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Part II

Department of Health and Human Services

**Health Care Financing Administration
42 CFR Parts 411 and 424
Medicare and Medicaid Programs;
Physicians' Referrals to Health Care
Entities With Which They Have Financial
Relationships; Final Rule**

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 411 and 424

[HCFA-1809-FC]

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: Final rule with comment period.

SUMMARY: This final rule with 90-day comment period (Phase I of this rulemaking) incorporates into regulations the provisions in paragraphs (a), (b), and (h) of section 1877 of the Social Security Act (the 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 (DHS) under the Medicare program, unless an exception applies. The following services are DHS: 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; and inpatient and outpatient hospital services.

In addition, section 1877 of the Act 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 DHS furnished under a prohibited referral, nor may we make payment for a designated health service furnished under a prohibited referral.

Paragraph (a) of section 1877 of the Act includes the general prohibition. Paragraph (b) of the Act includes exceptions that pertain to both ownership and compensation relationships, including an in-office ancillary services exception. Paragraph (h) includes definitions that are used throughout section 1877 of the Act, including the group practice definition and the definitions for each of the DHS.

We intend to publish a second final rule with comment period (Phase II of

this rulemaking) shortly addressing, to the extent necessary, the remaining sections of the Act. Phase II of this rulemaking will address comments concerning the ownership and investment exceptions in paragraphs (c) and (d) and the compensation exceptions in paragraph (e) of section 1877 of the Act. Phase II of this rulemaking will also address comments concerning the reporting requirements and sanctions provided by paragraphs (f) and (g) of the Act, respectively, and include further consideration of the general exception to the referral prohibition related to both ownership/investment and compensation for services furnished in an ambulatory surgical center (ASC), end-stage renal dialysis facility, or by a hospice in § 411.355(d) of the regulations (this exception presently is in force and effect as to clinical laboratory services). In addition, Phase II of this rulemaking will address section 1903(s) of the Act, which extends aspects of the referral prohibition to the Medicaid Program. Phase II will also address comments received in response to this rulemaking, as appropriate, and certain proposals for new exceptions to section 1877 of the Act not included in the 1998 proposed rulemaking, but suggested in the public comments.

DATES: *Effective date:* The regulations delineated in Phase I of this rulemaking are effective on January 4, 2002 except for § 424.22(d), which is effective on February 5, 2001.

Comment date: We will consider comments if we receive them at the appropriate address, as provided below, no later than 5 p.m. on April 4, 2001.

ADDRESSES: Mail written comments (one original and three copies) to the following address only: Health Care Financing Administration, Department of Health and Human Services, Attn: HCFA-1809-FC, P.O. Box 8013, Baltimore, MD 21244-8013.

Since comments must be received by the date specified above, please allow sufficient time for mailed comments to be received timely in the event of delivery delays. If you prefer, you may deliver your written comments (one original and three copies) by courier to one of the following addresses: Room 443-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or C5-15-03, Central Building, 7500 Security Boulevard, Baltimore, MD 21244-1850. Comments mailed to the two addresses provided in this paragraph may be delayed and received too late to be considered.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA-1809-FC.

Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 443-G of the Department's offices at 200 Independence Avenue, SW., Washington, DC 20201, 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.

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we provide a document on our website, the document that we publish in the **Federal Register** is the official HCFA publication.

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I. Background

A. Legislative and Regulatory History

1. Section 1877 of the Act

Section 6204 of the Omnibus Budget Reconciliation Act of 1989 (Pub. L. 101-239) (OBRA 1989), enacted on December 19, 1989, added section 1877 to the Act. Section 1877 of the Act prohibited a physician from referring a patient to an entity for clinical laboratory services for which Medicare might otherwise pay, if the physician or the physician's immediate family member had a financial relationship with the entity. The statute defined "financial relationship" as an ownership or investment interest in the entity or a compensation arrangement between the physician (or the physician's immediate family member) and the entity. The statute provided for several exceptions to the prohibition. Some applied to ownership/investment interests and compensation arrangements; others applied only to ownership/investment interests or only to compensation arrangements.

The statute further prohibited an entity from presenting or causing to be presented a Medicare claim or bill to any individual, third party payer, or other entity for clinical laboratory services furnished under a prohibited referral. Additionally, the statute

mandated refunding any amount collected under a bill for an item or service furnished under a prohibited referral. Finally, the statute imposed reporting requirements and provided for sanctions, including civil monetary penalty provisions. Section 1877 of the Act became effective on January 1, 1992.

Section 4207(e) of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101-508) (OBRA 1990), enacted on November 5, 1990, amended certain provisions of section 1877 of the Act to clarify definitions and reporting requirements relating to physician ownership and referral and to provide an additional exception to the prohibition.

Several subsequent laws further changed section 1877 of the Act. Section 13562 of the Omnibus Budget Reconciliation Act of 1993 (Pub. L. 103-66) (OBRA 1993), enacted on August 10, 1993, expanded the referral prohibition to cover 10 "designated health services," in addition to clinical laboratory services, modified some of the existing statutory exceptions, and added new exceptions. Section 152 of the Social Security Act Amendments of 1994 (SSA 1994) (Pub. L. 103-432), enacted on October 31, 1994, amended the list of designated services, effective January 1, 1995, changed the reporting requirements at section 1877(f) of the Act, and modified some of the effective dates established by OBRA 1993. Some provisions relating to referrals for clinical laboratory services were effective retroactively to January 1, 1992, while other provisions became effective on January 1, 1995.

2. Section 1903(s) of the Act

Title XIX of the Act established the Medicaid program to provide medical assistance to individuals who meet certain income and resource requirements. The States operate Medicaid programs in accordance with Federal laws and regulations and with a State plan that we approve. Though States administer the Medicaid programs, the Federal and State governments jointly finance them. We call the Federal government's share of medical assistance expenditures "Federal financial participation" (FFP).

Until OBRA 1993, there were no statutory or regulatory requirements affecting a physician's referrals for services covered under the Medicaid program. Section 13624 of OBRA 1993, entitled "Application of Medicare Rules Limiting Certain Physician Referrals," added a new paragraph (s) to section 1903 of the Act, that extends aspects of the Medicare prohibition on physician referrals to Medicaid. This provision

bars FFP in State expenditures for DHS furnished to an individual based on a physician referral that would result in a denial of payment for the services 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 statute also made certain reporting requirements in section 1877(f) of the Act and a civil monetary penalty provision in section 1877(g)(5) (related to the reporting requirements) applicable to providers of DHS for which payment may be made under Medicaid in the same manner as they apply to providers of such services for which payment may be made under Medicare. Section 1903(s) of the Act applies to a physician's referrals made on or after December 31, 1994.

B. Regulations History

1. Regulations Published by HCFA and the Office of the Inspector General (OIG) Relating to Section 1877 of the Act

The following is a summary of the series of regulations we have published in the **Federal Register** over the past several years to implement the provisions of section 1877 of the Act, as amended, and section 1903(s) of the Act:

- On December 3, 1991, we issued an interim final rule with comment period (54 FR 61374) to set forth the reporting requirements under section 1877(f) of the Act.

- On March 11, 1992, we issued a proposed rule (57 FR 8588) to implement the self-referral prohibition and exceptions related to referrals for clinical laboratory services established by section 1877 of the Act, and amended by OBRA 1990.

- On August 14, 1995, we issued a final rule with comment period (60 FR 41914) incorporating the provisions of OBRA 1993 and SSA 1994 that relate to referrals for clinical laboratory services under section 1877 of the Act, effective January 1, 1992, and revising the March 11, 1992 proposal based on the public comments we received.

- On January 9, 1998, we issued a proposed rule (63 FR 1659) to amend the provisions of the August 1995 final rule and to reflect other changes in section 1877 of the Act enacted by OBRA 1993 and SSA 1994 that were effective January 1, 1995. These include, among other changes, the expansion of the referral prohibition to the 10 additional DHS, and the Medicaid expansion.

- On January 9, 1998, we published a final rule with comment period (63 FR 1846) incorporating into our regulations

the specific procedures we will use to issue advisory opinions, as required under section 1877(g)(6) of the Act. Section 1877(g)(6) of the Act requires that we issue written advisory opinions to outside parties concerning whether the referral of a Medicare patient by a physician for DHS (other than clinical laboratory services) is prohibited under section 1877 of the Act.

We also note that on October 20, 1993, the OIG published a proposed rule (58 FR 54096) to implement the civil money penalty provisions under sections 1877(g)(3) and (g)(4) of the Act. The OIG followed with publication of a final rule with comment period (60 FR 16580) on March 31, 1995.

