to those exceptions for which the Secretary has authority to impose additional requirements, the Secretary invites comments from interested parties on whether additional conditions are necessary and if so, what conditions would be appropriate.

6. Exception for bona fide employment relationships

Section 1877(e)(2) excepts from a "compensation arrangement" any amount paid by an employer to a physician (or immediate family member) who has a bona fide employment relationship for the provision of services if the employment arrangement meets certain standards (these appear in § 411.357(c)). One standard specifies that remuneration under the employment cannot be determined in a manner that takes into account (directly or indirectly) the volume or value of referrals by the referring physician. Nonetheless, this exception specifically allows remuneration in the form of a productivity bonus based on services performed personally by the physician or an immediate family member. Thus, under the terms of the statute, physician or family member employees can receive payments based on any work they actually personally perform, including designated health services that a physician refers to him or herself. Under such a scheme, the more a physician self-refers, the more profit he or she will make.

Because we regard this provision as an open-ended invitation for physicians to generate self-referrals for designated health services, we are proposing to equalize this provision with the one

allowing productivity bonuses under the definition of a group practice in section 1877(h)(4)(B)(i). This provision allows group practices to pay members a productivity bonus only if the bonus is not directly related to the volume or value of a physician's own referrals. We are equalizing the provisions in this regard under the authority in section 1877(e)(2)(D), which allows the Secretary to impose by regulation other requirements as are needed to protect against patient or program abuse. Without this change, we believe that physicians have an incentive to overutilize designated health services, since they can be compensated directly for every self referral they make.

We would like to point out that because we have interpreted the concept of a "referral" to involve only a physician's requests for designated health services covered under Medicare or Medicaid, the new requirement will in no way affect a physician's ability to receive a productivity bonus for any nondesignated health services or noncovered services he or she refers or performs, or designated health services referred by another physician.

The bona fide employment exception does not, by its terms, allow for indirect compensation based on profit sharing and productivity bonuses for a physician's "incident to" services. The group practice definition does allow for such compensation. We do not believe that we can equalize the provisions in this regard, since it is our view that there are situations in which compensating a physician even indirectly for his or her self referrals could encourage overutilization and abuse.

7. Exception for personal services arrangements

Section 1877(e)(3) excepts from the referral prohibition situations involving remuneration from an entity under a personal services arrangement if certain criteria are met. The statute does not specify to whom the remuneration must be paid or for what kinds of services, although we believe the services must be "personal services."

One of the criteria for this exception requires that the arrangement cover all of the services to be furnished to the entity by the referring physician or an immediate family member of the physician. Therefore, we are interpreting this exception as covering services furnished by these individuals. We believe there is nothing in the statute to preclude a physician or family member from having personal services arrangements with several entities. (For example, a physician might have a

contract to serve as a hospital's medical director and another contract with an unrelated group practice to perform surgery.) However, the statute does appear to require, in section 1877(e)(3)(A)(ii), that an excepted arrangement with one entity cover all of the services to be provided by the physician (or family member) to that entity.

We are aware that at times it will not be logical for all of a physician's or family member's contracts for personal services to be in one agreement. However, we are also aware that entities have used multiple contracts, at times, in devising schemes to reward physicians for their referrals. In order to provide physicians and entities with more flexibility than the statutory requirement that all services appear in one agreement, we propose to allow multiple agreements, provided that the agreements each meet all of the requirements described in section 1877(e)(3) and all separate agreements between the entity and the physician and the entity and any family members incorporate each other by reference. We base our proposal on section 1877(b)(4), which allows the Secretary to specify, in regulations, an exception for any other financial relationship that she determines does not pose a risk of patient or program abuse. In this case, because all excepted agreements will be subject to the fair market value and other standards, and because each agreement will make us aware of all other agreements, we see no potential risk for abuse.

It is our view that "personal services" are not simply the generic Medicare services (which are defined in § 400.202 to include "items") but are services of any kind performed personally by an individual for an entity (but *not* including any items or equipment). We are using the broader, more common notion of what constitutes a "service" based on the fact that all kinds of business relationships can trigger the referral prohibition; hence, the exception should be read to apply to business-oriented services in general.

We are also interpreting the exception to mean that the physician or family member can actually perform the services, or that these individuals can enter into an agreement to provide the services through technicians or others whom they employ. A physician or family member cannot, though, include equipment or other items as part of an excepted personal services arrangement. For example, if a hospital contracts with a nephrologist to provide dialysis services to its patients, the physician could have a personal services

arrangement with the hospital even if the dialysis services are actually furnished by technicians whom the physician employs. However, if the physician also provides dialysis equipment to the hospital, this arrangement would have to separately meet the exception for the rental of equipment in section 1877(e)(1), since we do not regard items or equipment as "personal services."

The personal services exception specifies that compensation under an arrangement cannot be determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties. However, this requirement is qualified to allow compensation to reflect these under certain situations in which there is a physician incentive plan between a physician and an entity. We would like to emphasize that the physician incentive plan aspect of section 1877(e)(3) applies only in the context of personal services arrangements, and not to any other compensation arrangements.

"Physician incentive plans" are defined in section 1877(e)(3)(B)(ii) as certain compensation arrangements between an entity and a physician or physician group. We have defined a physician group for purposes of the physician incentive rules more broadly than a group practice under section 1877, so that a group practice is a subset of physician groups. (A final rule with comment period governing physician incentive plans was published on March 27, 1996, at 61 FR 13430. This rule was amended on December 31, 1996, at 61 FR 69034.)

A physician incentive plan is 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. We believe that the incentive plan qualification applies only when the entity paying the physician or physician group is the kind of entity that enrolls its patients, such as a health maintenance organization. Section 1877(b)(3), the exception for prepaid plans, does exempt from the referral prohibition almost all designated health services provided by these entities to Medicare patients who are enrollees. In addition, this regulation proposes to exempt services provided to Medicaid patients by analogous kinds of entities (see our discussion of this issue earlier in this preamble). Nonetheless, the personal services exception, with its physician incentive aspect, is still a viable exception. This exception could

apply, for example, to situations in which a physician refers a fee for service patient covered under Medicare to an HMO when he or she also has a contract to provide services to the HMO's enrollees. The physician's contract with the HMO is an underlying financial relationship and, in order for the physician to refer fee-for-service patients to the HMO, the financial relationship must meet an exception. In order to qualify for the personal services exception, the physician's payments from the HMO for treating HMO enrollees cannot vary with the volume or value of his or her referrals, except under a physician incentive plan, as described in section 1877(e)(3)(B).

The personal services exception in section 1877(e)(3) as a whole is silent about to whom an entity must be paying remuneration or with whom it must have an arrangement. As a result, we are interpreting the personal services exception to apply to situations in which an entity has an arrangement with either an individual physician (or family member) or a group practice to provide personal services. For example, a hospital could use the exception if it contracts with a group practice for purposes of having group members serve as the hospital's staff.

8. Exception for remuneration unrelated to the provision of designated health services

Section 1877(e)(4) provides for an exception for remuneration that is provided by a hospital to a physician if the remuneration does not relate to the provision of designated health services. (As we have noted earlier in this preamble, this exception does not apply to remuneration from entities other than hospitals, nor does it apply to payments to a physician's family members.) We are interpreting this provision to except any remuneration that is completely unrelated to the furnishing of designated health services. By this we mean that the parties must be able to demonstrate that the remuneration does not in any direct or indirect way involve these services, and that the remuneration in no way reflects the volume or value of a physician's referrals for designated health services. If a physician is receiving payments from a hospital that appear to be inordinately high for an "unrelated" item or service and is also making referrals to the hospital for designated health services, we will presume that the overpayments relate to the designated health services because they reflect the volume or value of the physician's referrals.

On the other hand, we realize there can be situations in which a hospital's payments are completely unrelated to the provision of designated health services. For example, a teaching hospital might pay a physician rental payments for his or her house in order to use the house as a residence for a visiting faculty member. If the parties involved can demonstrate that the rental payments are based on fair market value and in no way reflect the physician owner's referrals to the hospital, we believe this exception would apply. Similarly a physician might receive compensation for teaching or for providing an entity with general utilization review or administrative services.

We do not intend to apply this exception in any situation involving remuneration that might have a nexus with the provision of, or referrals for, a designated health service. For example, if a hospital pays a physician to supply a heart valve that the physician has perfected, we believe that the exception does not apply. It is our position that the physician is receiving payment for an item that will likely be used by the hospital in furnishing inpatient hospital services, which are a designated health service. Similarly, if a hospital pays for a physician's malpractice insurance or other general costs to enable the physician to provide a designated health service, such as radiology, the payments are related to furnishing a designated health service. Nonetheless, these financial relationships could still be excepted under one of the statutory exceptions or under the new exception we would include in § 431.357(l), which covers any compensation arrangement that meets certain criteria.

9. Exception for a hospital's payments for physician recruitment

Section 1877(e)(5) includes an exception for remuneration provided by a hospital to an individual physician 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. We believe that the terms of the statute dictate that this exception applies just to those situations in which a physician resides outside the geographic area and must actually relocate in order to join the hospital's staff.

We considered a number of ways to define the concept of a hospital's "geographic area," including mileage requirements or the likelihood that the physician would be able to bring patients along when he or she relocates. Because we believe that what constitutes a hospital's "geographic

area" may depend on a variety of circumstances, we are specifically soliciting comments on how to define this term.

If a hospital makes recruitment payments to physicians who are living in the hospital's geographic area (for example, to retain residents) or to a group practice that intends to employ the physician and contracts with the hospital, these payments might be excepted under the new compensation-related exception that we have included in § 431.357(l).

10. Exception for certain group practice arrangements with a hospital

Under section 1877(e)(7), this exception applies to only a limited number of arrangements; that is, arrangements that began before December 19, 1989, and have continued in effect without interruption since that date. We are interpreting this provision to mean that the arrangement between the hospital and the specific group practice must have been in effect within the timeframe specified in the statute. However, we realize that most agreements do not remain static over time. As a result, it is our view that this criterion may still be met, even if the agreement between the parties has changed over time so that it covers different services or so that the services are provided by different individuals within the same group practice.

We also intend in this provision to make an editorial change that we believe removes an ambiguity in the statutory language. Existing § 411.357(h)(2) states "[t]he arrangement began before December 19, 1989, and has continued in effect without interruption since then." Upon closer consideration, we believe that "since then" is ambiguous. (Does it mean since the actual date before December 19, 1989 on which the arrangement began, or does it mean since December 19, 1989?) We believe that by revising this provision to read "[t]he arrangement began before, and has continued in effect without interruption since, December 19, 1989," we have provided a reasonable interpretation that removes this ambiguity.

Section 1877(e)(7)(A)(ii) requires that, with respect to the designated health services covered under the arrangement, substantially all of the services furnished to patients of the hospital are furnished by the group under the arrangement. We believe this standard means that whatever portion of a particular designated health service the agreement covers, the group must actually provide "substantially all" of that portion. For example, if the group

has agreed to provide 35 percent of a hospital's laboratory services, the group must actually provide a substantial part of this percentage.

In keeping with our interpretation of the term "substantially all" in other parts of section 1877, we are interpreting that term here as being 75 percent of all the services at issue.

11. Exception for payments by a physician for items and services

Section 1877(e)(8) excepts payments that a physician makes to a laboratory in exchange for clinical laboratory services (we have discussed this provision in some detail in section III.A.8 of this preamble). In addition, the statute excepts payments that a physician makes to any entity for other items or services if these are furnished at fair market value. We are proposing to interpret "other items or services" to mean any kinds of items or services that a physician might purchase, but not including clinical laboratory services or those specifically listed under the other compensation exceptions. For example, we do not believe that Congress meant for the "items or services" exception to cover a rental agreement as a service that a physician might purchase, when it has already included in the statute a specific rental exception, with specific standards, in section 1877(e)(1).

F. The Reporting Requirements

1. Which financial relationships must be reported

Under section 1877(f), each entity providing Medicare-covered services must provide the Secretary with information concerning the entity's ownership, investment, and compensation arrangements, including the names and UPINs (unique physician identification numbers) of all physicians with an ownership or investment interest (as described in section 1877(a)(2)(A)) in the entity or with a compensation arrangement (as described in section 1877(a)(2)(B)) with the entity, or whose immediate relatives have such a relationship. The information must be provided in such form, manner, and at such times as the Secretary specifies.

Section 411.361 currently states that entities 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 request to provide the information. Thereafter, entities must provide updated information within 60 days from the date of any change in the submitted information.

At this time, we are still developing a procedure for implementing the reporting requirements and plan to notify affected parties about the procedure at a later date. Until that time, physicians and entities are not required to report to us. In addition, we are aware that the 60 day timeframe for updated information could be onerous, especially for large entities that must collect information about their employees, owners, and contractors and who would then have to update that information approximately every two months. As a result, we are proposing to modify § 411.361 to require that entities report to us once a year on all of the changes that have occurred in the previous 12 months.

Under the reporting regulation in § 411.361(d), a "reportable financial relationship" is any ownership or investment interest or any compensation arrangement, as described in section 1877 of the Act. Under section 1877(a)(2), a financial relationship of a physician (or family member) with an entity is defined as an ownership or investment interest in the entity, *except as provided in subsections (c) and (d)*, or a compensation arrangement between the physician (or family member) and the entity, *except as provided in subsection (e)*. Subsections (c) and (d) contain lists of ownership interests that "shall not be considered to be an ownership or investment interest described in subsection (a)(2)(A)." Subsection (e) contains a list of arrangements that are not to be considered as "compensation arrangements described in (a)(2)(B)." Thus, entities must only report their ownership or investment interests, or compensation arrangements, if these relationships do not meet the exceptions in subsections (c), (d), or (e) of section 1877. However, if an entity's financial relationship is excepted under subsection (b) of section 1877 (which contains exceptions for physician services, in-office ancillary services, services furnished under certain prepaid plans, or other new exceptions included by the Secretary) the entity must still report.

As the rule reads now, an entity can decide that it is excepted under (c), (d), or (e) and not report any data. As a result, we will have no opportunity to scrutinize the entity's arrangements to see if its assessment is correct. We believe that the statute allows us to gather a broader scope of data. We base this interpretation on the opening paragraph in section 1877(f), which states that each entity providing any covered items or services for which payment may be made under Medicare

shall provide the Secretary "with the information" concerning the entity's ownership, investment, and compensation arrangements, *including* the names and UPINs of all physicians with an ownership interest (as described in (a)(2)(A)), or with a compensation arrangement (as described in (a)(2)(B)). Thus, we believe the statute allows us to gather any data on financial relationships, *including*, but not necessarily limited to, relationships for which there are no exceptions under (a)(2)(A) or (B). Therefore, we are proposing to amend the rule, at § 411.361(d), to reflect our authority to ask for a broader scope of information than the regulation currently allows.

A number of entities have pointed out to us that the amounts of data they are required to report under the statute will, in some circumstances, be overwhelming and perhaps almost impossible to acquire. In addition, if we require every entity that is subject to the referral rules to report on every financial relationship, excepted or not, the administrative burden could be enormous. For example, a large publicly-held enterprise would be required to report (and hence retain records documenting) all of its owners who are physicians, all owners who are relatives of physicians, all physicians with whom it has compensation arrangements of any kind, and all relatives of physicians with whom it has compensation arrangements.

A publicly traded corporation with thousands of stockholders may find it extremely difficult to identify all of its owners and their relatives, and to identify which of these owners and relatives are physicians. In addition, such a corporation could be owned by mutual funds which in turn have hundreds of thousands of additional owners, some of whom may be physicians or have relatives who are physicians. In order to make the reporting requirements more manageable, we intend to develop a streamlined "reporting" system that does not require entities to retain and submit large quantities of data. However, we believe that entities should retain enough records to demonstrate, in the event of an audit, that they have correctly determined that particular relationships are excepted under the law.

We are proposing to limit the information that an entity must acquire, retain and, at some later point, possibly submit to us. We would include only those records covering information that the entity knows or should know about, in the course of prudently conducting business, including records that the

entity is already required to retain to meet Internal Revenue Service and Securities and Exchange Commission rules, and other rules under the Medicare or Medicaid programs. We are circumscribing these records under the Secretary's discretion in section 1877(f) to ask entities to provide information in such form, manner, and at such times as the Secretary specifies. When we develop a form for reporting information to us, we plan to first publish it as a proposed notice in order to receive public comment. If we later find that this plan is inadequate and elect to change the scope of the requirement, we will provide entities with adequate notice to comply. We specifically solicit comments on this proposal.

2. What entities outside the United States must report

Section 1877(f) states that the reporting requirements do not apply to designated health services furnished outside the United States. The reporting requirements in general apply to each entity furnishing services covered under Medicare, and not just to those furnishing designated health services. Arguably, then, the statute relieves an entity from the reporting requirements involved when it furnishes designated health services, but not when it furnishes other covered services. Because we believe that referrals for designated health services are the focus of section 1877, and because Medicare covers only a limited number of services when they are furnished outside of the United States, we are interpreting section 1877(f) to relieve an entity from reporting any Medicare services it has furnished outside of the United States.

G. How the Referral Prohibition Applies to the Medicaid Program

1. Who qualifies as a "physician" for purposes of section 1903(s)

Under the Medicare definition of "physician" in section 1861(r), paragraphs (r)(1) through (r)(5) cover a doctor of medicine or osteopathy, a doctor of dental surgery or of dental medicine, a doctor of podiatric medicine, a doctor of optometry, and a chiropractor. Under the Medicaid statute in section 1905(a)(5)(A), physician services are those furnished by a physician as defined in section 1861(r)(1), which covers only a doctor of medicine or osteopathy.

In determining whether an individual is a "physician" for purposes of section 1903(s), we believe that it is the Medicare definition that would apply. That is because this provision prohibits the Secretary from paying FFP to a State

for services that result from a referral for a designated health service that would be prohibited under Medicare if Medicare covered the service in the same way (to the same extent and under the same terms and conditions) as under the State plan. A referral by any of the "physicians" listed in section 1861(r) could result in a prohibited referral under Medicare.

We believe that a physician is still a physician for purposes of section 1903(s), even if he or she does not participate in the Medicaid program. For example, a provider of designated health services may participate in and bill Medicaid when the referring physician, who has an interest in the entity, does not participate. The rules in section 1877 apply to services furnished under Medicaid in the same manner as they would apply if furnished under Medicare. As a general rule under section 1877(a)(1), if a physician (or immediate family member) has a financial relationship with an entity, then the physician may not make a referral to the entity to furnish designated health services for which payment may otherwise be made under Medicare. This provision appears to apply to all physicians, regardless of whether they participate in either the Medicare or Medicaid programs, as long as the services involved are covered services under Medicare or Medicaid.

2. How the referral prohibition and sanctions affect Medicaid providers

Absent an exception, section 1877(a)(1) in general prohibits a physician from making a referral to an entity with which he or she has a financial relationship for the furnishing of a designated health service covered under Medicare. The entity, in turn, may not present a claim to Medicare or bill any other individual or entity for the service furnished as the result of a prohibited referral. If physicians or entities violate these rules, they are subject to certain sanctions under section 1877(g). However, we do not believe these rules and sanctions apply to physicians and providers when the referral involves Medicaid services. The first part of section 1903(s) prohibits the Secretary from paying FFP to a State for designated health services furnished on the basis of a referral *that would result in a denial of payment under Medicare if Medicare covered the services in the same way as the State plan*. This part of the provision is strictly an FFP provision. It imposes a requirement on the Secretary to review a Medicaid claim, *as if it were under Medicare*, and deny FFP *if a referral would result in the denial of payment under Medicare*.

Section 1903(s) does not, for the most part, make the provisions in section 1877 that govern the actions of Medicare physicians and providers of designated health services apply directly to Medicaid physicians and providers. As such, these individuals and entities are not precluded from referring Medicaid patients or from billing for designated health services. A State may pay for these services, but cannot receive FFP for them. However, States are free to establish their own sanctions for situations in which physicians refer to related entities.

3. How the referral rules apply when Medicaid-covered designated health services differ from the services covered under Medicare

The statute specifically provides that a State cannot receive FFP for a designated health service if it is furnished to an individual on the basis of a referral that would result in a denial of payment for the service under Medicare *if Medicare covered the services to the same extent and under the same terms and conditions as under the State plan*. We believe this means that Congress was aware of differences in the two programs and specifically intended to cover under section 1877 designated health services as they are covered under a State's Medicaid plan whenever this coverage differs from coverage under Medicare.

4. How the reporting requirements apply under the Medicaid program

Section 1903(s) states that subsections (f) and (g)(5) of section 1877 shall apply to a provider of Medicaid-covered designated health services in the same manner as these subsections apply to a provider of Medicare-covered designated health services. Section 1877(f) requires that each entity providing Medicare-covered items or services must provide the Secretary with certain information about the entity's ownership, investment, and compensation arrangements. The information must include the covered items and services the entity provides, and the names and UPINs of all physicians who have (or whose immediate relatives have) an ownership or investment interest in or compensation arrangement with the entity. These requirements do not apply to designated health services furnished outside of the United States, or to entities the Secretary determines furnish Medicare-covered services infrequently.

Section 1903(s) could be read to mean that section 1877(f) must apply identically to Medicare and Medicaid providers, so that Medicaid entities

must furnish information to the Secretary (that is, to HCFA). However, we are taking the position that the provision allows us to require that entities report directly to the States. Section 1903(s) provides that section 1877(f) applies "in the same manner" in the Medicaid program as it does in Medicare. In Medicare, the reports are made to the Secretary, the official who is responsible for making payment under Medicare. "In the same manner," in the context of the Medicaid program, would mean that the reports would be made to the entity that makes payment; that is, the State, thus maintaining a symmetry between reporting in the two programs.

We have taken this position because, under section 1903(s), it is the States that are at risk of losing FFP for paying improper claims for designated health services submitted by entities that have financial relationships with physicians. Therefore, in order to ensure that FFP will be available, States must determine whether a physician has a financial relationship with an entity that would prohibit referrals under Medicare. Our interpretation will allow States to protect themselves and to avoid any duplication of effort with HCFA.

We are amending the regulations to create a new Subpart C, "Disclosure of Information by Providers for Purposes of the Prohibition on Certain Physician Referrals." In § 455.108, "Basis," we state that, based on section 1903(s), we are applying the reporting requirements of section 1877(f) and (g) to Medicaid providers of designated health services. Section 455.109(a) would state that the Medicaid agency must require that each entity that furnishes designated health services submit information to the Medicaid agency concerning its financial relationships, in such form, manner, and at such times as the agency specifies. Although the statute requires that entities submit information to the Secretary, we believe that the State should receive this information in the Medicaid context, in order to help States ensure that they will receive FFP.

Section 455.109(b) would specify that the requirements of § 455.109(a) do not apply to entities that provide 20 or fewer designated health services under the State plan during a calendar year, or to any entity for items or services provided outside the United States. We have derived the limit of 20 or fewer designated health services from the Medicare regulation interpreting section 1877(f) (§ 411.361).

Section 455.109(c) would specify that the information submitted to the Medicaid agency under § 455.109(a) must include at least the following:

- The name and Medicaid State Specific Identifier (MSSI) of each physician who has a financial relationship with the entity that provides services.
- The name and MSSI of each physician who has an immediate relative (as defined in § 411.351) who has a financial relationship with the entity.
- The covered items and services furnished by the entity.
- With respect to each physician identified above, 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 the Medicaid agency.

Section 455.109(d) would define a reportable financial relationship as an ownership or investment interest or any compensation arrangement, as defined in § 411.351, including relationships that qualify for an exception described in §§ 411.355 through 411.357.

Section 455.109(e) would specify that—

- Entities that are subject to the reporting requirements must submit the required information on a prescribed form within the time period specified by the Medicaid agency. Similarly, entities must report to the Medicaid agency all changes in the submitted information within a timeframe specified by the State. We believe that States have the discretion to determine these deadlines in line with § 455.109(a), which requires that the Medicaid agency gather information on financial relationships in such form, manner, and at such times as the agency specifies.
- Entities must retain documentation sufficient to verify the information provided on the forms and, upon request, must make that documentation available to the Medicaid State agency, HCFA, or the OIG.

Section 455.109(f) would reflect section 1877(g)(5), specifying that any entity that is required, but has failed, to meet the reporting requirements of § 455.109(a), is 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 until the information is submitted. It would further specify that assessment of the penalty will comply with the applicable provisions of 42 CFR part 1003.

IV. Our Responses to Questions About the Law

In this section of the preamble, we have included some of the most common questions concerning physician referrals that we have

received from physicians, providers, and others in the health care community. (Note that, in this section, we are using the term "provider" in the generic sense to include all providers of health care services. That is, we are not using the term with the special meaning given in our regulations at § 400.202.) We summarize these questions below and present our interpretation of how we believe the law applies in the situations that have been described to us. We have organized this section so that the issues raised by the questions appear in the order in which they appear in the regulation.

A. Definitions

1. Compensation Arrangement

What is an "indirect" compensation arrangement? We defined a "compensation arrangement" in the August 1995 final rule, in line with the statute, as any arrangement involving any remuneration, *direct or indirect*, between a physician (or family member) and an entity. This means that a compensation arrangement can result when remuneration flows from an entity to a physician or family member, or from a physician or family member to an entity. We have received a number of inquiries on what constitutes an "indirect" compensation arrangement. We believe that a physician or family member can receive compensation from an entity, even if the payment is "funneled through" a business or other entity or association and even if the payment changes form before the physician actually receives it.

For example, suppose that a hospital has contracted with a group practice for the group to furnish physician services and to otherwise staff the hospital. The hospital pays the group practice, which might be a professional corporation or a similar association or entity, for the physician services under a personal services arrangement, rather than directly compensating the individual physicians. The group practice, in turn, pays the individual physicians a salary that in some way reflects the hospital's payments.

It is our position that, in such a scenario, each physician has been indirectly compensated by the hospital for his or her own services. As a result, the physicians have a compensation arrangement with the hospital. In the absence of an exception, the physicians would be prohibited from referring to the hospital for the furnishing of designated health services.

We believe that a physician has received indirect compensation whether the "intervening" professional

association, corporation, or other entity directly receiving payment is a group practice or any other type of physician or nonphysician owned entity. We also believe a physician can receive indirect compensation through a nonprofit enterprise if that enterprise is controlled by an individual who is in a position to influence the physician's referrals. For example, the owner of a clinical laboratory who also serves as the director of a nonprofit research facility could provide a physician with research grants in exchange for referrals to the laboratory. We are considering regarding as indirect compensation any payment to a physician that passes from an entity that provides for the furnishing of designated health services, no matter how many intervening "levels" the payment passes through or how often it changes form. We directly solicit comments on this approach.

We would also like to reiterate a point that we made in the preamble to the August 1995 final rule. Just because a hospital or similar entity is affiliated with a physician or group of physicians does not automatically mean that the hospital or similar entity is compensating the physicians. Physicians and entities can have joint ventures and similar relationships in which the hospital or similar entity and the physicians share profits, but do not compensate each other.

Which exceptions apply in indirect situations? We have also received questions about which exception applies when an indirect payment changes form. For example, in the situation described above, a hospital makes payments to a group practice under a personal services arrangement. The group practice, in turn, passes the payments on in the form of salary payments to its physician employees. We believe that the compensation at issue involves a personal services arrangement between the hospital and the group practice (see the discussion in III.E.6 of this preamble about personal services arrangements between entities and group practices, rather than between entities and individual physicians).

We are interpreting the statute to focus on the payment the entity furnishing designated health services initially makes to determine the appropriate exception. In this case, the hospital is making a payment under a personal services arrangement, and is not in any way making a salary payment to its own employees. Thus, we believe the physicians could make referrals to the hospital if the group practice's personal services arrangement with the

hospital meets the criteria under the personal services exception.

It is our view that the salary payment from the group practice to its physician employees is a payment separate from the remuneration flowing indirectly from the hospital to the physicians. As a result, this payment, as a payment from the group practice, should itself have no additional effect on a physician's ability to refer to the hospital. (The nature of the payment might, however, affect whether the physicians qualify as a group practice. See the discussion in section III.A.6 of this preamble covering the characteristics of a group practice.)

2. Entity

What are the characteristics of an "entity" that provides for the furnishing of designated health services? We have received a number of questions about what constitutes an "entity" involved in the furnishing of designated health services and who owns that entity. For example, a group of individuals asked us whether they own a hospital based solely on the fact that they own the building that houses the hospital. We believe that an "entity" for purposes of section 1877 is the business, organization, or other association that actually furnishes, or provides for the furnishing of, a service to a Medicare or Medicaid patient and bills for that service (or receives payment for the service from the billing entity as part of an "under arrangements" or similar agreement).

An "entity," therefore, does not include any person, business, or other organization or association that owns the components of the operation—such as owning the building that houses the entity or the equipment the entity uses—without owning the operation itself. For example, a physician might own and operate an MRI machine in his or her office. If this physician enters into a lease arrangement for the use of the MRI machine every Tuesday by the physician down the hall, who bills for the services, we believe that the physician down the hall is the entity providing MRI services to his or her patients on Tuesday. This physician could refer patients for MRI services if he or she qualifies for an exception, such as the in-office ancillary services exception.

When is an entity furnishing, or providing for the furnishing of, designated health services? Section 1877(a)(1)(A) prohibits a physician from making a referral to an entity "for the furnishing of designated health services" if the physician or a family member has a financial relationship

with that entity. The health care community has expressed some confusion about when an entity is one involved in the "furnishing of" designated health services.

We have, for example, received questions about which entities are the relevant ones when some entities only bill for services, while others actually directly "furnish" the services. For example in an "under arrangements" situation, a hospital, rural primary care hospital, skilled nursing facility (SNF), home health agency, or hospice program contracts with a separate provider to furnish services to the hospital's, SNF's, or other contracting entity's patients, for which the hospital, SNF or other contracting entity ultimately bills.

The statutory provisions that mention "under arrangements" draw a distinction between services that are actually furnished by the hospital or SNF and those that are actually furnished by the separate, outside entity. (Under section 1861(w)(1), HCFA's payment to the hospital, SNF, or other contracting entity discharges the beneficiary's liability. "Under arrangements" situations are further referenced in sections 1861(b)(3) and 1862(a)(14).) We are aware that there are comparable agreements in the community between entities other than hospitals, SNFs, and the other contracting entities listed above, such as agreements between group practices that furnish services to HMO patients, with the HMO billing for the services.

We believe that, absent an exception, the referral prohibition applies to a physician's referrals to any entity that directly furnishes designated health services to Medicare or Medicaid patients. We believe the prohibition also applies to referrals to any entities that arrange "for the furnishing of" these services to Medicare or Medicaid patients by contracting with other providers, whenever it is the arranging entity that bills for the services.