2. Details About Prior Related Regulations

On August 14, 1995, we published in the **Federal Register** a final rule with comment period (60 FR 41914) that incorporated into regulations the provisions of section 1877 of the Act prohibiting physician referrals for clinical laboratory services under the Medicare program. That rule incorporated certain expansions and exceptions created by OBRA 1993, and the amendments in SSA 1994. It included only the expansions and other changes that related to prohibited referrals for clinical laboratory services that were retroactively effective to January 1, 1992, and interpreted the new provisions only in a few limited instances in which it was essential to implement the law. That rule also included our responses to the public comments we received on both the December 3, 1991 interim final rule with comment period (56 FR 61374) that established the reporting requirements under section 1877(f) of the Act, and the March 11, 1992 proposed rule (57 FR 8588) that covered section 1877 of the Act, as amended by OBRA 1990, and related to referrals for clinical laboratory services.

Because the August 1995 rule addressed only those changes made by OBRA 1993 and SSA 1994 that had a retroactive effective date of January 1, 1992, we explained our intent to later publish a proposed rule to fully implement the extensive revisions to section 1877 of the Act made by OBRA 1993 and SSA 1994, and to interpret those provisions when necessary. In the later proposed rule, we intended to include the revisions that relate to referrals for the additional DHS (including clinical laboratory services) that became effective January 1, 1995, and to implement the Medicaid expansion in section 1903(s) of the Act

that became effective for referrals made on or after December 31, 1994.

As intended, on January 9, 1998, we published the proposed rule (63 FR 1659). The rule was organized as follows: In section I (63 FR 1661 through 1663), we summarized the problems associated with physician self-referrals and the relevant legislative and regulatory background. In section II (63 FR 1663 through 1673), part A, we summarized the provisions of our proposed rule and described how we proposed to alter the final regulation covering referrals for clinical laboratory services to apply it to the additional DHS and to reflect the statutory changes in section 1877 of the Act that were effective on January 1, 1995. In section II, part B, we described the changes we proposed to make to the Medicaid regulations to incorporate section 1903(s) of the Act. In section III (63 FR 1673 through 1705), we discussed in detail how we proposed to interpret any provisions in sections 1877 and 1903(s) of the Act that we believed were ambiguous, incomplete, or that provided us with discretion. We also discussed policy changes or clarifications we proposed to make to the August 1995 rule covering referrals for clinical laboratory services. Section IV (63 FR 1705 through 1715) of the proposed rule included our responses to some of the most common questions concerning physician referrals that we received from physicians, providers, and others in the health care community. We included our interpretations of how the law applies in the situations described to us. Section V (63 FR 1715 through 1719) included a Regulatory Impact Analysis, and section VI (63 FR 1719 through 1720) covered our policy on responding to comments. The proposed regulation text appeared at 63 FR 1720 through 1728.

In the January 1998 proposed rule, we proposed to incorporate the Medicaid expansion in section 1903(s) of the Act into § 435.1012(a) (Limitation to FFP related to prohibited referrals). Section 435.1012(a) stated that no FFP was available for a State's expenditures for certain DHS, as they are defined in proposed § 411.351, furnished to an individual under the State plan. No FFP is available if the services are those furnished 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. In § 435.1012(c), we included a cross reference to the procedures we

established for individuals or entities to request advisory opinions from us on whether a physician's referrals relating to DHS (other than clinical laboratory services) are prohibited under section 1877 of the Act. Although these advisory opinions were meant to reflect our interpretation of section 1877 of the Act, they can potentially affect FFP payments to States under the Medicaid program.

Section 1877(b)(3) of the Act excepts from the referral prohibition services furnished to enrollees of certain "prepaid" health plans; however, these exceptions extend only to services furnished to Medicare beneficiaries under Medicare contracts and demonstration projects. As a result, the exception for prepaid arrangements does not apply to physicians who wish to refer in the context of the Medicaid program. In order to give effect to this exception in the Medicaid context, we included, in the January 1998 proposed rule, in § 435.1012(b) an exception for DHS furnished by managed care entities analogous to the Medicare entities excepted under section 1877(b)(3) of the Act. The new exception was meant to cover entities that provide services to Medicaid-eligible enrollees under contract with State Medicaid agencies and under certain demonstration projects. (We discussed these analogous entities in detail in the proposed rule at 63 FR 1697.)

To accommodate the Congress's subsequent creation of the Medicare+Choice (M+C) Program in the Balanced Budget Act of 1997 (Pub. L. 105-33) (BBA 1997), we included an amendment to the physician referral regulations as part of the June 26, 1998 interim final rule with comment period (63 FR 35066) establishing the M+C Program. We amended the final physician self-referral regulations covering referrals for clinical laboratory services by adding an exception in § 411.355(c)(5) for services furnished to prepaid enrollees by a coordinated care plan. We defined a coordinated care plan as such a plan, within the meaning of section 1851(a)(2)(A) of the Act, offered by an organization in accordance with a contract with us under section 1857 of the Act and the M+C regulations. We are reprinting that provision in Phase I of this rulemaking.

II. Development of Phase I of This Final Rulemaking

A. Technical Explanation of Bifurcation of the Regulation

Phase I of this rulemaking implements subsections (a) and (b) of section 1877 of the Act, and related definitions, as

applied to the Medicare program. We intend to issue Phase II of this rulemaking to cover the remainder of section 1877 of the Act, including its application to the Medicaid program, shortly.

Phase I of This Rulemaking

Given the importance of subsections (a) and (b), and the substantial changes we are making to the January 1998 proposed rule, we are proceeding with the issuance of Phase I of this rulemaking at this time. Further, we are issuing Phase I for comment and delaying its effective date for 1 year to allow individuals and entities engaged in business arrangements affected by Phase I time to restructure those arrangements to comply with the provisions of Phase I, except for § 424.22(d), which is effective February 5, 2001. The statutory provisions interpreted by Phase I remain in effect, as they have been since 1989 for clinical laboratory services and 1993 for all other DHS.

Phase I of this rulemaking differs substantially from the January 1998 proposed rule in several major respects, which include the following:

- Clarification of the definitions of DHS.
- Clarification of the concept of "indirect financial relationship" and creation of a new exception for indirect compensation arrangements.
- Substantial broadening of the in-office ancillary services exception by easing the criteria for qualifying as a group practice and conforming the supervision requirements to HCFA coverage and payment policies for the specific services.
- Expansion of the in-office ancillary services exception to cover certain DME provided in physicians' offices to patients to assist them in ambulating, and blood glucose monitors.
- Allowance of shared facilities in the same building where physicians routinely provide services that are in addition to Federal and private pay DHS.
- Exclusion of services personally performed by the referring physician from the definition of "referral."
- Creation of a new exception for compensation of faculty in academic medical centers.
- Addition of a new "risk-sharing" exception for commercial and employer-sponsored managed care plans.
- Interpretation of the "volume or value" standard for purposes of section 1877 of the Act as permitting unit of service or unit of time-based payments, so long as the unit of service or unit of time-based payment is fair market value

and does not vary over time. (The details of these and other changes are explained at length in section VI of this preamble.)

- Creation of an exception where DHS are furnished by entities that did not know of or have reason to suspect the identity of the referring physician.

In developing Phase I of this rulemaking, we have carefully reconsidered the January 1998 proposed rule given both the history and structure of section 1877 of the Act and the extensive comments we received on the January 1998 proposed regulation. We believe that Phase I of this rulemaking addresses many of the industry's primary concerns, is consistent with the statute's goals and directives, and protects beneficiaries of Federal health care programs.

Our paramount concern is to implement section 1877 of the Act consistent with congressional intent. Prior to enactment of section 1877, there were a number of studies, primarily in academic literature, that consistently found that physicians who had ownership or investment interests in entities to which they referred ordered more services than physicians without those financial relationships (some of these studies involved compensation as well). Increased utilization occurred whether the physician owned shares in a separate company that provided ancillary services or owned the equipment and provided the services as part of his or her medical practice. This correlation between financial ties and increased utilization was the impetus for section 1877 of the Act.

The approach chosen by the Congress in enacting section 1877 of the Act is preventive because it essentially prohibits many financial arrangements between physicians and entities providing DHS. Specifically, section 1877 of the Act imposes a blanket prohibition on the submission of Medicare claims (and payment to the States of FFP under the Medicaid program) for certain DHS when the service provider has a financial relationship with the referring physician, unless the financial relationship fits into one of several relatively specific exceptions. Significantly, no wrongful intent or culpable conduct is required. The primary remedy is simply nonpayment by the program, without penalties. In other words, the basic remedy is recoupment of overpayments by the program. (Of course, wrongful conduct, such as knowingly submitting a claim in violation of the prohibition, can be punished through recoupment of overpayments and imposition of

penalties, the False Claims Act, and other Federal statutory and common law remedies.)

The effect of this statutory scheme is that failure to comply with section 1877 of the Act can have a substantial financial result. For example, if a hospital has a \$5,000 consulting contract with a surgeon and the contract does not fit in an exception, every claim submitted by the hospital for Medicare beneficiaries admitted or referred by that surgeon is not payable, since all inpatient and outpatient hospital services are DHS.

While the statutory scheme of the physician self-referral prohibition is, in large part, the key to its effectiveness, it obligates us to proceed carefully in determining the scope of activities that are prohibited. In Phase I of this rulemaking, we have attempted to minimize the impact of the rule on many common physician group governance and compensation arrangements.