This interpretation is consistent with the intent of the statute. Congress intended, in enacting section 1877, to prohibit referrals in situations in which a physician has a financial incentive to overutilize the various designated health services and to steer patients toward certain providers of these services. For example, a physician might routinely refer patients to a SNF in which he has a financial interest and prescribe occupational therapy (OT) services. The SNF, in turn, might contract with a separate, unrelated entity to furnish SNF patients with the OT, for which the SNF bills. Even if the physician has no relationship with the separate OT provider, he does have a

financial relationship with the SNF that is providing for "the furnishing of" OT to referred patients. As a result, the physician can potentially profit from each referral he or she makes for OT, even if the SNF must first purchase those services from an outside source before passing on the cost to its patients.

If, however, the unrelated OT entity itself bills for the services under Part B, so that the SNF only helps to make these services available to its patients, our conclusion would be different. In this situation, we do not believe that the physician has a financial incentive to overutilize OT services. As a result, we would not regard the SNF as an entity involved in "the furnishing of" a designated health service.

We also believe that a physician can have an incentive to overutilize services if he or she has a financial relationship with the entity that directly furnishes designated health services, even if this is not the entity ultimately billing for the services. In these situations, the physician can potentially recognize a profit from each referral based on the fact that the designated health services will, in essence, be sold to the entity that bills.

For example, a physician who is a member of a group practice might work in a hospital as a staff physician and refer patients to the group's own outside laboratory in which the physician has an ownership interest. The laboratory, in turn, furnishes services to hospital patients under arrangements. The hospital will therefore be billing Medicare for laboratory services furnished by the physician's own laboratory. In this case, the physician is in a position to influence how many services the laboratory will be able to "sell" to the hospital. Thus, the physician should be prohibited from making these referrals, unless one of the exceptions applies.

We believe our policy of including entities that contract for services as those that provide for "the furnishing of" designated health services is consistent with the structure of section 1877 and the way the exceptions are drafted. For example, under section 1877(b)(3), services are excepted if furnished by an organization that functions under a prepaid plan, such as an HMO. It is our understanding that such services are very often made available in a manner that is comparable to "under arrangements" situations; that is, the prepaid organization contracts with a broad range of independent suppliers and providers to furnish services to its enrollees. This exception makes no distinction between services that are furnished directly by the HMO

and those that are furnished under contract by outside providers: all such services appear to be considered as furnished by the HMO, and would be excepted.

Similarly, section 1877(d)(3) excepts certain "designated health services provided by a hospital," but makes no distinctions between services the hospital itself furnishes and those furnished by the hospital under arrangements.

3. Financial Relationship

How do equity and debt qualify as ownership? The statute states that an ownership interest can be through equity or debt. We have received a number of inquiries about what this provision means and what kinds of debt situations constitute a form of ownership. We believe that "ownership through equity" refers to a direct ownership interest that does not involve debt; for example, one in which the physician or family member has actually purchased assets of a business entity with cash or other property. This interest could be in the form of stock in a publicly-held entity or an investment (such as a capital contribution) in a partnership.

We believe that a physician or family member holds an ownership interest in an entity "through debt" anytime the physician or family member has lent money or given other valuable consideration to the entity and the debt is secured (in whole or in part) by the entity or by the entity's assets or property. For example, the physician could hold such an interest by providing the entity with a note, a mortgage or by purchasing bonds. This interpretation is consistent with the definition of an ownership or control interest in section 1124(a)(3) of the Act, which governs which suppliers and providers must disclose these interests to us for purposes other than the referral prohibition. Section 1124(a)(3)(A)(ii) defines a person with an ownership or control interest as a person who is the owner of a whole or part interest in any mortgage, deed of trust, note, or other obligation secured (in whole or in part) by the entity or any of the entity's property or assets, if the interest is worth a certain amount.

We also believe that ownership through debt can exist in any other debtor-creditor relationships that have some indicia of ownership. For example, such indicia could include the creditor's participation in revenue or profits, subordinated payment terms, low or no interest terms, or ownership of convertible debentures (bonds that a physician or family member can convert

into the common stock of the issuer or an affiliate until the convertible feature expires).

However, if a physician or family member has made an unsecured or nonconvertible loan to an entity, or a loan with no other indicia of ownership, we do not believe the loan is an ownership interest. The loan would likely qualify as a compensation arrangement, to which an exception might apply.

We do not believe that a physician or family member has "ownership through debt" when either of them has received a loan from an entity. In ordinary business transactions, when a debtor receives a loan, this transaction in no way establishes for the debtor an ownership interest in the creditor. We also assume that in providing the loan, the creditor entity has provided remuneration to the physician or family member, resulting in a compensation arrangement. This kind of compensation arrangement could meet one of the exceptions to the prohibition. For example, the loan might be one form of payment an entity makes to a physician to recruit the physician or as part of the physician's employment contract. The loan would be an excepted arrangement if it met the fair market value and other standards in these exceptions.

Is membership in a nonprofit corporation an ownership or investment interest? We have received a number of inquiries concerning whether membership in a nonprofit corporation constitutes an ownership or investment interest in that corporation. (We are assuming that a "member" is someone who establishes, sponsors, directs, or controls a nonprofit corporation.) Most nonprofit health care corporations that are exempt from Federal income taxation are exempt under section 501(c)(3) or (4) of the Internal Revenue Code. These provisions state that the net earnings of such a corporation cannot inure to the benefit of any private shareholder or individual. Therefore, while members of such a nonprofit corporation may exercise control over the activities of the corporation, they do not have the pecuniary incentive that for-profit investors have to enhance their investment interests. As such, we do not regard being a member of these kinds of nonprofit corporations as an ownership or investment interest analogous to being a shareholder in a for-profit corporation. However, any remuneration that the physician or family member receives from the corporation, such as a salary, would be compensation and must meet an exception.

Do stock options and nonvested interests constitute ownership? We have been asked whether a physician or family member has an ownership interest in an entity if he or she receives an option to purchase the stock of the entity or an affiliate, such as when an employee has a stock option that constitutes part of his or her pay. We have also received questions about retirement funds or similar options that do not vest until a future date. For example, a physician might hold an option to purchase stock at a particular price, but not be able to exercise that option until he or she retires. Similarly, a physician might be entitled to certain retirement funds only after he or she has retired after having worked a specified number of years.

The statute defines an ownership interest in section 1877(a)(2) as an interest held through equity, debt, or other means. It is our view that options and nonvested interests are inchoate or partial ownership interests that qualify as "ownership" for purposes of this law. We base our interpretation on the fact that a physician has a tremendous incentive to refer to an entity in which he or she is invested, whether the interest is a present or future one. For example, if a physician has an option to buy stock at a certain price in a clinical laboratory, the physician will have an interest in generating business for the entity in order to enhance the value of that stock.

4. Group practice

What is the "full range of services" test? One of the criteria in the statutory definition of a group practice is that each member must furnish substantially the full range of 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. We have been asked about the meaning and purpose of this provision, and how it will affect a physician's normal practice patterns, only token tasks, for the group. It is our view that this standard should not alter a physician's ordinary schedule or practice habits. For example, one physician described himself as having two specialty areas, which resulted in his providing dermatology services to one group one day a week, and another kind of service to another group on a different day. We believe that different kinds of services such as these on different days can reflect a physician's normal "routine of services." That is, a physician can furnish one type of service that is that physician's "full range of services" on a

particular day, as long as the physician is legitimately practicing medicine for the group practice on that day.

5. Immediate family member or member of a physician's immediate family

How does the prohibition affect a physician's referrals to immediate family members? The referral prohibition in section 1877(a) states that if a physician, or immediate family member, has a financial relationship with an entity, the physician cannot refer a Medicare patient to that entity for the furnishing of designated health services, unless an exception applies. In § 411.351 of the August 1995 final rule, we listed the individuals who qualify as a physician's "immediate" family members. These individuals include, among others, spouses and children of a referring physician.

We have received a number of inquiries from physicians about whether the statute precludes a physician from referring patients to a family member to receive designated health services, if the referring physician has no financial relationship with the entity furnishing the services. We believe the answer to this question depends upon the nature of the family member's financial relationship with the furnishing entity.

If a family member has a compensation arrangement with the entity furnishing the designated health services, the physician cannot refer to the entity, unless the arrangement meets one of the exceptions under the statute. For example, a physician might wish to refer a patient to her husband for occupational therapy services. The husband furnishes OT services as an employee of an occupational therapy facility. The husband, who is an immediate family member of the referring physician, has a compensation arrangement with an entity that furnishes a designated health service (the OT facility pays him a salary). However, the referral would be acceptable if the arrangement meets the requirements in section 1877(e)(2), which excepts bona fide employment relationships between employers and physicians or immediate family members if the relationship meets fair market value and other standards.

The situation is similar if a physician refers a patient to an immediate family member who has an ownership or investment interest in the facility that furnishes the designated health services. For example, the physician may wish to refer a patient to his wife, who is a solo practicing physician who herself furnishes OT. If the wife owns the practice, she would have a financial relationship with the entity that

furnishes the designated health services. The husband's referral would not be prohibited if the wife's relationship qualifies for one of the exceptions under the statute. For example, the wife's practice might qualify as a rural entity, the ownership of which is excepted under section 1877(d)(2) of the Act. However, if an exception does not apply, the referring physician would be precluded from referring to his spouse.

Physicians have also asked us whether the in-office ancillary services exception in section 1877(b)(2) applies to those situations in which a physician refers a patient to an immediate family member who furnishes designated health services outside of the referring physician's practice. The ancillary services exception applies when a physician refers a patient for a service that the referring physician either will personally perform or directly supervise, or that will be personally performed or directly supervised by another member of the referring physician's group practice. As a result, referring physicians can refer patients to and among themselves, within their own practices, if they meet the section 1877(b)(2) requirements. However, the exception does not apply when physicians refer to their spouses or to other close relatives who furnish services outside of the practice.

In creating the in-office ancillary services exception, we believe that Congress made a policy decision not to restrict certain referrals that occur within the confines of one practice. We are not aware of any rationale for extending this "single practice" exception to any outside entities, whether or not those entities have a financial relationship with an immediate family member.

We would also like to point out that a physician may send a patient to an immediate relative without actually "referring" that patient for a designated health service. A referral is defined in section 1877 for purposes of Part B services as, with an exception for certain specialized services, the request by a physician for an item or service, including the request for a consultation with another physician (including any test or procedure ordered by, or to be performed by (or under the supervision of) that other physician). We have interpreted this provision in section III.A.7 of this preamble to apply to just requests by the physician for designated health services covered under Part B, rather than any Part B item or service. For other kinds of items and services, a referral is, with an exception for certain specialized services, the request or establishment of a plan of care by a

physician, which includes the provision of a designated health service.

We believe a referral would be acceptable where the referral is not for a designated health service. For example, a physician who is a general practitioner might believe that a patient has a neurological problem, but be unsure of a diagnosis. This physician could refer the patient to his or her neurologist spouse, if the referral is not a "consultation" (see our discussion of "consultations" in section III.A.7 of this preamble). That is because the referring physician has not requested a designated health service or established a plan of care including one, nor has he or she requested a consultation. We believe the referral, in this case, is for physician services, which are generally not designated health services. If the spouse, in turn, determines that the patient requires an MRI, the spouse would be the one making the referral for this designated health service.

If one member of a group practice cannot make a referral to an entity, are all other group practice physicians also precluded? Group practices have informed us that they are concerned about the definition of a "referring physician" in § 411.351, and how it affects a group when one member is precluded from referring to a particular entity that furnishes designated health services. In particular, several groups wondered whether having a physician member whose immediate relative has an unexcepted ownership interest in an entity would preclude all group practice members from referring to that entity. Groups believe that the preamble to the final rule covering referrals to clinical laboratories implied that the referral prohibition would be imputed to all physician members.

Section 411.351 defines a "referring physician" as a physician (or group practice) who makes a referral (as defined elsewhere in the regulations). We interpreted this definition to mean that when an individual group member refers, the entire group has referred. As a result, any member of a group who has an unexcepted financial relationship (or whose relative has such a relationship) with an entity could "taint" the referrals of the entire group.

We have reconsidered this issue and now propose to amend the definition to exclude any reference to the entire group practice. We believe that the statute was drafted to cover the referral behavior of individual physicians and to regulate the entities to which they refer. There does not appear to us to be any clear reason to extend the effects of one physician's relationships and behaviors to other physicians, just because they

are all members of the same group practice. As several practices have pointed out to us, being members of the same group practice does not mean that physicians automatically have the opportunity, power, or incentive to exert pressure on each other to refer to their related entities.

However, in any instance in which a group member is in a position to exert influence or control over the referrals of other group physicians, the prohibition could still apply. For example, group members could be subject to sanctions if their referral patterns reveal a circumvention scheme between them. Similarly, if a group practice owner conditions payment to his or her employee members on referrals to the owner's laboratory, the employment could be a compensation arrangement that triggers the prohibition.

6. Remuneration

Do payments qualify as remuneration only if they result in a net benefit?

Certain members of the provider community have requested that we interpret a payment as remuneration only if it is made in exchange for identifiable property or services. Under this theory, if the physician or entity making the payment has no expectation of or entitlement to something of value in return for the payment, there would be no compensation arrangement, even if other physicians or entities might benefit from the exchange.

In the August 1995 final regulation, we defined remuneration as "any payment, discount, forgiveness of debt, or other benefit made directly or indirectly, overtly or covertly, in cash or in kind," except for a narrow list of remuneration excluded from the definition by section 1877(h)(1)(C). We believe that remuneration generally involves any payment of cash, property, or services, whether or not either or both parties receive a net benefit. For example, we would regard as remuneration the repayment of a loan, even if there are no accompanying interest payments.

We base this interpretation on the statute, which excepts from compensation arrangements under section 1877(h)(1)(C) only very limited and specific types of remuneration. Among the list is the forgiveness of amounts for the correction of minor billing errors; that is, small amounts that are excused by one party in order to even out the parties' accounts. However, the statute does not except amounts that are forgiven to even out larger billing errors, nor does it contain a general exception for remuneration that does not result in a net benefit for one or both

of the parties. (The correction of a large billing error might, however, qualify as an "isolated transaction" or qualify for the new exception in § 411.357(l) as part of a fair market value exchange.)

We believe that the statute is designed to prohibit referrals whenever a physician makes a payment to an entity or an entity makes a payment to a physician, regardless of who profits or gains. The statute, in our view, contains a presumption that if there has been a payment of any kind, a physician should not refer. As a result, the agency need not "look behind" each transaction to ascertain whether the physician has gained some benefit as a result of the transaction, has realized little or no net benefit, or has benefitted too much. The law does, however, designate certain very specific compensation arrangements that require that the Secretary "look behind" them and except them if the exchanges of payment meet fair market value and certain other standards.

It is our view that the one-way payments described by the providers are remuneration. If a payment does not reflect an actual fair market value exchange, it could easily serve as the vehicle for referral payments. We believe the law was meant to prevent a physician from referring to an entity if that physician (or a family member) is receiving payments of any kind that cannot be accounted for as part of a fair exchange.