The potential impact of the regulation was further confirmed by the voluminous comments we received from the public and health care community in response to the January 1998 proposed rule. In addition to specific complaints and objections about the January 1998 proposed rule, the commenters expressed several general concerns, which include the following:

- The rule inappropriately intruded into the organization and delivery of medical care within physicians' offices.
- The rule, in many respects, was counter to our other long-standing policies on coverage and similar issues.
- The rule was unclear in many areas and that given the potentially serious consequences (for example, payment denial), "bright line" rules were essential.
- Some aspects of the rule, such as its treatment of indirect financial relationships, were administratively impractical or would have been prohibitively costly in terms of monitoring compliance.

With these overall considerations in mind, we have developed several criteria for evaluating our regulatory options. First, we have tried in Phase I of this rulemaking to interpret the prohibitions narrowly and the exceptions broadly, to the extent consistent with the statutory language and intent. As a practical matter, we believe that, while the statute must be implemented to achieve its intent, we should be cautious in interpreting its reach so broadly as to prohibit potentially beneficial financial arrangements. Accordingly, we have

tried to focus the regulation on financial relationships that may result in overutilization, which we believe was the main abuse at which the statute was aimed. Some provisions of the January 1998 proposed rule did not appear to address overutilization so much as other potential abuses, such as unfair competition. At the same time, we do not believe the Congress intended us to review every possible designated health service to determine its potential for overutilization. The Congress has already made that determination, and we believe that compliance with the exceptions in Phase I of this rulemaking should not cause undue disruption of the health care delivery system.

Second, a corollary of the above interpretation is that the Congress only intended section 1877 of the Act to establish a minimum threshold for acceptable financial relationships, and that potentially abusive financial relationships that may be permitted under section 1877 of the Act could still be addressed through other statutes that address health care fraud and abuse, including the anti-kickback statute (section 1128B(b) of the Act). In some instances, financial relationships that are permitted by section 1877 of the Act might merit prosecution under section 1128B(b) of the Act. Conversely, conduct that may be proscribed by section 1877 of the Act may not violate the anti-kickback statute.

Third, we have attempted to ensure that Phase I of this rulemaking will not adversely impact the medical care of Federal health care beneficiaries or other patients. In those instances in which we have determined that the provisions of Phase I of this rulemaking may impact current arrangements under which patients are receiving medical care, we have attempted to verify that there are other ways available to structure the arrangement so that patients could continue to receive the care in the same location. In almost all cases, we believe the provisions of Phase I of this rulemaking should not require substantial changes in delivery arrangements, although they may affect the referring physician's or group practice's ability to bill for the care. In other words, while the provisions of Phase I of this rulemaking may affect a physician's ability to profit financially from the provision of some services, there should be alternative providers available to provide the services in the same setting or alternative business structures that would permit the services to be provided (again, possibly without physician financial interest).

Fourth, we have revised the provisions of our January 1998 proposed

rule to conform, as much as possible, to our other policies that affect the same or similar activity. For example, we are dropping the requirement that an in-office ancillary service be supervised under the strict "direct supervision" standards of the "incident to" billing rules in favor of requiring the level of supervision that is mandated under Medicare payment and coverage rules applicable to particular DHS.

Fifth, we have attempted, as much as possible, to establish "bright line" rules so that physicians and health care entities can ensure compliance and minimize administrative costs. We agree with the commenters that as a payment rule, the regulations implementing section 1877 of the Act should establish clear standards, and we have attempted to do so within the constraints of the statutory and regulatory scheme.

We believe Phase I of this rulemaking substantially addresses the concerns raised by the commenters and, yet, is consistent with the statute. Given the breadth of the statute and the myriad of financial relationships to which it applies, it is impossible to satisfy all concerns in all instances. We have attempted to read the statute narrowly to avoid adversely impacting potentially beneficial arrangements. However, we will continue to monitor financial arrangements in the health care industry and will revisit particular regulatory decisions if we determine there is abuse or overutilization.

B. General Comments Regarding the January 1998 Proposed Rule and Responses

Comment: Many commenters echoed the general views expressed by a major physician trade association. The trade association noted that section 1877 of the Act significantly impacts the manner in which physicians deliver health care services and the manner in which they relate to one another and to other health care providers. The trade association urged us to give physicians and other providers clear direction on how to structure their financial arrangements, while providing sufficient flexibility for physicians and providers practicing in numerous and varying arrangements throughout the health care industry. The trade association and other commenters expressed concern that the January 1998 proposed rule failed to reflect the fundamental changes occurring in the health care marketplace—especially the consolidation and integration of physician practices, hospitals, and other health care entities. Indeed, the commenters perceived the proposed regulations as hostile to those changes.

The trade association and others believe that section 1877 of the Act and our regulations should focus on passive ownership and referral arrangements and not on partially and fully integrated practices demanded by the current competitive marketplace.

In addition, some commenters, including the trade association, thought that the provisions of the January 1998 proposed rule exceeded our statutory authority and imposed unnecessary and costly burdens on physicians that would harm patient access to health care facilities and services, with no apparent public benefit. In their view, the provisions of the January 1998 proposed rule (1) micro-managed physician practices in situations that do not pose a real potential for abuse, (2) limited proper and reasonable management practices, and (3) inappropriately interfered with the practice of medicine. Finally, a number of commenters suggested that, instead of promulgating a set of regulations that micro-manage the business of medicine, we could better control overutilization of DHS by monitoring the medical necessity of such services and the competency of those providing them.

Response: In developing Phase I of this rulemaking, we have been mindful of the criticism that the provisions of the January 1998 proposed rule inappropriately micro-managed physician practices. Given the purpose, structure, and scope of section 1877 of the Act, some impact on physician practices is inevitable and, frankly, intended. In Phase I of this rulemaking, we have endeavored to create “bright line” rules that are easily applied, while providing the health care industry with as much flexibility as possible. Where possible, we have tried to simplify the requirements in Phase I of this rulemaking, consistent with the clear congressional mandate to prohibit certain physician referrals tainted by physician financial self-interest. We believe Phase I of this rulemaking offers adequate flexibility to physician practices as they integrate and consolidate. For example, the revised unified business test, in the group practice definition, no longer bars cost-center or location-based distribution of a group practice’s revenues from services that are not DHS. Another example: the in-office ancillary services exception covers certain ancillary services provided in facilities shared by practitioners in the same building in which they practice.

The provisions of Phase I of this rulemaking do not prevent physicians from directly providing their patients with convenient, cost-effective DHS.

Consistent with the purpose of the statute, however, the provisions of Phase I of this rulemaking do restrict the circumstances under which physicians can financially benefit from DHS they order that are provided by others. This distinction is important. Section 1877 of the Act regulates the financial relationship between referring physicians and the provider of the DHS. If a physician determines not to provide access to such services in the absence of personal profit, the decision is the physician’s, not the statute’s. Nothing in section 1877 of the Act restricts patient access to those services.

Finally, we cannot agree with the claim that medical necessity reviews are always an effective control on overutilization. Medical necessity reviews alone cannot control unnecessary utilization and contain health care costs. These reviews are costly and only effective in controlling the most aberrant behavior. Most importantly, the statute does not permit us—nor would we choose—to override the Congress’ judgement by substituting medical necessity reviews for existing statutory standards.

Comment: Other commenters expressed concern that neither the statute nor the January 1998 proposed rule goes far enough in preventing abusive referral arrangements. Several commenters complained that allowing physicians to provide ancillary services competitively disadvantages independent ancillary services providers that are not owned or controlled by physicians. These commenters believe that an obvious referral-for-profit scheme occurs when a physician employs his or her own ancillary personnel. While most commenters who expressed this view were independent ancillary services providers, one physician also complained about fellow physicians who “churn” patients through CT/MRI machines in their offices, resulting in what the commenter termed, a “cash spigot.” The commenter expressed the view that such machines are not standard in a physician’s office and are solely added to physicians’ offices to generate profits. Commenters also expressed concern that, in some cases, physicians do not have appropriate oversight or credentialing for the ancillary services they provide. One commenter suggested that physicians should only be permitted to provide ancillary services if no other provider is available in the area.

Response: While we believe the commenters raised valid concerns about abuses in the health care system, the plain language of the statute makes clear

that the Congress did not intend section 1877 of the Act to bar all physician-owned ancillary services facilities. To the contrary, these facilities are expressly allowed under certain specific circumstances (see sections 1877(b), (c), and (d) of the Act). Simply stated, the law is meant to prevent only the most egregious financial relationships; it does not address every potential act of fraud and abuse. As we caution throughout this preamble, section 1877 of the Act provides only a threshold check against fraud and abuse; many arrangements that are lawful under section 1877 of the Act may still violate other fraud and abuse laws, including the Federal anti-kickback statute (section 1128B(b) of the Act).