B. General Prohibition—What Constitutes a Prohibited Referral

Does the prohibition apply only if a physician refers directly to a particular related entity? As we mentioned in the section above covering the definition of "entity," section 1877(a)(1) prohibits a physician from making a *referral to an entity* for the furnishing of designated health services if the physician or immediate family member of the physician *has a financial relationship* with that entity. Section 1877(h)(5) defines a referral very broadly: A referral is the request by a physician for a Part B item or service (including certain consultations). In addition, "the request or establishment of a plan of care by a physician that includes the provision of [a] designated health service" constitutes a "referral" by a "referring physician." We have interpreted this provision in § 411.351 of the August 1995 final clinical laboratory rule to mean that a physician has made a referral if he or she has made a request for a Part B item or service or a request for other items or services that includes the provision of laboratory services or if he or she has

established a plan of care that includes the provision of laboratory services.

The "referral" provision requires that a physician only request an item or service or include it in a plan of care; it does not require that the physician directly send a patient to a particular entity or specifically indicate in a plan of care that the service must be provided by a particular entity. However, section 1877(h)(5) must be read in conjunction with the prohibition in section 1877(a)(1). The general prohibition applies only when a physician makes a referral to an entity for the furnishing of a designated health service if the physician or a family member has a financial relationship with that entity.

For example, a physician might have a small noncontrolling ownership interest in a provider of a designated health service, such as a physical therapy (PT) facility. The physician does not directly refer patients to this provider. However, the physician does establish plans of care for patients in a hospital setting, which include PT services. When a particular patient leaves the hospital, the physician may refer the patient to an unrelated skilled nursing facility (SNF) that, in turn, refers the patient to the related PT provider. The PT facility bills the patient separately. As a result, the patient may receive services prescribed by the physician from an entity with which the physician has a financial relationship.

In situations such as this one, the physician has prescribed a plan of care that includes designated health services, an action that constitutes a referral. However, the physician has not made the referral to an entity with which he or she has a financial relationship. Instead, the physician has made the referral to an SNF with which he or she has no financial relationship. As such, the referral prohibition would generally not apply. Nonetheless, if there was any evidence that the physician has an agreement with the SNF that involves the SNF systematically referring the physician's Medicare patients to the physician's PT facility, we would likely investigate the situation as a possible circumvention scheme.

When is the owner of a designated health services provider considered as equivalent to that provider? We have received several comments about when a physician who has an ownership interest in an entity that furnishes designated health services should be equated with that entity. For example, suppose that a physician regularly refers patients to an SNF in which the physician has no investment interest. The SNF, in turn, buys PT services from a PT facility that also provides other

noncovered items and services to the SNF and is owned solely by the physician. Arguably the referring physician, as sole proprietor of the PT facility, is related to the SNF because the physician's PT facility sells PT and other, noncovered services to the SNF. We believe that it is likely, in this situation, that the physician is in a position to negotiate or influence the terms of the arrangement, as well as to initiate patient referrals to the SNF.

We believe that there is a potential for abuse in such situations. For example, the physician may be referring as many patients as possible to the SNF in exchange for inflated rates from the SNF for the variety of noncovered items and services that the PT facility furnishes, or for any covered services that are not subject to a fee schedule. Although the SNF may be negotiating with the PT facility as a corporate or other business entity, we would equate the referring physician and the PT facility with each other when the referring physician (or a family member) has a significant ownership or controlling interest that allows him or her to determine how the PT facility conducts its business and with whom. We will consider a number of factors in these situations, such as whether the physician or the physician in combination with his or her immediate family members owns all or a controlling amount of the stock of an entity, and whether the physician and/or the family members are making decisions for the entity, particularly on a day-to-day basis. Our analysis will depend upon the entire record of the interrelationship between the physician and/or immediate family members and the entity, whether the relationships are direct or indirect, and the totality of the circumstances.

We believe the analysis is similar when a referring physician receives compensation from an entity that is owned or controlled by a party that also owns a designated health services provider. For example, suppose that a physician owns a controlling interest in a general practice clinic, and also independently owns a controlling interest in an outside laboratory in which the clinic itself has no interest. The clinic also employs a number of physicians who receive salaries from the clinic corporation.

Arguably, the employee physicians in this situation have no financial relationship with the outside laboratory. That is, they do not themselves own any part of the laboratory, nor do they receive compensation from or pay compensation to the laboratory entity. However, if we were to take the position that there is no financial relationship, and hence no referral prohibition, the

physician owner of the laboratory, by controlling the clinic, could arrange to compensate the employee physicians with inflated salaries based directly on the number of referrals they make to the outside laboratory.

In order to avoid this result, we propose to equate the owner physician with the outside laboratory and with the clinic when he or she owns or controls them. Under this interpretation, we would regard the employee physicians as receiving compensation from the laboratory. Although this compensation is indirect, we believe it is covered by the statute. Section 1877(h)(1) defines a "compensation arrangement" as any arrangement involving any remuneration (with certain narrow exceptions). "Remuneration," in turn, is defined as any remuneration paid directly or indirectly.

If the physician, on the other hand, has a noncontrolling interest in the outside laboratory, we would not equate the owner physician with the laboratory. However, we would regard this situation as a potential circumvention scheme. That is, we would regard the physician owner in this situation as referring indirectly, through the employee physicians, to a designated health services provider to which the owner physician cannot personally refer. The inflated salaries of the employee physicians, in fact, could serve as evidence of the existence of such a circumvention scheme.

The analysis would vary somewhat if the referring physicians are compensated by an entity, rather than an individual physician. Suppose, for example, that a hospital hires physicians to serve on its staff. The hospital compensates the physicians for their services, but inflates their salaries to reflect all the referrals they make to a separate MRI subsidiary that is not part of the hospital but is owned by it. If the hospital owns a controlling share of the MRI entity, we would regard the hospital and the entity as equivalent.

The analysis would be different if the hospital owns less than a controlling interest in the MRI facility. Arguably, the physicians are compensated by an entity (the hospital) that is technically separate from the one providing the referred MRI services. The physicians do not own the MRI facility, nor do they receive payment from it. Nonetheless, if the physicians receive payments from the hospital that exceed fair market value for the services they are otherwise providing, we propose to presume that they are being indirectly compensated by the MRI facility, through the hospital, for their referrals.

Has a physician made a referral to a particular entity if another individual directs the patient there?

We have received inquiries about situations in which a physician requests a designated health service, but it is another individual, such as a discharge planner, who follows the physician's plan of care and refers the patient directly to a specific provider. We discussed this issue in the August 1995 final rule. In the preamble to that rule at 60 FR 41941, we stated that a physician who establishes a plan of care or requests an item or service is responsible for the referral, even if it is another individual or an institutional entity that carries out that plan of care for the physician. For example, we stated that we would not allow a hospital physician to avoid the referral prohibition by claiming that it is the hospital that actually makes the referral or selects the provider in his or her place. We took this position in order to prevent a physician from disavowing all referrals by having personnel or employers carry them out.

In light of our analysis in the responses to the last two questions, we would like to refine our position on this issue. That is, we want to qualify our position to "impute" a physician's referrals to others only in those situations in which the physician has the ability to control or influence the individuals who select an entity. We would also "impute" referrals if a physician is him or herself in a position to be compensated for the referrals by those who can control or influence the actions of the person who actually selects the entity.

For example, suppose that a physician works for a hospital and refers a patient to the hospital's discharge planner for laboratory tests. The discharge planner in turn refers the patient to the hospital's laboratory. We would regard the physician's request and referral to the discharge planner as a referral to an agent of the entity that owns the laboratory; that is, to an agent of the entity that furnishes designated health services. We believe that such a referral would be governed by the rules in section 1877. Suppose, on the other hand, that the discharge planner refers the patient to an outside laboratory that happens to be owned by the hospital. The physician in this situation may not be able to compensate the discharge planner or otherwise in any way influence that individual's actions. Nonetheless, if the hospital pays the physician to order as many laboratory tests as possible, and in turn pays the discharge planner to refer patients directly to a hospital-owned provider,

we would impute the referral to the physician.

We can translate these rules into a group practice setting. For example, a group practice member might request a designated health service, but allow a nonphysician employee to direct the patient to a particular provider. If the nonphysician refers the patient to the group's own provider, we would regard the referral as the physician's own referral to an agent of a provider of designated health services. This arrangement, we believe, would be subject to the referral rules. For outside referrals, we would gauge whether the physician member is in any position to control the actions of the nonphysician. In order to gauge whether a physician is in a position to affect a nonphysician's actions, we propose to use the same ownership and control rules that we mentioned above. We would also impute the referral to the physician if the entity compensating the physician is in a position to both compensate the physician for his or her referrals and to control the actions of the individual who selects the provider.

How will HCFA interpret situations in which it is not clear whether a physician has referred to a particular entity?

A physician might request or order a designated health service for a patient without establishing a record of whether he or she referred the patient to a specific provider. If the patient receives the designated health service from an entity with which the physician (or a family member) has a financial relationship, as the result of the referral, we will presume that the service results from the physician referring to that specific entity. We will allow physicians to rebut that presumption by establishing that they mentioned no specific provider or supplier or that the patient was directly referred by some other independent individual or through an unrelated entity.

C. General Exceptions That Apply to Ownership or Investment Interests and to Compensation Arrangements

1. The in-office ancillary services exception

Can a physician supply crutches as in-office ancillary services? The in-office ancillary services exception in section 1877(b)(2) applies to services that meet the requirements for supervision, location, and billing, but not to any parenteral and enteral nutrients, equipment and supplies or to durable medical equipment (DME) (although the exception does apply to infusion pumps). Many physicians have brought to our attention the problems with

excluding crutches from the exception. That is, an orthopaedist might diagnose a patient with a broken leg, set the leg, personally furnish the patient in his or her own office with crutches, and then bill for those crutches. If the patient will use the crutches at home, they qualify as DME. Physicians have pointed out that this exclusion will cause great inconvenience to such patients, who will have to obtain crutches or similar equipment elsewhere.

We agree that excluding crutches from the section 1877(b)(2) exception could cause great inconvenience to patients, and disrupt the efficient delivery of health care services. We regard crutches as different from other DME in that a patient very often needs them immediately after treatment for an injury that has resulted from an unexpected traumatic event. Thus, patients may often be precluded from arranging to receive crutches in advance from other, unrelated entities. Nonetheless, the Secretary does not have the authority to simply create a blanket exception for crutches. The Secretary only has the authority, under section 1877(b)(4), to create new exceptions in the case of any other financial relationship that the Secretary determines, and specifies in regulations, does not pose a risk of program or patient abuse. We have no evidence that allowing physicians a blanket exception to self-refer for crutches will be free from abuse. In the ownership context, for example, each referral will inherently increase a physician's or group practices' profits.

We are thus proposing to create an exception, at § 411.355(e), that we believe will remedy this problem, while meeting the statutory condition. That is, the exception would apply only to situations in which a physician furnishes crutches in a manner that meets the in-office ancillary services requirements in section 1877(b)(2) (and in § 411.355(b)), provided the physician realizes no direct or indirect profit from furnishing the crutches. In other words, Medicare will pay for the crutches if the physician bills only for the cost he or she incurred to acquire and supply the crutches or to create or manufacture the crutches. We believe that there is no threat of abuse in these situations, since physicians will have no incentive to overutilize crutches.

2. Exception for services furnished by organizations operating under prepaid plans

Can a physician refer non-enrollees to a related prepaid organization or to its physicians and providers?

We have been asked about situations in which a physician furnishes services to managed care patients under a personal services contract, but wishes to refer his or her own outside, fee-for-service Medicare patients for designated health services to the managed care entity, or to physicians, suppliers, or providers that are affiliated with the managed care entity. If the physician refers to an otherwise unrelated physician, provider, or supplier that is affiliated with the managed care entity, but is not part of it and accepts the fee-for-service patient independently, the referral prohibition should not apply. That is, the physician would not be referring to the managed care entity with which he or she has a financial relationship.

The analysis would be different, however, if the other physician, provider, or supplier is functioning as part of the managed care entity. For example, a physician might provide services to enrollees of a Federally qualified HMO under a contract arrangement. These services are excepted from the referral prohibition by section 1877(b)(3). However, when the physician wishes to refer a fee-for-service Medicare patient to the HMO's laboratory, the physician is making a referral to an entity with which the physician has a financial relationship. That is, the physician's personal services contract constitutes a compensation arrangement with the HMO.

In order for the physician in this situation to refer, the financial relationship must meet one of the compensation-related exceptions in section 1877 or in this proposed rule. For example, the physician could continue to refer if his or her arrangement meets the criteria in the personal services exception in section 1877(e)(3) and in § 411.357(d) of this proposed rule. The compensation the physician receives from the HMO would have to be, among other things, consistent with fair market value, and could not reflect the volume or value of the physician's referrals (except as allowed under a physician incentive plan). We have proposed to define the concept of a "referral," for purposes of section 1877, as limited to a referral for a designated health service that may be covered under Medicare or Medicaid (see our discussion of the definition in section III.A.7 of this preamble). Thus, the "volume or value" standard would automatically be met if (in the context of the physician's HMO practice) the physician treated and referred only non-Medicare or non-Medicaid HMO enrollees (that is, the physician's HMO

compensation would never reflect the volume or value of Medicare or Medicaid referrals).

If, on the other hand, the physician is compensated by the HMO for treating HMO enrollees who are covered by Medicare or Medicaid, the compensation would be subject to the "volume or value" standard. Hence, the arrangement could still meet the personal services exception if the physician's compensation does not reflect Medicare or Medicaid covered referrals or reflects them only as part of a physician incentive plan, as these plans are described in section 1877(e)(3)(B), and in § 411.351 of this proposed rule.

As noted earlier in this preamble, we believe that, for the most part, physicians working for managed care organizations or as part of an integrated delivery system will be able to refer Medicare and Medicaid patients within these systems, provided their arrangements with these entities meet certain standards. However, we anticipate that there may be some unusual situations in which an exception does not apply. One example of providers in a delivery system who may be adversely affected by the referral prohibition involves providers under Medicaid primary care case management (PCCM) programs.

We are aware that, under certain circumstances, some providers contracting under these managed fee-for-service programs may not be eligible for any of the existing exceptions written into the law or proposed in this rule. Because the Secretary can only create new exceptions for financial relationships which she determines pose no risk of program or patient abuse, we have not created a blanket exception for Medicaid PCCM programs. However, we do not wish, as an unintended consequence of this decision, to discourage the participation of Medicaid providers in PCCM programs, thereby threatening Medicaid beneficiaries' access to care. Therefore, we are soliciting comments from States and others on the potential impact of the referral prohibition on Medicaid PCCM programs and the providers who contract under them.

One example of a situation in which a PCCM provider might be prohibited from making a referral involves HMOs that contract as primary care case managers. While HMO participation in PCCM programs is relatively rare, HMOs in some States have contracted to serve as case managers to the disabled population. Such contracts allow the HMO to gain experience in serving the disabled without having to accept the

financial risk that an HMO would normally accept under a capitation contract. As States move to enroll more of their disabled populations into capitated programs, involving HMOs in PCCM programs could serve as a transitional method of developing a managed care provider network that is experienced in caring for the disabled.

If an HMO physician who is required by contract to refer within the HMO's network wishes to refer a PCCM patient within that network, his or her financial relationship with the HMO would have to meet one of the existing exceptions in the law or in this proposed rule. Because the HMO in the above example is paid on a fee-for-service basis under the PCCM program, none of the exceptions for services furnished by pre-paid risk plans would be appropriate.