Comment: Several commenters believe that section 1877 of the Act and implementing regulations would not permit patients to receive services, such as x-rays, physical therapy, or crutches, at a physician’s office or in a long term care facility where the patient resides. The commenters observed that requiring patients to seek services related to their diagnoses or treatment at several different locations is an inconvenience to patients and may require them to travel long distances to obtain services, thus, discouraging elderly or disabled patients from seeking needed health care services.

Response: The commenters misunderstand section 1877 of the Act. Section 1877 of the Act regulates financial relationships; it does not regulate the delivery of services. Section 1877 of the Act does not bar the provision of ancillary services in a physician’s office, in a long term care facility, or at nearby, convenient locations. The law only imposes restrictions on a physician who makes a referral for a designated health service if he or she has a financial relationship with the ancillary services provider, such as an employment contract, an office space lease, or an ownership interest. Depending on the structure of the financial relationship, the physician may be able to profit from ordering ancillary services, thereby creating a risk that his or her orders may be motivated, in part, by personal financial considerations. Statutory and regulatory exceptions are designed to enable physicians to make ancillary services available on-site to their own patients, provided they meet the conditions set forth in the applicable exception. However, nothing in the law prevents physicians from making available convenient ancillary services when the physician has no financial interest in the provision of the services. For example, a physician may arrange for a

diagnostic services provider to perform diagnostic tests in the physician's office for which the diagnostic services provider bills, provided that any rental arrangement meets the rental exception in § 411.357(b) and does not violate the anti-kickback statute. Section 1877 of the Act reflects the Congress' unmistakable intent to recognize and accommodate the traditional role played by physicians in the delivery of ancillary services to their patients, while constraining the abuse of the public fisc that results when physician referrals are driven by financial incentives. These regulations reflect that policy balance.

Comment: One commenter stated that we had not informed Medicare beneficiaries about the potential restrictions on their access to care under section 1877 of the Act and its regulations, or informed Medicare providers about the potential restrictions on their ability to provide ancillary services.

Response: Once both Phase I and Phase II of this rulemaking are published, we intend to educate providers further about the new regulations. Providers have been on notice as to section 1877 of the Act since 1989 with respect to clinical laboratory services and 1993 with respect to all other DHS. We intend to provide general information to beneficiaries as well. However, we do not believe beneficiaries will face the restrictions on access that the commenters contemplate. Indeed, these regulations do not restrict the provision of services to Medicare beneficiaries. If a physician chooses not to make services available to patients if he or she cannot personally benefit financially from services he or she orders, but which are provided by others, the physician is responsible for restricting access. Finally, Phase I of this rulemaking is being, and Phase II of this rulemaking will be, published in the **Federal Register** and noted on the Department's website, which serves as notice to the affected community. We believe most providers will also be informed through their trade press, trade associations, and other sources.

Comment: Two commenters expressed concern that section 1877 of the Act and associated regulations would criminalize common conduct in physicians' offices.

Response: Section 1877 of the Act is a civil, not a criminal, statute. A violation of section 1877 of the Act results in nonpayment of claims and monetary sanctions. Criminal penalties or deprivation of liberty are not authorized by section 1877 of the Act.

Comment: Given the alleged complexity of the physician self-referral law and regulations and their impact on physicians' traditional business practices, several commenters requested that the effective date of the regulation be delayed to allow a reasonable time for physicians to familiarize themselves with the law and that the regulations be applied prospectively only. One commenter asked that we issue compliance guidelines. Another commenter inquired about penalties if physicians ignore the physician self-referral law.

Response: We agree with the commenters that the health care providers engaged in business arrangements affected by Phase I of this rulemaking may need time to restructure those arrangements to comply with Phase I of this rulemaking where it proscribes conduct not previously prohibited. We are, therefore, delaying the effective date of Phase I of this rulemaking for 1 year, except for § 424.22(d), which is effective February 5, 2001. In the meantime, the statute, in its entirety, remains in full force and effect with respect to all DHS listed in section 1877(h)(6) of the Act. Until the effective date of these new final regulations, the August 1995 final rule covering referrals for clinical laboratory services remains in full force and effect with respect to clinical laboratory services referrals and claims for services. Any party or parties who do not comply with the provisions of the statute, the August 1995 final rule covering referrals for clinical laboratory services, or the provisions of Phase I of this rulemaking (when it becomes effective one year from the date of publication of this **Federal Register** notice) are subject to all applicable penalties and sanctions, including those that appear in section 1877(g) of the Act. (Section 1877(g)(3) and (g)(4) sanctions are covered in an OIG regulation that was published at 60 FR 16580 on March 31, 1995.)

Because of the significant changes we are making in Phase I of this rulemaking, we are publishing these regulations in final form with a 90-day comment period. We are interested in the industry's views as to the changes we have incorporated into these regulations. Any further changes we deem necessary based on comments will be addressed in Phase II of this rulemaking or shortly thereafter.

Regarding the issue of compliance guidelines, we often issue guidelines in the form of manual provisions or operational policy letters when we find that the statute and regulations do not

address particular issues in sufficient detail.

Comment: A number of commenters objected to what they perceived as disparate treatment of solo and group practitioners. One commenter, for example, complained that under the proposed rule, a solo practitioner could provide, and keep the profits from, unlimited ancillary services provided to his or her patients, regardless of how much the physician self-refers in his or her own office, whereas a group practitioner could not.

Response: Certain disparities between the treatment of group and solo practitioners are inherent in the statutory language and structure. For example, the Congress expressly limited profit shares for group practice members to methodologies that do not directly take into account the member's DHS referrals. For obvious reasons, solo practitioners cannot be similarly limited. On the other hand, the statute allows group practices greater flexibility in terms of the locations where they can provide DHS to their patients and still come within the in-office ancillary services exception. To the extent possible, and consistent with the statute, we have tried in Phase I of this rulemaking to minimize the regulatory disparities between group and solo practitioners.

Comment: In noting that the January 1998 proposed regulation interpreted the statute to minimize any risk of fraud or abuse, several commenters stated that the marginal anti-fraud benefit of this approach is low because of additional post-1993 fraud and abuse legislation, the implementation of the anti-kickback statute, computer claims payment edits instituted by our carriers, and the creation of the National Practitioners Data Bank. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) increased funding for Medicare program safeguards such as increased coordination between Federal, State, and local authorities; investigations, audits, and inspections; and guidance to the industry. HIPAA also established the Medicare Integrity Program to encourage private entities to engage in anti-fraud activities. The BBA in 1997 also created more severe criminal penalties for health care fraud. The commenters stated that the January 1998 proposed regulation prohibits many otherwise appropriate relationships in order to deter a small proportion of inappropriate practices. The commenters asked that the final rule be more flexible and not overcompensate for potential risks because the commenters believe that post-1993 legislation and enforcement

efforts can address any inappropriate practices that may or may not be deterred by the physician self-referral law.

Response: As described above, the approach taken by the Congress in enacting section 1877 of the Act results in important differences between it and other anti-fraud and abuse measures, especially the criminal anti-kickback statute (section 1128B(b) of the Act). The laws are complementary and, although overlapping in some aspects, not redundant. We believe the Congress intended to create an array of fraud and abuse authorities to enable the government to protect the public fisc, beneficiaries of Federal programs, and honest health care providers from the corruption of the health care system by unscrupulous providers. We have revisited the January 1998 proposed rule in significant respects that minimize any unnecessary impact on providers.

Comment: A number of commenters objected to the inclusion in several of the proposed regulatory exceptions, such as the exception for fair market value transactions, of a requirement that the transaction be in compliance with the anti-kickback statute. According to the commenters, the two statutes are separate and, since the anti-kickback statute is intent-based, it would be impossible to determine with certainty whether a transaction meets the exceptions.

Response: We recognize that section 1877 of the Act and the anti-kickback statute, section 1128B(b) of the Act, are different statutes and compliance with one does not depend on compliance with the other in most situations. Notwithstanding, the Secretary's authority to create additional regulatory exceptions to section 1877 of the Act is limited by the requirement in section 1877(b)(4) that she determine that the excepted financial relationship "does not pose a risk of program or patient abuse." Section 1877 of the Act sets a *minimum* standard for acceptable financial relationships; many relationships that may not merit blanket prohibition under section 1877 of the Act can, in some circumstances and given necessary intent, violate the anti-kickback statute. If the requirement that a financial relationship comply with the anti-kickback statute were dropped, unscrupulous physicians and entities could potentially protect intentional unlawful and abusive conduct by complying with the minimal requirements of a regulatory exception created under section 1877(b)(4) of the Act. (By contrast, the statutory exceptions require no finding by the Secretary and, thus, carry no

presumptive protection under the anti-kickback statute.) In addition, some arrangements may pose a risk of improper billing or claims submission.

As a practical matter, the statutory language authorizing exceptions leaves us two choices: (1) we can limit the exceptions to those situations that pose no risk of fraud or abuse—a very stringent standard that few, if any, of the proposed regulatory exceptions meet; or (2) we can protect arrangements that, in most situations, would not pose a risk, and rely on the anti-kickback statute or other fraud and abuse laws to address any residual risk. Given the commenters' expressed preference for flexibility, we have chosen the latter alternative. Moreover, since the parties should be in compliance with the anti-kickback statute, the additional regulatory burden is minimal. In the interest of simplification, we are considering an additional exception under section 1877 of the Act for any arrangement that fits squarely in an anti-kickback "safe harbor" (section 1001.952 (Exceptions)) and plan to address the matter further in Phase II of this rulemaking.

III. The General Prohibition Under Section 1877 of the Act

Section 1877(a) of the Act establishes the basic structure and elements of the statutory prohibition: A physician cannot (1) refer patients to an entity (2) for the furnishing of DHS (3) if there is a financial relationship between the referring physician (or an immediate family member of the referring physician) and the entity, (4) unless the financial relationship fits within one of the specific exceptions in the statute or regulations issued by the Secretary. (DHS are defined in § 411.351 and discussed at length in section VIII.A of this preamble.) In this section, we discuss our interpretations of what constitutes a financial relationship, especially an indirect financial relationship, and what constitutes a referral, including an indirect referral.

Existing Law: Subject to certain exceptions, section 1877(a)(1) of the Act prohibits a physician from making a referral to an entity for the furnishing of DHS for which Medicare would otherwise pay, if the physician (or an immediate family member) has a financial relationship with the DHS entity, and prohibits the DHS entity from billing Medicare or any individual (including, but not limited to, the beneficiary), third party payer, or other entity for those services. A financial relationship is (i) either an ownership or investment interest in the DHS entity (or in another entity that holds an

ownership or investment interest in the entity) or (ii) a compensation arrangement with the DHS entity, either directly or indirectly. An ownership or investment interest may exist through equity, debt, or other means.

As defined by section 1877(h)(5) of the Act, a "referral" means a request by a physician for an item or service for which payment may be made under Medicare Part B, including a request for a consultation (including any tests or procedures ordered or performed by the consulting physician or under the supervision of the consulting physician), and the request or establishment of a plan of care by a physician that includes the furnishing of DHS, with certain exceptions for consultations by pathologists, diagnostic radiologists, and radiation oncologists.

Proposed Rule: In general, we proposed interpreting the concept of "indirect financial relationship" very broadly. In the January 1998 proposed rule, we proposed including within the reach of section 1877 of the Act any ownership or investment interest, including ownership or investment interests through intermediate entities, no matter how indirect, and we proposed to include indirect compensation relationships by tracing compensation paid by an entity furnishing DHS through other entities, regardless of how the compensation might be transformed.

We similarly proposed a broad interpretation of the phrase "referral to an entity." As defined in the statute, a referral is a "request" by a physician for a DHS. We proposed defining a "request" as any step taken after a physician performs an initial examination or a physician service on a patient that indicates that the physician believes the DHS is necessary. Under this broad reading, a referral could be either written or oral, made on medical charts or records, or indicated by a prescription or written order. We also proposed that a referral could be direct or indirect, meaning that a physician would be considered to have made a referral if he or she caused the referral to have been made by someone else (for example, an employee, a hospital discharge planner, or a staff member of a company that the physician owns or controls). We interpreted "referrals" to include DHS services subsequently performed by the referring physician.

The Final Rule: Given the significance of the general prohibition, we received many comments related to various aspects of the January 1998 proposed rule. In particular, commenters sought clarification of fundamental statutory concepts, including direct and indirect

compensation and ownership or investment arrangements. In addition, many commenters took issue with our interpretation of several of the key terms, including "referral," "consultation," and "furnishing."

We are making a number of significant changes to the general prohibition sections in Phase I of this rulemaking. These revisions include the following:

- Clarification as to what constitutes a "direct" versus an "indirect" financial arrangement, including the addition of a "knowledge" element for indirect financial relationships.

- Creation of a new exception for indirect compensation arrangements.

- Clarification that payment obligations that are secured, including those secured by a revenue stream, are among the relationships considered to be ownership or investment interests.

- Revision of the definition of "referral" to exclude services personally performed by the referring physician.

- Creation of an exception under section 1877 of the Act for entities submitting claims for DHS that did not know of and did not have reason to suspect the identity of the physician who made the DHS referral to the entity.

These changes are discussed in greater detail below. First, we address the definition of a "financial relationship;" second, we address the definition of "referral." These two aspects of the general prohibition under section 1877 of the Act are analytically distinct and require separate analyses. In general, we believe a sensible approach is to ask two questions: (1) Is there a direct or indirect financial relationship between the referring physician and the entity furnishing DHS? (2) Is there a referral for DHS from the physician to the entity? If the answer to both questions is affirmative, section 1877 of the Act is violated, unless an exception applies.

A. When Is There a Financial Relationship Between the Physician and the Entity?

The existence of a financial relationship between the referring physician (or an immediate family member) and the entity furnishing DHS is the factual predicate for triggering the application of section 1877 of the Act. Section 1877(a)(2) defines a financial relationship as: (1) An ownership or investment interest of a referring physician (or immediate family member) in the entity furnishing DHS, or (2) a compensation arrangement between the referring physician (or an immediate family member) and the entity furnishing DHS. Any financial

relationship between the referring physician and the DHS entity triggers application of the statute, even if the financial relationship is wholly unrelated to a designated health service payable by Medicare. In many instances, the financial relationship will not relate to DHS. Unless the financial relationship fits into a statutory or regulatory exception, however, referrals for DHS are prohibited.

The statute expressly contemplates that "financial relationships" include both direct and indirect ownership and investment interests and direct and indirect compensation arrangements between referring physicians and DHS entities (sections 1877(a)(2) and 1877(h)(1) of the Act, respectively). We consider a "direct" financial relationship to be an arrangement between the entity furnishing DHS and a referring physician or immediate family member with no person or entity (other than agents) interposed between them. While some commenters inquired whether particular arrangements or relationships, such as stock options or vesting in retirement plans, could be characterized as ownership or compensation arrangements, there were no substantive comments as to the underlying definition of a direct financial relationship. The specific questions raised by the commenters are addressed in the comments and responses that follow.

With respect to "indirect" financial relationships, in the preamble to the January 1998 proposed rule, we proposed to include as an "indirect" financial relationship any ownership or investment interest, including ownership or investment interests through intermediate entities, no matter how indirect, and we proposed to include indirect compensation relationships by tracing compensation paid by an entity furnishing DHS through other entities, regardless of how the compensation might be transformed. In short, we proposed very broad interpretations of indirect financial relationships.

We have generally adopted the overall interpretations of "financial relationship" in the January 1998 proposed rule, with the important exception of "indirect" financial relationships. Many commenters objected to the discussions in the preamble to the January 1998 proposed regulations relating to indirect financial relationships on the grounds that the discussions were confusing, inconsistent, administratively impracticable, or unfair. We have responded to the commenters by substantially revising the regulations

pertaining to indirect financial relationships, especially indirect compensation arrangements. As described in the paragraphs that follow, we have added a knowledge element to the definitions of "indirect" financial relationships. We have also made other significant changes in the treatment of indirect compensation arrangements.

Knowledge Element for Establishing the Existence of an Indirect Financial Arrangement

We are amending the definitions of (i) "indirect ownership or investment interest" and (ii) "indirect compensation arrangement" in § 411.354 to include a knowledge element. Many commenters expressed concern that by extending liability for indirect financial relationships to relationships involving any number of intermediate persons or entities, the January 1998 proposed regulation imposed an unfair burden on entities furnishing DHS affirmatively to ferret out and discover potential indirect financial relationships or else risk submitting improper claims because of relationships they knew nothing about. While we believe that, in most circumstances, the referring physician (or his or her immediate family member) will only be one or two degrees of separation from the entity furnishing the DHS, we have nevertheless modified the January 1998 proposed regulation to add a "knowledge" element in cases of indirect financial relationships. This modification limits exposure under section 1877 of the Act to those circumstances in which the entity furnishing DHS has actual knowledge of an indirect financial relationship or acts in reckless disregard or deliberate ignorance as to the existence of an indirect financial relationship. (We sometimes refer to this "actual knowledge or reckless disregard or deliberate ignorance" standard in this preamble by the shorthand phrase "knows or has reason to suspect.") We define the "knowledge" element in a manner consistent with Federal law, as described below.

In order to satisfy this "knowledge" element in the case of an indirect ownership or investment interest, the DHS entity need only know or have reason to suspect that the referring physician (or immediate family member) has some ownership or investment interest in the entity furnishing the DHS (or in an entity that holds an ownership or investment interest in the DHS entity). Likewise, to satisfy this "knowledge" element in the case of an indirect compensation arrangement, the DHS entity need only

know or have reason to suspect that the referring physician (or immediate family member) is receiving some aggregate compensation that varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician for the entity furnishing DHS. In other words, we are not requiring that the DHS entity have knowledge of every link in the chain of entities having financial relationships that connects the DHS entity to the referring physician (or immediate family member).