The manner in which we have interpreted the volume or value of referrals standard in this proposed rule could prevent the financial relationship from qualifying for one of the compensation-related exceptions. Most of these exceptions can be satisfied only if a physician's compensation does not reflect the volume or value of his or her referrals. Certain provider contracts that require a physician to refer within a defined network of providers could violate that standard. (We discuss our interpretation of this standard in section III.E.3.) That is, regardless of whether the physician's income actually varies based on the volume or value of referrals, the physician's income reflects the referrals because it could be lost entirely if the physician repeatedly refers patients out-of-network. If the financial relationship does not qualify for an exception, there may be no Federal matching funds for any in-network referral of PCCM patients made by this physician.

3. Other permissible exceptions for financial relationships that do not pose a risk of program or patient abuse

Should situations that meet a safe harbor under the anti-kickback statute be automatically excepted? We have received inquiries about the Secretary's authority under section 1877(b)(4) to create additional exceptions for financial relationships which the Secretary determines, and specifies in regulations, do not pose a risk of program or patient abuse. We have had some requests that the Secretary create an exception for any financial relationship that meets a safe harbor under the anti-kickback statute. As we have stated elsewhere in this preamble, the anti-kickback statute in section 1128B(b) and section 1877 are totally independent laws, with separate

requirements. In order for a physician who has a financial relationship with an entity to refer to that entity, the arrangement must meet the requirements in both laws. However, we are willing to consider this option and specifically solicit comments on whether meeting a safe harbor would qualify an arrangement as one that involves no risk of program or patient abuse.

D. Exceptions That Apply Only to Ownership or Investment Interests

1. Exception for ownership in publicly traded securities or mutual funds

Does the exception for publicly traded securities apply to stock options? We have been asked whether ownership of an option to purchase stock in an entity that furnishes a designated health service constitutes an excepted ownership interest in the entity. As we stated in section IV.A.3 above, we regard the option to purchase stock in an entity as an inchoate ownership interest that could subject a physician to the referral prohibition. As such, all of the exceptions that ordinarily apply to ownership interests would apply. However, the exception for publicly traded securities would not apply if the stock option involves investment securities that may not be purchased on terms generally available to the public, as required by section 1877(c)(1).

2. Exception for services provided by a hospital in which a physician or family member has an interest

Can a physician or family member own an interest in a chain of hospitals? Section 1877(d)(3) contains an exception for designated health services provided by a hospital (other than a hospital in Puerto Rico) if the referring physician is authorized to perform services there, and the ownership or investment interest is in the hospital itself (and not merely in a subdivision of the hospital). We discussed at some length in the August 1995 final rule how we believe an individual can hold an interest in a subdivision of a hospital.

We have received inquiries about whether this exception applies if a physician or family member holds an interest in a company or network that owns a chain of hospitals, rather than an interest in the one hospital to which the physician makes referrals. It is our view that a physician can have an ownership or investment interest in a hospital that is part of a chain by virtue of holding an interest in the organization that owns the chain. We base our position on the language of the exception, which does not require that the physician have a

direct interest in the hospital. In addition, we believe that the exception in section 1877(d)(3) must be read in conjunction with section 1877(a)(2), which states that a physician's or family member's ownership or investment interest in an entity that provides a designated health service constitutes a financial relationship with that entity. This provision further defines an ownership or investment interest in an entity to include an interest in an entity that holds an ownership or investment interest in any entity providing the designated health services. Thus, by definition, a physician who has an ownership interest in a health system that owns a hospital that provides designated health services has an ownership interest in that individual hospital. If that indirect interest is in the hospital as a whole, and not in a subdivision, then the exception should apply. In fact, we believe that it would be illogical to specifically apply the referral prohibition in section 1877(a)(1) to any indirect ownership interest, yet deny an exception in section 1877(d) that is based on ownership just because the interest is indirect, especially when the exception itself does not require a direct interest.

Nonetheless, in order to meet the hospital ownership exception, we believe the law requires that the physician be authorized to perform services at the hospital to which he or she wishes to refer. We do not believe that this last requirement is met if the physician has these privileges with any one of the other hospitals in the chain, but not with the referral hospital.

We also wish to make the point that any ownership interest a physician or family member has in a hospital could involve a separate compensation arrangement. For example, if a physician acquires an interest in a hospital from a health care network, this acquisition could constitute remuneration from an entity that provides designated health services. Consequently, for the physician to refer to the entity, the arrangement would have to meet a compensation-related exception.

E. Exceptions That Apply Only to Compensation Arrangements

1. Compensation arrangements in general

Can a lease or arrangement for items or services have a termination clause? The lease exceptions for space and equipment and a number of the other compensation exceptions require that, among other things, the arrangement be in writing and provide for a term of at

least 1 year. We believe that this requirement has been met as long as the arrangement clearly establishes a business relationship that will last for at least 1 year. Nonetheless, it is our view that the arrangement can still qualify for the exception even if it also includes a clause allowing the parties to terminate sooner for good cause, provided the parties do not enter into a new arrangement within the originally established 1 year time period.

We believe that Congress included the 1 year requirement with the intention of excepting stable arrangements that cannot be renegotiated frequently to reflect the current volume or value of a physician's referrals. Nonetheless, we do not believe that Congress intended, in creating this requirement, to bind parties to an arrangement once that arrangement has become unsatisfactory to some or all of the parties. Therefore, we are interpreting all of the exceptions with the 1 year requirement to allow terminations for good cause, provided the parties do not, within the 1 year period, enter into a new arrangement. We also believe that a lease or arrangement must be renewed in at least 1 year increments, so that it is always an agreement that provides for a term of at least 1 year. That is, once the first year of an agreement expires, it cannot be converted into, for example, a month-by-month arrangement that could fluctuate with a physician's referrals.

Will a physician's referrals be prohibited if an entity pays for certain incidental benefits? Entities, such as hospitals, often provide physicians with certain incidental benefits, such as their malpractice insurance, or with reduced or free parking, meals, or other incidental benefits. We believe the answer to this question hinges on the nature of any other financial relationship the physician has with the entity. For example, if a physician receives free "extras" such as malpractice insurance, parking, or meals while he or she serves as the entity's employee, then these extras might qualify as part of the compensation that the physician receives under a bona fide employment relationship, provided they are specified in the employment agreement. If the physician or entity can demonstrate that the extras constitute part of the payment that such entities typically provide to physicians, regardless of whether they make referrals to the entity, the extras might constitute payment that is consistent with fair market value and that furthers the entity's legitimate business purposes. If an incidental benefit cannot meet the requirements under a statutory exception or the new general exception

for compensation arrangements we have included in § 411.357(l), it might still meet the de minimis exception we have added in § 411.357(k) if it has limited value. We have also been asked about parking spaces that a hospital provides to physicians who have privileges to treat their patients in the hospital. It is our view that, while a physician is making rounds, the parking benefits both the hospital and its patients, rather than providing the physician with any personal benefit. Thus, we do not intend to regard parking for this purpose as remuneration furnished by the hospital to the physician, but instead as part of the physician's privileges. However, if a hospital provides parking to a physician for periods of time that do not coincide with his or her rounds, that parking could constitute remuneration.

2. Exception for agreements involving the rental of office space or equipment

Can a lessee sublet office space or equipment? Section 1877(c)(1) and (2) exempts from compensation arrangements that trigger the referral prohibition, payments made by a lessee to a lessor for the use of premises or equipment if certain criteria are met. We have listed these requirements in the regulation at § 411.357(a) and (b). Among these is the requirement that the office space or equipment be "used exclusively by the lessee when being used by the lessee." We believe Congress included this requirement to ensure that excepted rental agreements are valid ones, rather than "paper" leases that might involve payments passing between the lessor and lessee, when the lessee is not actually using or intending to use the space or the equipment. As a result, we believe that this requirement precludes the lessee from subletting the space or equipment during any portion of a lease during which the lessee is expected to be using them.

A sublease arrangement might nonetheless qualify under the new compensation exception that we are proposing under § 411.357(l). That exception requires, among other things, that the rental payments be consistent with fair market value and not take into account the volume or value of any referrals between the parties. In addition, the lease arrangement must be commercially reasonable and further the legitimate business purposes of the parties. We envision that there could be arrangements in which both the lease arrangement and the sublease would meet all of these criteria.

Does the lease exception apply to any kind of lease covering space or equipment? As we understand general

accounting principles, there are differences between operational leases and capital leases that may be relevant to our application of section 1877. Operational leases are basic, simple leases in which the lessee makes rental payments to the lessor in order to use the lessor's property or space. These kinds of leases, we believe, could fall within the exceptions in section 1877(e)(1)(A) and (B) because they constitute payments made by the lessee for the use of space or equipment.

Capital leases, on the other hand, are very much like installment sales purchases. Upon entering into such a lease, the lessee receives all of the benefits and obligations of ownership of the property. That is, the lessee (and not the lessor) can depreciate the property and record it on its books as a capital asset and the long-term capital lease payments as a liability (very much like the way the lessee would record a loan). In most cases, the title to the property at issue will pass to the lessee at the end of the term of the lease. In other words, the property that is covered by capital leases is treated by accountants as property that a lessee has purchased or is in the process of purchasing. We believe that such leases go beyond the section 1877(e)(1) exceptions, which except only payments for the use of equipment or space.

Can a lease provide for payment based on how often the equipment is used? We have been asked about situations in which a physician rents equipment to an entity that furnishes a designated health service, such as a hospital that rents an MRI machine, with the physician receiving rental payments on a "per click" basis (that is, rental payments go up each time the machine is used). We believe that this arrangement will not prohibit the physician from otherwise referring to the entity, provided that these kinds of arrangements are typical and comply with the fair market value and other standards that are included under the rental exception. However, because a physician's compensation under this exception cannot reflect the volume or value of the physician's own referrals, the rental payments cannot reflect "per click" payments for patients who are referred for the service by the lessor physician.

3. Exception for personal services arrangements

How does the physician incentive plan exception apply when an enrolling entity contracts with a group practice? The exception for personal services arrangements includes the criteria that any compensation paid by an entity

under the arrangement cannot reflect the volume or value of a physician's referrals, unless the compensation is paid under a physician incentive plan, as that term is defined in section 1877(e)(3)(B). A physician incentive plan is defined by this provision 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 furnished with respect to individuals enrolled with the entity. We have defined "physician group" broadly in our March 27, 1996, final rule (61 FR 13430) interpreting physician incentive plans under section 1876(i)(8), of which group practices as defined under section 1877(h) are a subset.

Although an entity can compensate a physician group to reflect the volume or value of referrals under a physician incentive plan, the definition of a group practice under section 1877(h)(4)(A)(iv) precludes the group, with certain exceptions, from compensating its members based directly or indirectly on the volume or value of their referrals (it does not contain the exception for physician incentive plans). As we have described earlier in this preamble, we believe the volume or value standard applies only to a physician's own referrals for designated health services covered under Medicare or Medicaid.

Several interested parties have asked us whether these provisions contain contradictory standards, which could make it difficult for entities that enroll patients to continue their common practice of contracting with group practices to provide services to the entities' enrollees. We believe that the two provisions need not be read as contradictory. While the group practice definition in general precludes a group from compensating its physician members based on their referrals, it does allow groups to pay physicians a share of the overall profits of the group, or a productivity bonus based on services personally performed or services incident to such personally performed services, so long as the share or bonus is not determined in a manner that is directly related to the volume or value of a physician's own referrals. We have discussed our interpretation of these principles elsewhere in this preamble. In the context of a physician incentive plan, a physician group as a whole could be compensated more by an entity based on providing or referring for fewer services. We believe that the group practice could then pass any additional compensation it receives from a physician incentive plan on to the individual physician members via overall profit sharing, which would only

indirectly compensate them for the volume of their referrals. Also, the physicians could receive a productivity bonus for their decreased utilization of any services that are not designated health services covered under Medicare or Medicaid.

V. Regulatory Impact Statement

A. Background

We have examined the impacts of this proposed rule as required by Executive Order 12866 and the Regulatory Flexibility Act (RFA) (Public Law 96-354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, most hospitals, and most other providers, physicians, and health care suppliers are small entities, either by nonprofit status or by having revenues of \$5 million or less annually.

Section 202 of the Unfunded Mandates Reform Act provides for "Regulatory Accountability and Reform." It requires the agency to engage in certain procedures, including a cost benefit analysis and consultation with affected State and local governments, for proposed and certain final rules that include "Federal mandates" that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more annually. Section 201 of the Unfunded Mandates Reform Act requires this assessment only to the extent that a regulation incorporates requirements other than those specifically set forth in the law.

Section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis for any proposed rule that 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 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside a Metropolitan Statistical Area and has fewer than 50 beds.

Sections 1877 and 1903(s) of the Act were enacted in order to correct an abuse highlighted by a number of studies: The ordering by some physicians of unnecessary services because they have a financial incentive

do so. (See section I.A. of this preamble for citations to the studies.) The legislation identified those types of services (referred to as "designated health services") where the existence of, or potential for, abuse appeared to be the greatest. The approach taken in the legislation was to assume that, in general, if a financial relationship exists between a physician or a physician's immediate family member and an entity that provides designated health services, an incentive to overutilize those services also exists. The statute defined a financial relationship as an ownership or investment interest in, or compensation arrangement with, an entity. Congress created a number of exceptions to the prohibition in recognition of certain existing business practices. In addition, the legislation provides the Secretary with authority to create new exceptions. However, we must first determine, and specify in regulations, that any new exception will not pose a risk of program or patient abuse.

Because of its exceptions, the current law is complicated. However, the essence of the prohibition in section 1877 is clear: If a physician or a physician's immediate family member has a financial relationship with an entity, the physician cannot refer patients to that entity for the furnishing of a designated health service for which payment otherwise may be made under Medicare. Unlike the anti-kickback statute discussed in the preamble, the law is triggered by the mere fact that a financial relationship exists; the intention of the referring physician is not taken into consideration.

Section 1903(s) denies Federal financial participation payment under the Medicaid program to a State for designated health services furnished to an individual on the basis of a physician referral that would result in a denial of payment under the Medicare program if Medicare covered the services to the same extent and under the same terms and conditions as under the State Medicaid plan.

The goal of this proposed rule is to integrate section 1877 (as amended by OBRA '93 and SSA '94) into the Medicare regulations and section 1903(s) into the Medicaid regulations, and to interpret the statute in accordance with its language and intent.

B. Anticipated Effects and Alternatives Considered

For the reasons described below, we believe any estimate of the individual or aggregate economic impact of the provisions of this proposed rule would be purely speculative. Although the

provisions proposed in this rule do not lend themselves to a quantitative impact estimate, for reasons discussed below and elsewhere in the preamble, we do not anticipate that they would have a significant economic impact on a substantial number of small entities. However, to the extent that our proposals may have significant effects on some health care practitioners or be viewed as controversial, we believe it is desirable to inform the public of what we view as the possible effects of the proposals. This analysis, together with the other sections of the preamble, constitutes a regulatory flexibility analysis and analysis for purposes of section 1102(b) of the Act.

We expect that some kinds of entities could be affected to varying degrees by this proposed rule. Following are the groups we believe are most likely to experience some economic impact:

1. Physicians

A physician can be financially related to an entity either through an ownership or investment interest in the entity, or through a compensation arrangement with the entity. We begin by first discussing ownership/investment interests.

Ownership or investment interests. A physician who has (or whose immediate family member has) an ownership or investment interest in an entity and does not qualify for an exception is prohibited from referring Medicare patients to that entity for the provision of designated health services. Also, when a physician with such an ownership or investment interest makes a prohibited referral, there is a risk that the entity will receive no Medicare payment for those designated health services. Under Medicaid, a State may receive no FFP for services that result from a referral that would be prohibited under Medicare, if Medicare covered the same designated health services as are covered under the State plan. The State may, in turn, choose not to pay the furnishing entity.