Specifically, we are providing that, in the case of indirect financial relationships, referrals will only be prohibited (and claims disallowed) if the DHS entity (i) has actual knowledge that the referring physician (or immediate family member) has an indirect financial relationship (that is, that the referring physician or immediate family member (a) has some ownership or investment interest in the DHS entity or (b) receives aggregate compensation that takes into account or otherwise reflects referrals or other business generated by the referring physician for the entity furnishing DHS), or (ii) acts in reckless disregard or deliberate ignorance of whether such an indirect financial relationship exists. Essentially, we are adopting a "knowledge" element comparable to the *scienter* standard in the Civil Monetary Penalty Law, section 1128A of the Act. This "knowledge" element generally imposes a duty of reasonable inquiry on providers. In the specific context of indirect financial relationships under section 1877 of the Act, we wish to make clear that, given the impracticability of investigating every possible indirect financial relationship involving a referring physician, the knowledge element does not impose an affirmative obligation to inquire as to indirect financial relationships. A duty of reasonable inquiry does require, however, that providers in possession of facts that would lead a reasonable person to suspect the existence of an indirect financial relationship take reasonable steps to determine whether such a financial relationship exists and, if so, whether that indirect financial relationship falls within an exception to the statute (such as the new exception for certain indirect compensation arrangements in § 411.354) or whether the DHS being furnished fall within an exception (such as the in-office ancillary services exception) *before* submitting a claim for the referred item or service or making a referral. The reasonable steps to be taken will depend on the circumstances. Reasonable steps may

include the DHS entity obtaining, in good faith, a good faith, written assurance from the referring physician (or immediate family member, as applicable) or the entity from which the referring physician (or immediate family member) receives direct compensation that the physician's or immediate family member's aggregate compensation is fair market value for services furnished and does not take into account or otherwise reflect referrals or other business generated by the referring physician for the DHS entity, so as to qualify under the new exception for certain indirect financial relationships in § 411.354 (discussed below). A written assurance is not determinative, however, especially if the DHS entity has knowledge of, or reason to suspect, other, contradictory evidence or information.

The addition of a knowledge requirement as an element of an improper indirect financial relationship addresses the concerns expressed by many commenters that it would be impossible continuously to investigate and uncover indirect financial relationships of every referring physician and his or her immediate family members. While the "knowing" element we are adopting may allow more claims to be paid than a requirement that would interpret the statute to impose an absolute duty to investigate (and may impose a higher evidentiary burden on the government in an enforcement action), we believe that incorporating a knowledge element in the definition of indirect financial relationships more fairly balances the burden of compliance against the risk of abuse the statute was intended to prevent. We iterate that for purposes of section 1877 of the Act, the DHS entity has no affirmative duty to inquire or investigate whether an indirect financial relationship with a referring physician (or immediate family member) exists, absent some information that would put a reasonable person on alert, and that the duty that is imposed is one of reasonable inquiry in the circumstances.

Indirect Compensation Arrangements

We have substantially revised the January 1998 proposed regulations by restructuring our approach to indirect compensation arrangements. In the January 1998 proposed regulation, we had proposed to trace compensation paid by an entity furnishing DHS through any number of other persons or entities, regardless of how the compensation might be transformed. Many commenters complained that the examples provided in different parts of the preamble to the January 1988

proposed rule were inconsistent or unclear. Upon reviewing the comments and the preamble, we understand the commenters' confusion and have revised the provisions that apply to indirect compensation arrangements by:

- Defining "indirect compensation arrangement" to establish a "bright line" test, including the "knowing" element described above; and
- Creating a new exception under section 1877(b)(4) of the Act for certain indirect compensation arrangements that is generally consistent with the new "fair market value" exception for direct compensation arrangements.

This treatment of indirect compensation arrangements more clearly parallels the analysis and regulatory treatment of direct compensation arrangements by (i) defining the universe of financial relationships that potentially triggers disallowance of claims (that is, the definition of "indirect compensation arrangement"); and (ii) creating an exception for the subset of "indirect compensation arrangements" that will not trigger disallowance. The standards in the new exception for indirect compensation arrangements are based in large part on the standards found in the various statutory and proposed regulatory exceptions for direct compensation arrangements, especially the fair market value exception proposed in the January 1998 proposed regulations, which was received favorably by the commenters and has been incorporated into the final regulations in § 411.354(d).

The definition of an "indirect compensation arrangement" and the new exception are discussed in detail below.

- *Definition of "Indirect Compensation Arrangement."* We have developed a simple test to identify whether an indirect compensation relationship exists. We are adopting in Phase I of this rulemaking, a definition of "indirect compensation arrangement" that has three elements: (1) There must exist between the referring physician (or immediate family member) and the DHS entity an unbroken chain of persons or entities that have financial relationships between them (that is, each link in the chain has either an ownership or investment interest or compensation arrangement with the preceding link); (2) the aggregate compensation received by the referring physician (or immediate family member) from the person or entity in the chain with which the physician has a direct financial relationship varies with, or otherwise reflects, the volume or value of referrals or other business generated by the

referring physician for the entity furnishing DHS; and (3) the DHS entity must have actual knowledge that the aggregate compensation received by the referring physician (or immediate family member) from the entity with which the physician has a direct financial relationship varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician for the entity furnishing DHS, or act in reckless disregard or deliberate ignorance of the existence of such relationship.

The first element of the indirect compensation arrangement definition is met if there is an unbroken chain of financial relationships from the DHS entity to the referring physician (or immediate family member), regardless of the form or purpose of the payments or their relationship to the DHS referrals. This element is relatively straightforward. The unbroken chain that creates an indirect compensation arrangement can consist of any combination of excepted or unexcepted financial relationships, whether ownership or investment interests or compensation arrangements.

One issue raised by several commenters was whether an ownership or investment interest could also create a compensation arrangement. An ownership or investment interest creates a direct compensation arrangement between the owner/investor and the owned/investment entity, since the ownership or investment establishes an arrangement for the distribution of any profits or other benefits (for example, tax benefits in the case of a pass-through entity) from the venture to the owners/investors. However, when the ownership or investment interest itself meets a specific statutory exception under section 1877 of the Act, any anticipated return on investment or other remuneration flowing from the ownership or investment is similarly excepted, provided the return or other remuneration is *bona fide* and not a sham (sham returns would include, for example, use of loan proceeds to make distributions in the absence of *bona fide* profits from the venture).

An excepted financial relationship may still constitute a link in a chain that establishes an indirect compensation arrangement between a referring physician and a DHS entity. For example, if a referring physician owns an interest in a hospital that meets the exception under section 1877(d)(3) of the Act (which allows a referring physician to own an interest in a hospital as a whole, but not in a subdivision of the hospital), and the hospital contracts for services with a

clinical laboratory to which the physician refers, there would exist a chain of persons or entities having financial relationships between the referring physician and the DHS entity (referring physician → whole hospital → clinical laboratory), even though the financial relationship between the referring physician and the hospital fits in an exception. We address this issue further in the responses to comments that follow.

The second element of the definition of indirect compensation arrangement is that the aggregate compensation received by the referring physician (or immediate family member) from the person or entity in the chain with which the referring physician (or immediate family member) has a direct financial relationship varies with, or otherwise reflects, the value or volume of referrals or other business generated by the referring physician for the entity furnishing DHS. For the purpose of the definition of indirect compensation arrangements, we are looking at whether aggregate compensation in the direct financial relationship varies with, or otherwise reflects, the value or volume of referrals or other business generated by the referring physician for the entity furnishing DHS. Accordingly, for purposes of this element, any “per service” or “per use” payment arrangement between the physician and the person or entity with which the physician has the direct relationship that is based, in whole or in part, on referrals or other business generated for the DHS entity would satisfy this element. So too, any payment or other remuneration conditioned more generally on referrals or business generated for the DHS entity would satisfy this element of the definition of “indirect compensation arrangement,” except as described in § 411.354(d)(5) (describing limited circumstances when an entity may condition compensation on referrals). (For a discussion of § 411.354(d)(5), see section V of this preamble).

If the financial arrangement between the physician (or immediate family member) and the person or entity in the chain with which the physician has the direct financial relationship is an ownership or investment interest, we will look at the relationship between that person or entity (that is, the “owned entity”) and the next person or entity in the chain with which the owned entity has a direct financial relationship (if that financial relationship is also an ownership or investment interest, we will look to the next direct financial relationship in the chain, and so forth, until we reach a

compensation arrangement with an “unowned” entity with which there is a compensation arrangement—a chain consisting entirely of owned entities is an indirect ownership or investment interest, not an indirect compensation arrangement). The inquiry then becomes whether the aggregate compensation the owned entity receives varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician for the entity furnishing DHS.