The American Medical Association's (AMA) Center for Health Policy Research (hereafter, the Center) reviewed three studies that analyze self-referral: (1) "Financial Arrangements Between Physicians and Health Care Businesses: Report to Congress," Office of Inspector General, DHHS, pages 18 and 21 (May 1989); (2) "Joint Ventures Among Health Care Providers in Florida," State of Florida Health Care Cost Containment Board (Sept. 1991); and (3) "Frequency and Costs of Diagnostic Imaging in Office Practice—A Comparison of Self-Referring and Radiologist-Referring

Physicians," Bruce J. Hillman and others, *The New England Journal of Medicine* (December 1990; pp. 1604–1608). As reported in the *Journal of the American Medical Association* (JAMA, May 6, 1992, Vol 267, No. 17), the Center found that approximately 10 percent of physicians nationwide have ownership interests in health care entities that have been associated with potential self-referral issues. It pointed out, however, that not all of these physicians engage in self-referral. The Center also reported that there was no evidence in the studies they reviewed on the extent to which physicians may profit from self-referrals. Therefore, it concluded that the degree of conflict of interest presented by a physician's investment in entities to which he or she refers patients is unknown.

If we were to assume that the 10 percent figure cited above is currently true, this would mean, based on the number of active physicians in 1995, that approximately 79,000 physicians have an ownership interest in health care entities that furnish designated health services. Note, however, that others cite higher percentages. For example, the 1991 study issued by the Florida Health Care Cost Containment Board found that at least 40 percent of Florida physicians involved in direct patient care had an investment in a health care business to which they could—in the absence of prohibiting legislation—refer patients for services. We would also like to point out that ownership information or information on the investments of physicians and all of their immediate family members in the entities that furnish any of eleven designated health services constitutes an enormous amount of data that is continually subject to change.

In 1991, the AMA's Council on Ethical and Judicial Affairs had concluded that physicians should not refer patients to a health care facility outside their office at which they do not directly provide services if they have an investment interest in the facility. The Council stated that physicians have a special fiduciary responsibility to their patients and that there are some activities involving their patients that physicians should avoid whether or not there is evidence of abuse. In December 1992, the AMA voted to declare self-referral unethical, with a few exceptions. Exceptions are allowed if there is a demonstrated need in the community and alternative financing is not available.

As of October 1994, 27 States had enacted legislation that restricts or qualifies self-referral. There is great variation among the States. Some only

require disclosure of the financial relationship to the patient, while others prohibit such referrals.

We believe that this increased examination of self-referral arrangements and enactment of both Federal and State laws prohibiting such arrangements has led to a decline in self-referral activity and financial relationships between physicians and entities. However, we lack the data necessary to either confirm or refute this supposition. We also lack data that would tell us how many of the financial relationships that physicians have with an entity that furnishes a designated health service would be exempted under the statute. We would welcome receiving current relevant data.

One exception that may have broad application is the in-office ancillary services exception. With regard to this exception, which applies to both ownership/investment interests and compensation arrangements, we offer the following discussion.

To qualify as in-office ancillary services, the services must, among other things, be furnished personally by the referring physician or another physician in the same group practice as the referring physician, or be furnished by individuals who are directly supervised by one of these physicians. How we interpret a number of elements in this provision would affect whether certain referrals qualify for the in-office ancillary services exception. These include how we define "group practice," "members of the group," and "direct supervision." We discuss these definitions below.

The in-office ancillary services exception allows physicians who are members of a group practice to supervise designated health services referred by any group member. Paragraph (h)(4)(A) of section 1877 provides a definition of a "group practice." That definition, however, consists of elements that require interpretation—for example, what qualifies a group of physicians as "a legal entity," what is meant by the "full range of a physician's services," which must be furnished through group arrangements, and what constitutes "substantially all" of a physician's services, which must also be furnished through the group. We discuss these elements in section III.A.6 of this preamble. As noted in that discussion, we propose to modify some of the interpretations that we made in the August 1995 final rule. We believe that these modifications, which recognize established business practices that do not pose the risk of program or patient abuse, will enable more physicians to

meet the definition of a group practice than would the interpretations in the August 1995 rule. If a group of physicians qualifies as a group practice, services can be furnished by certain individuals other than the referring physician and still qualify for the in-office ancillary services exception. We are unable, however, to make an estimate of the economic impact of these modifications.

Also affecting the in-office ancillary services exception is how we would define "members of the group." Again, this proposed rule would modify the definition we established in the August 1995 final rule. This modification, discussed in detail in section III.A.6 of this preamble, would not regard independent contractors as members of the group. This interpretation may make it easier for a group of physicians to meet the "substantially all" test to qualify as a group practice than would the interpretation in the August 1995 rule. On the other hand, independent contractors could not supervise the provision of designated health services. We are unable to estimate the impact of these opposing effects.

The in-office ancillary services exception provides both solo practitioners as well as group practice physicians with the ability to refer within their own practices. As we discussed in detail in the August 1995 final rule, this provision can except solo practitioners with certain shared arrangements who do not wish to become a group practice. For example, two solo practitioners who share one office and jointly own a laboratory can continue to refer to that laboratory, as long as each physician furnishes physician services unrelated to the designated health services in the office, directly supervises the laboratory services for his or her own Medicare and Medicaid patients while they are being furnished, and bills for the services. If only one of the solo practitioners owns the laboratory in a shared office, the non-owning physician can refer to the laboratory as long as he or she is not receiving compensation from the owner in exchange for referrals. We are aware, however, that this exception may not accommodate the variety of different arrangements physicians have entered into to share facilities or otherwise group together without losing their status as solo practitioners. We directly solicit comments on the effects of the referral prohibition on these arrangements.

The proposed regulation defines the statutory requirement for a physician's "direct supervision" of individuals furnishing designated health services

under the in-office ancillary services exception. Under the definition, "direct supervision" requires that a physician be present in the office suite and immediately available to provide assistance and direction during the time services are being performed.

One option for defining "direct supervision" would be to say that it means that the service is furnished under the physician's overall supervision and control but that the physician need not be physically present in the office suite in which the services are performed while they are being performed. This rule would not adopt such a definition, however. We believe that the supervision requirement is meant to establish as "in-office ancillary" services those services that are integral to the physician's own practice and that are conducted within his or her own sphere of activity. We believe Congress intended this exception to apply to services that are closely attached to the activities of the referring physician.

If we were to allow physicians to supervise the furnishing of designated health services from a distance, we believe that we would be creating an opportunity for physicians to refer to entities outside their own practices, for services which are not actually "in-office ancillary" in nature. Although our proposed definition may result in fewer referrals qualifying for the "in-office" exception than a more liberal definition, we believe our definition is necessary to achieve the purposes of the statute. We are not, however, proposing that there must be a particular configuration of rooms for an office to qualify as a "suite," for example, that the rooms be contiguous. As stated in section III.A.2 of this preamble, the question of physician proximity for purposes of meeting the direct supervision requirement is a decision that would be made by the local carrier based on the circumstances. We have also proposed to liberalize the concept of "present in the office suite," as we interpreted it in the August 1995 final rule, to allow brief absences from the office under certain conditions.

Because we do not have data on how many physicians have financial relationships that already qualify for the in-office exception, and how many would have to alter their practices, even given the modifications discussed immediately above, we cannot judge the economic impact of our definition. We specifically solicit information on this issue.

As already stated, we do not have current data on the number of physicians with ownership/investment

interests in entities that furnish designated health services. Nor do we know how many of these physicians would qualify for an exception to the referral prohibition. However, even if we were to assume that a substantial number of physicians have nonexcepted ownership interests in entities that furnish a designated health service, we do not believe that, in general, the economic impact on these physicians necessarily has to be substantial, for the following reasons:

If a physician's ownership interest in an entity would lead to a prohibition on his or her referrals to that entity, the physician has three options: First, he or she can stop making referrals to that entity and make referrals to another unrelated entity. Second, the physician can divest him or herself of the interest. Third, the physician can, if possible, position him or herself to qualify for an exception. Below we discuss the economic impact of each of these options.

While the impact on an individual physician may be significant, we do not believe that physicians, in general, will be significantly affected if they have to stop making referrals to an entity in which they have an ownership interest. We come to this conclusion because we assume that the majority of physicians receive most of their income from the services they personally furnish, not from those they refer. In addition, we assume that unless the physician established the entity to serve only his or her own patients, the entity receives referrals from other sources. Thus, the physician may still receive a return on the investment. Further, it is possible that, if physician ownership of entities providing the particular designated health services is prevalent in the area, what may occur is a "shifting" of referrals; that is, the loss of a physician's own referrals to the entity might be offset by other physicians shifting referrals to unrelated entities. These shifts would be acceptable under section 1877, provided they do not result from circumvention schemes.

We do not believe the second option, divesting of the ownership interest, would necessarily have a significant economic effect. However, we assume, that, at least from an economic standpoint, most physicians invest in entities because they are income-producing. If an investment is successful, a physician may not have difficulty finding new investors willing to take over the physician's investment. The physician, in turn, can then invest the monies received in some other investment. We believe the cost of divesting will vary from situation to

situation. (A search of the literature on this issue resulted in only anecdotal information that indicated that some physicians sustained a loss in divesting, while others did not.) We do see the possibility of a significant effect in the case of a physician who has, at considerable expense, established an entity to serve only his or her own patients, with the expectation of future return on that investment. We believe, however, that the exceptions in the statute and regulation allowing physicians to refer within their own practices (primarily the in-office ancillary services exception) will greatly reduce the number of physicians otherwise subject to the prohibition.

It is difficult to estimate how many physicians would select the third option of changing the circumstances of their practices in order to meet an exception to the referral prohibition. It is also difficult to estimate the extent of the changes that would be necessary or the potential economic impact of any modifications. As an example of one modification, a physician maintains with other independently-practicing physicians a nonrural facility for furnishing X-rays. The physicians share premises, equipment, employees, and overhead costs. If an individual physician does not meet the requirements for the in-office ancillary exception found in section 1877(b)(2), the physician's Medicare referrals to that entity would be prohibited. In such a situation, as an alternative to options 1 and 2 above (stopping referrals or divesting), the physician could choose to form a group practice with the other physicians in order to qualify for the in-office ancillary services exception. By forming a group practice, the referrals would not be prohibited if the services were furnished personally by the referring physician, personally by another physician who is a member of the same group practice as the referring physician, or if they are furnished personally by individuals who are directly supervised by any of these physicians and the billing and location requirements specified in the in-office ancillary exception are met.

Although we realize that a physician reorganizing his or her practice in this way may be subject to various economic and noneconomic effects, we believe those effects will differ widely from case to case. Some physicians may need to make major alterations in their practices, while others may need only minor changes, with minimal or no help from legal or financial advisors. It is possible that some physicians would profit from reorganizing, while others might suffer losses. Thus, we cannot

judge whether any particular physician, or physicians in general, will sustain a significant economic impact because they have reconfigured their practices.

Compensation arrangements: The statute defines a compensation arrangement very broadly as any arrangement involving any remuneration between a physician (or an immediate family member) and an entity, with certain narrowly defined exceptions. We believe that this definition involves almost every situation in which a physician or relative receives payment from an entity or makes payments to an entity, including payments under personal services contracts, employment agreements, sales contracts, and rentals or leases. The amount of data we would need to account for every compensation arrangement that might be affected by the law would likely be overwhelming, as well as subject to the constant changes inherent in the business world. As a result, it is difficult for us to assess how many physicians (or their relatives) are currently involved in compensation arrangements.

We believe that most physicians who have compensation, rather than ownership, arrangements with an entity and are receiving fair payments will qualify for one of the many compensation-related exceptions set forth in this proposed rule, especially since we propose to exercise our authority to create several additional exceptions related to compensation. We expect that those who do not will be few in number, and, thus, this rule would not have an impact on a substantial number of physicians whose financial relationships are based on compensation.

2. Entities, Including Hospitals

We lack the data to determine the number of entities that would be affected by this proposed rule. However, even if we were to assume that a substantial number of entities would be affected, we do not believe that, in general, the impact would be significant. In order for the effect on a substantial number of entities to be significant, this rule would have to result in a very significant decline in utilization of the designated health services. The statute was enacted to curb an abusive practice: the ordering by some physicians of unnecessary services because they have a financial incentive to do so. We do not believe, however, that the abuse is so prevalent that the survival of entities would be threatened because a physician's financial incentive to make referrals is removed. It is our view that most health

care entities exist because they provide medically necessary services and that these services will continue to be furnished.

In addition, the statute contains a number of exceptions to the referral prohibition that will allow physicians to continue to refer to any entity furnishing designated health services if certain criteria are met. These exceptions are set forth in this proposed rule. For example, § 411.356(c) includes exceptions for ownership or investment interests in certain hospitals or in certain rural entities. Sections 411.357(c) and (d) include relevant exceptions related to compensation arrangements: Paragraph (c) provides an exception for bona fide employment relationships that meet certain conditions, and paragraph (d) provides an exception for remuneration for personal service arrangements that meet certain conditions. Also, this proposed rule would provide an additional exception for any compensation that is, among other things, based on fair market value. We believe many, if not most, of the financial relationships between physicians and entities, including hospitals, are covered by these exceptions.

C. Conclusion

For the reasons stated above, we have determined, and the Secretary certifies, that, based on the limited data currently available to us, this proposed rule would 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. In addition, for purposes of the Unfunded Mandates Reform Act, we believe that any significant economic results of this proposed rule originate from the general referral prohibition in the statute and not from an agency mandate. We have, in fact, liberalized the requirements in the law by adding new exceptions. In the relatively few instances in which we have added additional requirements, as authorized by the statute, our data is too limited for us to ascertain whether these new provisions alone may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more in any one year. In terms of requirements on State governments, it is the statute that applies aspects of the referral prohibition to State Medicaid agencies. This proposed rule does interpret the statute to apply the reporting requirements in section 1877(f) of the Act to States, but does not mandate any action. The proposed rule allows States to collect financial

information from Medicaid providers in any form, manner, and at whatever times they choose.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

VI. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Sections 411.360 and 411.361 of this proposed rule contain information collection requirements that are subject to the Paperwork Reduction Act of 1995. However, we are not requiring the public to comply with these reporting requirements at this time. Instead we are seeking public comment to determine possible methods of implementing these information collection and recordkeeping requirements. Once we have determined how to impose these requirements in the least burdensome method, while meeting program requirements, we will publish a separate 60-day notice in the **Federal Register** seeking comments on the proposed information collection before it is submitted to OMB for review.

Below is a discussion of the information collection requirements referenced in §§ 411.360 and 411.361.

As stated earlier in this preamble, a number of entities have pointed out to us that the amounts of data they are required to report under the statute as reflected in our current regulations will, in some circumstances, be overwhelming and perhaps almost impossible to acquire. Therefore, in order to make the reporting requirements more manageable, we intend to develop a streamlined "reporting" system that does not require entities to retain and submit large

quantities of data. We believe, however, that entities should retain enough records to demonstrate, in the event of an audit, that they have correctly determined that particular relationships are excepted under the law.