The third element in the definition of indirect compensation arrangement is that the entity furnishing DHS must know or have reason to suspect that the referring physician’s (or immediate family member’s) aggregate compensation varies with, or otherwise reflects, the value or volume of referrals or other business generated by the referring physician for the entity furnishing the DHS. As discussed above, reason to suspect a financial relationship will trigger a duty to make an inquiry into the relationship that is reasonable in the circumstances. In the context of indirect compensation arrangements, in most cases, the referring physician (or immediate family member) will have knowledge of the basis for his or her compensation and be in the best position to assure compliance with section 1877 of the Act. Thus, as noted above, reasonable inquiry by the DHS entity may include obtaining, in good faith, a good faith, written assurance from the referring physician (or immediate family member, as applicable) or the entity from which the referring physician (or immediate family member) receives direct compensation that the physician’s or immediate family member’s aggregate compensation falls within the indirect compensation arrangement exception in § 411.354 (that is, the compensation is fair market value for services furnished and does not take into account or otherwise reflect referrals or other business generated by the referring physician for the DHS entity). As discussed below, we are creating a new exception for indirect compensation arrangements, for which we believe most nonabusive indirect compensation arrangements can readily qualify.

- *Exception for Indirect Compensation Arrangements.* While the definition of an “indirect compensation arrangement” identifies the universe of potentially improper arrangements, we recognize that many of those indirect compensation arrangements may be substantially similar to direct compensation arrangements that fit in one of the existing statutory exceptions in section 1877 of the Act or one of the

regulatory exceptions we proposed in January 1998. However, many of these indirect compensation arrangements cannot fit in those direct compensation arrangement exceptions, because the arrangements are with persons or entities that are not the person or entity furnishing DHS. Accordingly, we are creating a new exception, using the Secretary's authority under section 1877(b)(4) of the Act, to provide an exception for certain indirect compensation arrangements. The new exception would protect an indirect compensation arrangement if the following conditions are satisfied:

- The compensation received by the referring physician (or immediate family member) from the person or entity in the chain with which the referring physician (or immediate family member) has the direct financial relationship is fair market value for the items or services provided under the arrangement and does not take into account the value or volume of referrals or other business generated by the referring physician for the entity furnishing DHS;

- The compensation arrangement between the referring physician (or immediate family member) and the person or entity in the chain with which the physician (or immediate family member) has the direct financial relationship is set out in writing, signed by the parties, and specifies the services covered by the arrangement (in the case of a bona fide employment relationship, the arrangement need not be set out in a written contract, but it must be for identifiable services and be commercially reasonable even if no referrals are made to the employer);
- The compensation arrangement does not violate the anti-kickback statute or any laws or regulations governing billing or claims submission.

Where the financial relationship between the physician and the person or entity with whom he or she has a direct financial relationship is an ownership or investment interest, we will apply the requirements of this exception to the first compensation arrangement in the chain of relationships between the physician and the entity furnishing DHS.

For purposes of the new exception, in determining whether compensation takes into account the value or volume of referrals or other business generated by the referring physician for the DHS entity, we will apply the tests for "volume or value of referrals" and "other business generated" that are discussed in section V of this preamble and set forth in § 411.354(d) of these regulations. This is consistent with our

determination to interpret those phrases uniformly in all exceptions in which they appear. Thus, "per service" or "per use" compensation arrangements can fit in the new exception for indirect compensation arrangements, provided the "per use" or "per service" payments are fair market value for the items or services provided (and do not include any additional amount that might be attributable to the volume or value of referrals or other business generated between the referring physician and the entity furnishing DHS) and the payments do not vary during the term of the compensation arrangement in any manner that takes into account referrals to the DHS entity.

Some of the statutory and regulatory exceptions operate to exclude certain categories of services from the reach of section 1877 of the Act, when certain criteria are satisfied. In effect, services described in these exceptions are not DHS for purposes of the statute. These service-based exceptions include the physicians' services exception, in-office ancillary services exception, prepaid plans exception, and academic medical center exception, in § 411.355 of these regulations. Thus, even if there is an indirect compensation arrangement between a referring physician and an entity furnishing DHS, these exceptions may apply to referrals of the particular services described in the exception. Referrals of DHS that do not fit in a services-based exception would be prohibited unless the indirect compensation arrangement fits in the new exception for indirect compensation arrangements.

Finally, we are not adopting our interpretation in the January 1998 proposed rule with regard to common ownership or investment in the same entity (which is not the entity furnishing DHS) by the referring physician (or immediate family member) and the entity furnishing DHS. In the January 1998 proposed rule, we proposed that such common ownership would not create a compensation arrangement between the referring physician and the DHS entity. However, in the light of our modified and more limited definitions of indirect financial relationships, we have revisited the issue of common ownership. We believe that such relationships should be analyzed in the same manner as any indirect financial relationship.

We are also making the following changes in the general prohibition sections of the regulations:

- Clarification that an ownership or investment interest in a subsidiary corporation will not be considered a direct ownership or investment interest

in the parent or a sibling corporation. However, an owner of a subsidiary corporation may have an indirect financial relationship with the parent or sibling company that could trigger a violation of section 1877 of the Act.

- Treatment of stock options as creating a compensation relationship and not an ownership interest until such time as the options are exercised.

- Clarification that payment obligations that are secured, including those that are secured by a revenue stream, are considered ownership or investment interests.

In the following paragraphs, we address the specific comments we received on the discussion and proposed interpretations of financial relationships set out in the January 1998 proposed rule and our responses to them.

Comment: A number of commenters objected to the concept of "tracing" compensation from, and ownership or investment interests in, an entity furnishing DHS through any number of intermediate entities to a referring physician. According to these commenters, the administrative burden of trying to comply would be costly and ultimately impossible. These commenters believe that our proposed interpretation would place the entities furnishing the services, as well as physicians making referrals, at risk for what was unknowable given potentially complex business arrangements. One commenter suggested that we keep the same definition of financial relationship as the August 1995 final rule, which the commenter stated was limited to direct ownership and compensation arrangements.

Response: The commenter who suggested that the August 1995 final rule was limited to direct financial relationships is mistaken. In the August 1995 final rule, we defined financial relationship to include indirect financial relationships. We did not, however, expand on how we would interpret and apply the term "indirect." We believe that limiting the statutory prohibition to direct ownership and compensation arrangements would seriously weaken the statute. Unscrupulous physicians and entities furnishing DHS would simply interpose entities between themselves and funnel the money through them. Furthermore, as we stated in the preamble to the January 1998 proposed rule, the statute, by its terms, applies to indirect ownership and investment interests and compensation arrangements.

As discussed above, we have revised the treatment of indirect compensation arrangements. First, we are no longer

requiring any tracing of payments. The initial screen is simply whether there is an unbroken chain of persons or entities having financial relationships between the referring physician (or an immediate family member) and the entity furnishing DHS, regardless of the nature of the payments or financial relationships. Second, we have limited liability to instances in which the DHS entity knows or has reason to suspect that aggregate compensation received by the referring physician (or immediate family member) varies with, or otherwise reflects, the volume or value of referrals or other business generated for the DHS entity. Finally, we have made clear that absent information that would put a reasonable person on alert, a DHS entity has no affirmative duty to inquire or investigate such arrangements.

Comment: A major trade association representing physicians (and other commenters) claimed that our explanations of how we would treat several types of situations involving indirect financial relationships appeared inconsistent. Specifically, the association referred to the example of a hospital contracting with a group practice to furnish physician services and to staff the hospital, and the hospital paying the group practice for these services, and with the group practice, in turn, compensating the physicians through salaries that “in some way” reflect the hospital services. According to the January 1998 proposed rule, the physicians would have an indirect compensation relationship with the hospital that would require an exception. The commenter complained that this position is inconsistent with another example in the preamble in which we stated that, when a physician who owned a physical therapy (PT) company referred patients for treatment including PT to a skilled nursing facility (SNF) that contracted with the physician’s PT company, we would equate the physician with the PT provider.

Response: We believe the new provisions for indirect compensation arrangements address the commenters’ concerns.

In the example cited by the commenter involving the payments by a hospital to a group practice that, in turn, pays its employees a salary, we would not require evidence that the salary is “in some way” related to the hospital payment. It is enough that the hospital has a financial relationship (that is, a personal services contract) with the medical group, which, in turn, has a financial relationship with its employees. Since there is an unbroken

chain of financial relationships between the referring physician and the DHS entity, the first element in the indirect compensation definition is satisfied.

The second element of the definition of an indirect compensation arrangement would be satisfied if the aggregate compensation to the referring physician from the medical group varied with, or otherwise reflected, the volume or value of referrals or other business generated by the referring physician for the DHS entity (that is, the hospital)—a fact that should be relatively easy to establish.

The final element in the definition of an indirect compensation relationship requires that the hospital (that is, the DHS entity) (i) have actual knowledge or reason to suspect that the referring physician is receiving compensation from the medical group (that is, the entity in the chain with which the referring physician has a direct financial relationship) that varies with, or otherwise reflects, the volume or value of referrals or other business generated for the hospital.

Indirect compensation arrangements that do not fit in the new exception for such arrangements can be restructured or abandoned. Arrangements under which a referring physician receives compensation tied to the volume or value of his or her referrals or other business generated for a DHS entity are the very arrangements at which section 1877 of the Act is targeted.