We are proposing to limit the information that an entity must acquire, retain and, at some later point, possibly submit to us. We would include only those records covering information that the entity knows or should know about, in the course of prudently conducting business, including records that the entity is already required to retain to meet Internal Revenue Service and Security Exchange Commission rules, and other rules under the Medicare or Medicaid programs. We are circumscribing these records under the Secretary's discretion in section 1877(f) to ask entities to provide information in such form, manner, and at such times as the Secretary specifies. As stated above, when we develop a form for reporting information to us, we plan to first publish it as a proposed notice in order to receive public comment. If we later find that this plan is inadequate and elect to change the scope of the requirement, we will provide entities with adequate notice to comply.

While we are not at this time proposing to impose reporting requirements, we do propose to make modifications to the existing information collection requirements referenced in this proposed rule. Existing § 411.361 reflects the reporting requirements in section 1877(f) of the Act. Specifically, § 411.361 requires, with certain exceptions, that all entities furnishing services for which payment may be made under Medicare submit information to us concerning their financial relationships (as described in § 411.361(d)). The requirement does not apply to entities that furnish 20 or fewer Part A and Part B services during a calendar year, or to designated health services furnished outside the United States. Paragraph (a) of § 411.361 requires that all entities furnishing services for which payment may be made under Medicare submit information to us concerning their financial relationships in the form, manner, and at the times we specify. We would revise this to add that this information must be submitted on a HCFA-prescribed form. As stated above, this form would first be published as a proposed notice in order to receive public comment.

Paragraph (c) of § 411.361 requires that the entity submit information that includes at least the following with regard to each physician who has, or whose immediate family member has, a

financial relationship with the entity: The name and unique physician identification number (UPIN) of the physician, the covered services furnished by the entity, and the nature of the financial relationship. We now propose to specify that the entity submit information that may include the information described above depending upon the process we select.

Existing § 411.361(d) provides that a reportable financial relationship is any ownership or investment interest or any compensation arrangement, as described in section 1877 of the Act. This proposed, would revise this section to specify that a financial relationship is any ownership or investment interest or any compensation arrangement, as defined in § 411.351, including those relationships excepted under §§ 411.355 through 411.357.

We would also revise existing § 411.361(e) as follows. Currently that paragraph requires that an entity provide updated information within 60 days from the date of any change in the submitted information. We propose to require instead that an entity report to HCFA once a year all changes in the submitted information that occurred in the previous 12 months.

OBRA '93 amended section 1903 of the Act by adding a new paragraph(s) that, among other things, applied the reporting requirements of 1877(f) to a provider of a designated health service for which payment may be made under Medicaid in the same manner as those requirements apply to a Medicare provider. Therefore, at § 455.109(a) of this proposed rule, we would specify that the Medicaid agency must require that each provider of services that furnishes designated health services that are covered by Medicaid submit information to the Medicaid agency concerning its financial relationships in such form, manner, and at such times as the agency specifies. Paragraph (c) of § 445.109 would specify that the entity submit the same information identified with regard to Medicare providers/suppliers except that, instead of the UPIN, the entity would report the Medicaid State Specific Identifier of each physician who has, or whose immediate relative has, a financial relationship with the entity. Paragraph (d) of § 445.109 would establish the same definition of what constitutes a reportable financial relationship as under Medicare, and paragraph (e) would give States the discretion to establish the timeframes within which providers must submit and update information. We solicit comments on these proposed changes to the existing reporting requirements.

This proposed rule would also retain existing § 411.360, which requires that a group practice that wants to be identified as such submit a written statement to its carrier annually to attest that it meets the "substantially all" test, one of the criteria that qualifies a group of physicians as a group practice (the criteria are set forth under the definition of a group practice in § 411.351). This provision would now apply to any group of physicians who refer for or furnish designated health services and who wish to qualify as a group practice. We believe that, since this requirement has already been established by the August 1995 final rule, a significant number of physician groups may already be subject to the reporting requirements. We base this conclusion on the fact that many groups have their own clinical laboratories and will already be prepared to attest for purposes of complying with the final regulation covering referrals for clinical laboratory services. Once a group is identified as a group practice for purposes of laboratory services, it is identified as a group practice for all services. Thus it was the August 1995 final rule that established the burden for those groups. However, we have no way of estimating how many other groups of physicians will want to try to qualify as group practices exclusively for purposes of referring for some or all of the other designated health services. We specifically solicit information on this issue. A group of physicians must submit the attestation required by § 411.360 within 60 days after receiving attestation instructions from its carrier.

If you comment on these information collection and recordkeeping requirements, please mail copies directly to the following:

Health Care Financing Administration,
Office of Financial and Human
Resources, Management Planning and
Analysis Staff, Attention: HCFA-
1809-P, Room C2-26-17, 7500
Security Boulevard, Baltimore, MD
21244-1850.

Office of Information and Regulatory
Affairs, Office of Management and
Budget, Room 10235, New Executive
Office Building, Washington, DC
20503, Attn: Allison Herron Eydt,
HCFA Desk Officer.

VII. Response to Comments

Because of the large number of items of correspondence we normally receive on a proposed rule, we are not able to acknowledge or respond to them individually. We will, however, consider all comments that we receive by the date specified in the DATES section of this preamble and, if we

proceed with a final rule, we will respond to the comments in the preamble of the final rule. We will also respond, in that final rule, to comments that we received on the August 1995 final rule with comment covering referrals for clinical laboratory services.

List of Subjects

42 CFR Part 411

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

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare.

42 CFR Part 435

Aid to Families with Dependent Children, Grant programs-health, Medicaid, Reporting and recordkeeping requirements, Supplemental Security Income (SSI), Wages.

42 CFR Part 455

Fraud, Grant programs-health, Health facilities, Health professions, Investigations, Medicaid, Reporting and recordkeeping requirements.

42 CFR chapter IV would be amended as set forth below:

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

A. Part 411 is amended as follows:

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

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

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

§ 411.1 Basis and scope.

(a) *Statutory basis.* Sections 1814(a) and 1835(a) of the Act require that a physician certify or recertify a patient's need for home health services, but in general, prohibit a physician from certifying or recertifying the need for services if the services will be furnished by a home health agency in which the physician has a significant ownership interest, or with which the physician has a significant financial or contractual relationship. 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 designated health services furnished by entities with which the referring physician (or an immediate family member of the referring physician) has a financial relationship.

* * * * *

3. In § 411.350, paragraphs (a) and (c) are revised, and paragraph (b) is republished, 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 designated health 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 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. Section 411.351 is revised 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.

Designated health services means any of the following services (other than those provided as emergency physician services furnished outside of the United States), as they are defined in this section:

- (1) Clinical laboratory services.
- (2) Physical therapy services.
- (3) Occupational therapy services.
- (4) Radiology services and radiation therapy services and supplies.
- (5) Durable medical equipment and supplies.
- (6) Parenteral and enteral nutrients, equipment, and supplies.
- (7) Prosthetics, orthotics, and prosthetic devices and supplies.
- (8) Home health services.
- (9) Outpatient prescription drugs.
- (10) Inpatient and outpatient hospital services.

Direct supervision means supervision by a physician who is present in the office suite in which the services are being furnished, throughout the time they are being furnished, and immediately available to provide assistance and direction. "Present in the office suite" means that the physician is actually physically present. However, the physician is still considered "present" during brief unexpected absences as well as during routine absences of a short duration (such as during a lunch break), provided the absences occur during time periods in which the physician is otherwise scheduled and ordinarily expected to be present and the absences do not conflict with any other requirements in the Medicare program for a particular level of physician supervision.

Durable medical equipment has the meaning given in section 1861(n) of the Act and § 414.202 of this chapter.

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).)

Enteral nutrients, equipment, and supplies means items and supplies needed to provide enteral nutrition to a patient with a functioning gastrointestinal tract who, due to pathology to or nonfunction of the structures that normally permit food to reach the digestive tract, cannot maintain weight and strength

commensurate with his or her general condition, as described in section 65–10 of the Medicare Coverage Issues Manual (HCFA Pub. 6).

Entity means a physician's sole practice or a practice of multiple physicians that provides for the furnishing of designated health services, or any other 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. "General market value" means the price that an asset would bring, as the result of bona fide bargaining between well-informed buyers and sellers, or the compensation that would be included in a service agreement, as the result of bona fide bargaining between well-informed parties to the agreement, on the date of acquisition of the asset or at the time of the service agreement. Usually the fair market price is the price at which bona fide sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition, or the compensation that has been included in bona fide service agreements with comparable terms at the time of the agreement. With respect to the rentals and leases described in § 411.357(a) and (b), *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 means a direct or indirect ownership or investment interest (including an option or nonvested interest) in any entity that exists through equity, debt, or other means and includes any indirect ownership or investment interest no matter how many levels removed from a direct interest (for example, a financial relationship in an entity furnishing designated health services exists if the individual has an ownership or investment interest in an entity that holds an ownership or investment interest in an entity that furnishes designated health services), or a compensation arrangement with an entity.

Group practice means a group of two or more physicians, legally organized as a single partnership, professional corporation, foundation, not-for-profit corporation, faculty practice plan, or similar association, with the exception

that a group can consist of physicians who are also individually incorporated as professional corporations. To qualify as a group practice, a group must meet 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 under a billing number assigned to 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.

(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 overhead expenses of and income from the practice are distributed according to methods that are determined prior to the time period during which the group has earned the income or incurred the costs.

(4) The overhead expenses of and the income from the practice are distributed according to methods that indicate that the practice is a unified business. That is, the methods must reflect centralized decision making, a pooling of expenses and revenues, and a distribution system that is not based on each satellite office operating as if it were a separate enterprise.

(5) No physician who is a member of the group directly or indirectly receives compensation based on the volume or value of referrals by the physician,

except that a physician in a group practice may be paid a share of overall profits of the group or a productivity bonus based on services he or she has personally performed or services incident to these personally performed services, as long as the share or bonus is not determined in any manner that is directly related to the volume or value of referrals by the physician.

(6) Members of the group personally conduct no less than 75 percent of the physician-patient encounters of the group practice.

(7) 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.

Home health services means the services described in section 1861(m) of the Act and part 409, subpart E of this chapter.

Hospital means any entity that qualifies as a "hospital" under section 1861(e) of the Act, as a "psychiatric hospital" under section 1861(f) of the Act, or as a "rural primary care hospital" under section 1861(mm)(1) of the Act, and refers to any separate legally-organized operating entity plus any subsidiary, related entity, or other entities that perform services for the hospital's patients and for which the hospital bills. However, a "hospital" does not include entities that perform services for hospital patients "under arrangements" with the hospital.

HPSA means, for purposes of this subpart, 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.

Inpatient hospital services are those services defined in section 1861(b) of the Act and § 409.10(a) and (b) of this chapter, and include inpatient psychiatric hospital services listed in section 1861(c) of the Act and inpatient rural primary care hospital services, as defined in section 1861(mm)(2) of the Act. "Inpatient hospital services" do not include emergency inpatient services provided by a hospital located outside the United States and covered under the authority in section 1814(f)(2) of the Act and part 424, subpart H of this chapter and emergency inpatient services provided by a nonparticipating hospital within the United States, as authorized by section 1814(d) of the Act and described in part 424, subpart G of this chapter. These services also do not include dialysis furnished by a hospital that is not certified to provide end stage renal dialysis (ESRD) services under subpart U of 42 CFR 405.

Inpatient hospital services include services that a hospital provides for its patients that are furnished either by the hospital or by others under arrangements with the hospital. They do not encompass the services of other physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse midwives, and certified registered nurse anesthetists and qualified psychologists who bill independently.

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 other physician owners (including physicians whose interest is held by an individual professional corporation), and full-time and part-time physician employees. These physicians are "members" during the time they furnish "patient care services" to the group.

Occupational therapy services means those services described at section 1861(g) of the Act and § 410.100(c) of this chapter. Occupational therapy services also include any other services with the characteristics described in § 410.100(c) that are covered under Medicare Part A or B, regardless of who furnishes them, the location in which they are furnished, or how they are billed.

Orthotics means leg, arm, back, and neck braces, as listed in section 1861(s)(9) of the Act.

Outpatient hospital services means the therapeutic, diagnostic, and partial hospitalization services listed under section 1861(s)(2)(B) and (C) of the Act; outpatient services furnished by a psychiatric hospital, as defined in section 1861(f); and outpatient rural primary care hospital services, as defined in section 1861(mm)(3); but excluding emergency services covered in nonparticipating hospitals under the conditions described in section 1835(b) of the Act and subpart G of part 424 of this chapter.

Outpatient prescription drugs means those drugs (including biologicals) defined or listed under section 1861(t) and (s) of the Act and part 410 of this chapter, that a patient can obtain from a pharmacy with a prescription (even if the patient can only receive the drug under medical supervision), and that are furnished to an individual under Medicare Part B, but excluding erythropoietin and other drugs furnished as part of a dialysis treatment for an individual who dialyzes at home or in a facility.

Parenteral nutrients, equipment, and supplies means those items and supplies needed to provide nutriment to a patient with permanent, severe pathology of the alimentary tract that does not allow absorption of sufficient nutrients to maintain strength commensurate with the patient's general condition, as described in section 65–10 of the Medicare Coverage Issues Manual (HCFA Pub. 6).

Patient care services means any tasks performed by a group practice member that address the medical needs of specific patients or patients in general, regardless of whether they involve direct patient encounters, or tasks that generally benefit a particular practice. They can include, for example, the services of physicians who do not directly treat patients, such as time spent by a physician consulting with other physicians or reviewing laboratory tests, or time spent training staff members, arranging for equipment, or performing administrative or management tasks.

Physical therapy services means those outpatient physical therapy services (including speech-language pathology services) described at section 1861(p) of the Act and at § 410.100(b) and (d) of this chapter. Physical therapy services also include any other services with the characteristics described in § 400.100(b) and (d) that are covered under Medicare Part A or B, regardless of who provides them, the location in which they are provided, or how they are billed.

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 services.

Prosthetic device and supplies:

Prosthetic device means a device (other than a dental device) listed in section 1861(s)(8) that replaces all or part of an internal body organ, including colostomy bags and including one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens. *Prosthetic supplies* are supplies that are necessary for the effective use of a prosthetic device (including supplies directly related to colostomy care).

Prosthetics means artificial legs, arms, and eyes, as described in section 1861(s)(9) of the Act.

Radiology services and radiation therapy and supplies means any diagnostic test or therapeutic procedure using X-rays, ultrasound or other imaging services, computerized axial tomography, magnetic resonance imaging, radiation, or nuclear medicine, and diagnostic mammography services, as covered under section 1861(s)(3) and (4) of the Act and §§ 410.32(a), 410.34, and 410.35 of this chapter, including the professional component of these services, but excluding any invasive radiology procedure in which the imaging modality is used to guide a needle, probe, or a catheter accurately.

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, or the certifying or recertifying of the need for, any designated health service for which payment may be made under Medicare Part B (or, for purposes of the Medicaid program, a comparable service covered under the Medicaid State plan), 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 any other designated health service for which payment may be made under Medicare (or, for purposes of the Medicaid program, a comparable service covered under the Medicaid State plan) the establishment of a plan of care by a physician that includes the provision of such a designated health service, or the certifying or recertifying of the need for such a designated health service.

(2) Does not include a request by a pathologist for clinical diagnostic laboratory tests and pathological examination services, by a radiologist for diagnostic radiology services, and by a radiation oncologist for radiation therapy, if—

(i) The request results from a consultation initiated by another physician; and

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

Referring physician means a physician 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 or other business generated between the parties.

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

5. Section 411.353 is revised to read as follows:

§ 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 designated health services for which payment otherwise may be made under Medicare.

(b) *Limitations on billing*. An entity that furnishes designated health 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 designated health services performed under that referral.

(c) *Denial of payment*. No Medicare payment may be made for a designated health service that is furnished under a prohibited referral.

(d) *Refunds*. An entity that collects payment for a designated health service that was performed under a prohibited referral must refund all collected amounts on a timely basis, as defined in § 1003.101 of Chapter V.

6. Section 411.355 is revised to read as follows:

§ 411.355 General exceptions to the referral prohibition 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) *Physician 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 (including infusion pumps and

crutches, but excluding all other durable medical equipment and parenteral and enteral nutrients, equipment, and supplies), 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 member of the same group practice as the referring physician.

(2) They are furnished in one of the following locations:

(i) The same building in which the referring physician (or another physician who is a member of the same group practice) furnishes physician services unrelated to the furnishing of designated health services. The “same building” means the same physical structure, with one address, and not multiple structures connected by tunnels or walkways.

(ii) A building that is used by the group practice for the provision of some or all of the group’s clinical laboratory services.

(iii) A building that is used by the group practice for the centralized provision of the group’s designated health services (other than 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 under a billing number assigned to the group practice.

(iii) An entity that is wholly owned by the physician or the physician’s group practice.

(4) In the case of crutches, the physician realizes no direct or indirect profit from furnishing the crutches.

(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 Medicare 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 under certain payment rates.* (1) Services furnished in an ambulatory surgical center (ASC) or ESRD facility or by a hospice if payment for those services is included in the ASC payment rate, the ESRD composite payment rate, or as part of the hospice payment rate, respectively; and

(2) Services furnished under other payment rates that the Secretary determines provide no financial incentive for under or overutilization, or any other risk of program or patient abuse.

7. Section 411.356 is revised to read as follows:

§ 411.356 Exceptions to the referral prohibition 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 at the time they were obtained could be purchased on the open market 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) They are in a corporation that had 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. "Stockholder equity" is the difference in value between a corporation's total assets and total liabilities.

(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, for purposes of the services specified:

(1) A rural provider, in the case of designated health services furnished in a rural area by the provider. A "rural provider" is an entity that furnishes substantially all (not less than 75 percent) of the designated health services that it furnishes to residents of a rural area (that is, an area that is not an urban area as defined in § 412.62(f)(1)(ii) of this chapter).

(2) A hospital that is located in Puerto Rico, in the case of designated health services furnished by such a hospital.

(3) A hospital that is located outside of Puerto Rico, in the case of designated health services furnished by such a hospital, if 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.

8. Section 411.357 is revised to read as follows:

§ 411.357 Exceptions to the referral prohibition 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, is signed by the parties, and specifies the premises it covers.

(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 agreement 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, is signed by the parties, and specifies the equipment it covers.

(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 agreement provides for a term of rental or lease of at least 1 year.

(4) The rental charges over the term of the agreement 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 agreement 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 or other business generated between the parties.

(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) if the bonus is not directly related to the volume or value of a physician's own referrals.

(d) *Personal service arrangements—*

(1) *General.* Remuneration from an entity under an arrangement or multiple arrangements to a physician, an immediate family member of the physician, or to a group practice, including remuneration for specific physician services furnished to a

nonprofit blood center, if the following conditions are met:

(i) Each arrangement is set out in writing, is signed by the parties, and specifies the services covered by the arrangement.

(ii) The arrangement(s) covers all of the services to be furnished by the physician (or an immediate family member of the physician) to the entity, and all separate arrangements between the entity and the physician and the entity and any family members incorporate each other by reference. A physician or family member can "furnish" services through employees whom they have hired for the purpose of performing the services.

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

(iv) The term of each arrangement is for at least 1 year.

(v) The compensation to be paid over the term of each 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 each 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 with the entity.

(ii) Upon request by the Secretary, the entity provides the Secretary with access to the information about the plan specified in 417.479(h) of this chapter.

(iii) In the case of a plan that places a physician or a physician group at substantial financial risk as determined by the Secretary under § 417.479(e) and (f) of this chapter, the entity complies with the requirements concerning physician incentive plans set forth at § 417.479(g) and (i).

(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 is set out 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 of the remuneration to the physician based on the volume or value of any referrals by the physician or other business generated between the parties.

(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 following conditions are met:

(1) The amount of remuneration under the transaction is—

(i) Consistent with the fair market value of the transaction; and

(ii) Not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician or other business generated between the parties.

(2) The remuneration is provided under an agreement that would be commercially reasonable even if the physician made no referrals.

(3) There are no additional transactions between the parties for 6 months after the isolated transaction, except for transactions that are specifically excepted under the other provisions in §§ 411.355 through 411.357.

(g) *Arrangements with hospitals.* Remuneration provided by a hospital to a physician if the remuneration does not relate, directly or indirectly, to the furnishing of designated health services. To qualify as "unrelated," remuneration must not in any way reflect the volume or value of a physician's referrals.

(h) *Group practice arrangements with a hospital.* An arrangement between a hospital and a group practice under which designated health services are furnished by the group but are billed by the hospital if the following conditions are met:

(1) With respect to services furnished 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, and has continued in effect without interruption since, December 19, 1989.

(3) With respect to the designated health services covered under the arrangement, at least 75 percent of these services furnished to patients of the hospital are furnished by the group under the arrangement.

(4) The arrangement is in accordance with a written agreement 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 any other items or services that are furnished at a price that is consistent with fair market value, and that are not specifically excepted under another provision in §§ 411.355 through 411.357. "Services" in this context means services of any kind (not just those defined as "services" for purposes of the Medicare program in § 400.202).

(j) *Discounts.* Any discount made to a physician that is passed on in full to either the patient or the patient's insurers (including Medicare) and that does not enure to the benefit of the referring physician.

(k) *De minimis compensation.* Compensation from an entity in the form of items or services (not including cash or cash equivalents) that does not exceed \$50 per gift and an aggregate of \$300 per year if—

(1) The entity providing the compensation makes it available to all similarly situated individuals, regardless of whether these individuals refer patients to the entity for services; and

(2) The compensation is not determined in any way that takes into account the volume or value of the physician's referrals to the entity.

(l) *Fair market value compensation.* Compensation resulting from an arrangement between an entity and a physician (or immediate family member) or any group of physicians (regardless of whether the group meets

the definition of a group practice set forth at § 411.351) if the arrangement is set forth in an agreement that meets the following conditions:

(1) It is in writing, signed by the parties, and covers only identifiable items or services, all of which are specified in the agreement. The agreement covers all of the items and services to be provided by the physician and any immediate family member to the entity or, alternatively, cross refers to any other agreements for items or services between these parties.

(2) It specifies the timeframe for the arrangement, which can be for any period of time and contain a termination clause, provided the parties enter into only one arrangement for the same items or services during the course of a year. An arrangement made for less than 1 year may be renewed any number of times if the terms of the arrangement and the compensation for the same items or services do not change.

(3) It specifies the compensation that will be provided under the arrangement. The compensation, or the method for determining the compensation, must be set in advance, be consistent with fair market value, and not be determined in a manner that takes into account the volume or value of any referrals (as defined in § 411.351), payment for referrals for medical services that are not covered under Medicare or Medicaid, or any other business generated between the parties.

(4) It involves a transaction that is commercially reasonable and furthers the legitimate business purposes of the parties.

(5) It meets a safe harbor under the anti-kickback statute or otherwise is in compliance with the anti-kickback provisions in section 1128B(b) of the Act.

9. In § 411.360, paragraphs (a), (b), and (d) are revised to read as set forth below, and paragraphs (c) and (e) are republished.

§ 411.360 Group practice attestation.

(a) Except as provided in paragraph (b) of this section, a group of physicians that wishes to qualify as a group practice (as defined in § 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 (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 or § 411.351, that wishes to qualify as a group practice, 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 that 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 designated health 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 be signed by an authorized representative of the group practice who is knowledgeable about the group, and must contain a statement that the information furnished in the attestation is true and accurate to the best of the representative's knowledge and belief. Any person filing a false statement will be subject to applicable criminal and/or civil penalties.

(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 (b)(1) of this section, as applicable, to its carrier no later than 60 days after receipt of the attestation instructions from its carrier.

10. In § 411.361, paragraphs (a) through (e) are revised to read as set forth below, and paragraphs (f) and (g) are republished.

§ 411.361 Reporting requirements.

(a) *Basic rule.* Except as provided in paragraph (b) of this section, all entities furnishing 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 the form, manner, and at the times that HCFA specifies using an HCFA-prescribed form.

(b) *Exception.* The requirements of paragraph (a) of this section do not apply to entities that furnish 20 or fewer Part A and Part B services during a calendar year, or to any Medicare covered services furnished outside the United States.

(c) *Required information.* The information requested by HCFA can include 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 services furnished by the entity.

(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 defined in § 411.351, including those relationships excepted under §§ 411.355 through 411.357.

(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 report to HCFA once a year all changes in the submitted information that occurred in the previous 12 months. 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.

PART 424—CONDITIONS FOR MEDICARE PAYMENT

B. Part 424 is amended as follows:

1. The authority citation for part 424 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

2. In § 424.22, paragraph (d) is revised to read as set forth below, and paragraphs (e), (f), and (g) are removed.

§ 424.22 Requirements for home health services.

* * * * *

(d) *Limitation on the performance of certification and plan of treatment functions.* The need for home health services to be provided by an HHA may not be certified or recertified, and a plan of treatment may not be established and reviewed, by any physician who has a financial relationship, as defined in § 411.351 of this chapter, with that HHA, unless the physician's relationship meets one of the exceptions in §§ 411.355 through 411.357 of this chapter.

PART 435—ELIGIBILITY IN THE STATES, DISTRICT OF COLUMBIA, THE NORTHERN MARIANA ISLANDS, AND AMERICAN SAMOA

C. Part 435 is amended as follows:

1. The authority citation for part 435 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

2. In § 435.1002, paragraph (a) is revised to read as follows:

§ 435.1002 FFP for services.

(a) Except for the limitations and conditions specified in §§ 435.1007, 435.1008, and 435.1012, FFP is available in expenditures for Medicaid services for all recipients whose coverage is required or allowed under this part.

* * * * *

3. Section 435.1012 is added to subpart K, under an undesignated centered heading, to read as follows:

Limitation on FFP Related to Prohibited Referrals

§ 435.1012 Limitation on FFP related to prohibited referrals.

(a) *Basic rule.* Except as specified in paragraph (b) of this section, no FFP in the State's expenditures for services is

available for expenditures for designated health services (as defined in § 411.351 of this chapter) furnished under the State plan to an individual on the basis of a physician referral that would, if Medicare provided for coverage of the services to the same extent and under the same terms and conditions as under the State plan, result in the denial of Medicare payment for the services under §§ 411.351 through 411.360 of this chapter. (Section 411.353 provides that if a physician (or an immediate family member) has a financial relationship with an entity, the physician may not make a referral to that entity for the furnishing of designated health services for which payment otherwise may be made under Medicare and denies payment for any service furnished under a prohibited referral. Section 411.351 contains definitions, and §§ 411.355 through 411.357 provide exceptions to the prohibition on referrals.) The provisions of this section are based on section 1903(s) of the Act, which applies to Medicaid aspects of the Medicare rules limiting physician referrals.

(b) *Exception for services furnished to enrollees on a predetermined, capitated basis.* The limitation on FFP in paragraph (a) does not apply to services furnished to, or arranged for, an enrollee by an entity with an HMO contract with a State under section 1903(m); a prepaid health plan (PHP) contract with a State under part 434, subpart C; or a health insuring organization (HIO) contract under part 434, subpart D.

(c) *Advisory opinions relating to physician referrals.* Sections 411.370 through 411.389 cover the procedures for obtaining an advisory opinion from HCFA on whether a physician's referrals relating to designated health services (other than clinical laboratory services) are prohibited under section 1877.

PART 455—PROGRAM INTEGRITY: MEDICAID

D. Part 455 is amended as follows:

1. The authority citation for part 455 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

2. Section 455.100 is revised to read as follows:

§ 455.100 Basis and Purpose.

(a) *Basis.* This subpart implements sections 1124, 1126, 1902(a)(38), 1903(i)(2), 1903(n), and 1903(s) of the Act.

(b) *Purpose.* This subpart does the following:

(1) Sets forth State plan requirements regarding—

(i) Disclosure by providers and fiscal agents of information concerning ownership and control, investment arrangements, and compensation arrangements; and

(ii) Disclosure of information on a provider's owners and other persons convicted of criminal offenses against Medicare, Medicaid, or the title XX services program.

(2) Specifies conditions under which the Administrator will deny Federal financial participation for services furnished by providers or fiscal agents that fail to comply with the disclosure requirements.

(3) Provides for a civil money penalty for failure to meet certain reporting requirements.

3. Section 455.103 is revised to read as follows:

§ 455.103 State plan requirement.

A State plan must provide that the requirements of §§ 445.104 through 455.109 are met.

4. A new subpart C, consisting of section §§ 455.108 and 455.109, is added to read as follows:

Subpart C—Disclosure of Information by Providers for Purposes of the Prohibition on Certain Physician Referrals

§ 455.108 Basis.

This subpart is based on section 1903(s) of the Act, which, in part, applies the reporting requirements of section 1877(f) and (g) of the Act to Medicaid providers of designated health services (as these services are defined in § 411.351).

§ 455.109 Disclosure of ownership, investment, and compensation arrangements.

(a) The Medicaid agency must require that each provider of services that furnishes designated health services covered by the State plan submit information to the Medicaid agency concerning its financial relationships (as defined in paragraph (d) of this section), in the form, manner, and at the times the agency specifies. The term "designated health services," for purposes of this section, refers to the services listed in § 411.351 of this chapter, as they are defined in that section, or as those services are otherwise defined under the State plan.

(b) *Exception.* The requirements of paragraph (a) of this section do not apply to providers of services that provide 20 or fewer designated health services covered under the State plan during a calendar year, or to designated

health services furnished outside the United States.

(c) *Required information.* The information requested by the Medicaid agency can include the following:

(1) The name and Medicaid State Specific Identifier (MSSI) of each physician who has a financial relationship with the provider of services.

(2) The name and MSSI of each physician who has an immediate relative (as defined in § 411.351 of this chapter) who has a financial relationship with the provider of services.

(3) The covered items and services furnished by the provider of services.

(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 the Medicaid agency).

(d) *Reportable financial relationships.* For purposes of this section, a financial relationship is any ownership or investment interest or any compensation arrangement, as defined in § 411.351, including those relationships excepted under §§ 411.355 through 411.357.

(e) *Form and timing of reports.* Providers of services that are subject to the requirements of this section must submit the required information on a prescribed form within the time period specified by the Medicaid agency. Thereafter, a provider must report to the Medicaid agency all changes in the submitted information within a timeframe specified by the Medicaid agency. Providers of services must retain documentation sufficient to verify the information provided on the forms and, upon request, must make that documentation available to the Medicaid State agency, HCFA, or the OIG.

(f) *Consequences of failure to report.* Any provider of services that is

required, but failed, to meet the reporting requirements of paragraph (a) of this section is 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 until the information is submitted. Assessment of the penalty will comply with the applicable provisions of part 1003 of this title.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; Program No. 93.774, Medicare—Supplementary Medical Insurance Program; and Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

Dated: November 10, 1997.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

Dated: December 17, 1997.

Donna E. Shalala,

Secretary.

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