Commenters claimed that our discussion at 63 FR 1710 in the preamble of the January 1998 proposed rule was confusing because of the way we described a physician’s referrals to a SNF, which, in turn, referred the patients to a PT company in which the referring physician had an ownership interest and which billed Medicare directly for services to SNF patients. In that example, the referring physician had a direct financial relationship (ownership) with the PT company. There was no indirect financial relationship involving the SNF. Rather, the referring physician had a referral arrangement with the SNF, but not a financial relationship, and the SNF had a referral arrangement with the PT provider, but not a financial relationship. We think the issue in the example is whether, by sending patients to the SNF, the physician is making referrals to the PT provider, with which the physician has a direct financial relationship. We discuss that issue in the following section on referrals.

However, we think it useful to reconsider the example in light of consolidated billing for SNFs. (We note that consolidated billing should not be

confused with composite rate payments. Consolidated billing is a process for submitting claims while composite rate payment constitutes a distinct payment methodology.) Under consolidated billing, the SNF in the example will be billing the PT services directly to Medicare. In this situation, there would be an indirect compensation relationship between the SNF—which is now the DHS entity—and the referring physician. Since the SNF would be purchasing PT services from the PT company owned by the referring physician, a financial relationship would exist between the SNF and the PT company, and the physician’s ownership interest in the PT company would complete the chain (SNF→PT company→referring physician). Thus, the first element of the definition of an indirect compensation arrangement would be satisfied. With respect to the second element, the financial relationship between the referring physician and the person or entity in the chain with which the referring physician has a direct financial relationship (that is, the PT company) is an investment interest. Accordingly, we look to the compensation paid by the SNF to the owned entity (that is, the PT company) in order to see if the second element is satisfied. Since the PT company is compensated on a per service basis that reflects referrals by the referring physician to the SNF, the second element is met. Assuming knowledge on the part of the SNF, there would be an indirect compensation arrangement, and the issue becomes whether the indirect compensation arrangement satisfies the new exception for indirect compensation arrangements in § 411.354.

Comment: Several commenters stated that when there is a chain of payments that begins with a payment by a provider of DHS to another entity controlled by it, the first payment outside the entities under common control should be the arrangement that has to meet an exception. For example, in looking at payments from a hospital to a physician group practice that is wholly owned by the hospital for hospital staffing and subsequent payments from the group to its employed physicians, the payments that would need to qualify for an exception are the payments to the employed physicians. One commenter proposed that when tracing indirect financial relationships, the inquiry should end any time a payment in the chain meets an exception.

Response: The first commenters’ suggested approach is problematic because the “volume or value” standard

for the employed physician's compensation is measured based on referrals to the physician's employer, the medical group. Applying the commenters' proposed test to the example, the medical group could pay the physician employees based on the volume and value of referrals and business generated for the hospital and still comply with the employment exception. Phase I of this rulemaking would require that the compensation to the physicians *not* vary with or otherwise reflect either referrals to the group (to comply with the employee exception) or referrals to, or other business generated for, the hospital (so that it does not qualify as an indirect compensation relationship). To the extent that the compensation paid to the physicians did vary based on referrals or other business generated for the hospital, the arrangement would still be protected if it complied with the new indirect compensation arrangements exception in § 411.354.

We also considered, but ultimately rejected, the second commenter's proposal that the inquiry end any time a financial relationship fits in an exception. The fact that one financial arrangement meets an exception does not necessarily prevent the referring physician from receiving payments based on DHS referrals to a DHS entity. For example, if a person or entity owns both a group practice and a DHS entity, a compensation arrangement with a physician employee of the group practice could fit in an exception so long as it did not take into account referrals between the employee and the group practice. The exception would not, however, prevent the compensation arrangement from taking into account referrals or other business generated by the physician employee for the DHS entity.

Having considered the several views of the commenters, we believe that Phase I of this rulemaking strikes a balance that protects the Medicare program while limiting the reach of the regulation to abusive relationships. Under Phase I of this rulemaking, there would be an unbroken chain of financial relationships (the DHS entity → the owner → medical group → referring physician). However, unless the compensation received by the employed physician varies with or otherwise reflects his or her referrals to, or other business generated for, the DHS entity, and the DHS entity has the requisite knowledge, there would not be an indirect compensation arrangement. If there were, the arrangement would have to meet an applicable exception.

Comment: One commenter asked whether there would be an indirect compensation arrangement if an employed physician refers patients for DHS to an entity that has an ownership or investment interest in the physician's employer.

Response: There may be an indirect compensation arrangement if a physician refers patients for DHS to an entity that has an ownership or investment interest in the physician's employer, since the physician would be referring to a DHS entity that has a financial relationship (ownership or investment) with an entity that has a financial relationship (compensation) with the physician. If the referring physician's compensation from his or her employer reflected DHS referrals or other business generated by the referring physician for the entity providing the DHS, and the DHS entity had actual knowledge or reason to suspect that the physician's aggregate compensation reflected the volume or value of referrals or other business for the DHS entity, there would be an indirect compensation arrangement. Unless the arrangement fit in the new indirect compensation arrangements or another exception, referrals to the entity would be prohibited.

Comment: Another commenter asked whether a physician's referrals would be prohibited in a situation involving a physician practice management company (PPMC). Specifically, the commenter asked about a referring physician who has an ownership or investment interest in a PPMC, which, in turn, controls a captive professional corporation (PC) through a web of legal agreements, including a long-term management contract. The physician refers patients for DHS to the captive professional corporation.

Response: In the scenario described by the commenter, there is very likely an indirect compensation arrangement, since the captive PC has a financial relationship with the PPMC (the management contract), which has a financial relationship (ownership or investment) with the referring physician. Since the financial relationship between the physician and the entity in the chain of financial relationships with which the physician has a direct financial relationship (that is, the PPMC) is an ownership or investment interest, we look to the compensation arrangement between the owned entity (that is, the PPMC) and the next entity in the chain, in this case, the captive PC, to determine whether the second element of the test for an indirect compensation arrangement is met. Accordingly, if the entity

furnishing the DHS (the captive PC in this example) knows or has reason to suspect that the PPMC's compensation from the captive PC varies with, or otherwise reflects, the value or volume of the captive PC's business (and consequently varies, in the aggregate, based on the referring physician's DHS referrals to the captive PC), there would be an indirect financial relationship between the captive PC and the referring physician. Unless the indirect compensation arrangement fits in the new indirect compensation arrangements or another exception, the physician could not refer DHS to the captive PC, and the captive PC could not submit claims for those DHS referrals.

Comment: Several commenters objected to our proposal that a physician can receive indirect compensation through a nonprofit enterprise if the enterprise is controlled by an individual who is in a position to "influence" the physician's referrals. The example was the owner of a clinical laboratory who is also the director of research at a nonprofit research facility that could provide physician research grants in exchange for referrals to the laboratory.

Response: The issue is whether there is a prohibited indirect financial relationship between the DHS entity (the clinical laboratory) and the referring physician. Assuming there is a financial relationship between the owner of the clinical laboratory and the nonprofit research facility, there would be a chain of persons or entities with financial relationships (clinical laboratory → research director → not-for-profit → referring physician), and the issues become (i) whether the aggregate amount of the research grants to the referring physician varies with, or otherwise reflects, the value or volume of referrals or other business generated by the referring physician for the clinical laboratory, (ii) whether the clinical laboratory knows of or has reason to suspect that the referring physician's aggregate compensation under the research grants varies with, or otherwise reflects, the volume or value of referrals or other business generated for the clinical laboratory, and (iii) if there is an indirect financial relationship, whether an exception applies. Of course, even if there is no financial relationship between the clinical laboratory and the nonprofit research facility, there could be a violation of the anti-kickback statute, section 1128B(b) of the Act, in the situation described in the comment.

Comment: Several commenters stated that compensation derived from an

ownership or investment interest (for example, a return on an investment interest or a dividend) should not give rise to indirect compensation. To support this position, they referred to discussions in the preamble to the January 1998 proposed rule and in the preamble to the August 1995 final regulations, in which we stated that compensation derived from, or ancillary to, an investment interest that qualified for an investment exception under sections 1877 (b) through (d) of the Act would not also have to meet a compensation exception.

Response: We agree with the commenters that dividends or profit distributions from an ownership or investment interest that qualifies for an ownership or investment interest exception under sections 1877(b) through (d) of the Act do not also have to meet a separate compensation exception. In other words, the ownership and investment exceptions in the statute protect the ownership or investment interest and any corresponding return on the excepted investment. Our discussion in the preamble to the January 1998 proposed rule specifically referenced and clarified the August 1995 final rule preamble discussion, which was limited to the issue of whether distributions from an excepted investment interest (that is, an ownership or investment interest protected under sections 1877(b) through (d) of the Act) had to meet an additional exception for compensation arrangements. Nothing in either preamble discussion was intended to be interpreted as saying that any other ownership or investment interests (that is, ownership or investment interests that are not specifically excepted) are not compensation arrangements. We believe that an ownership or investment interest (including distributions from the interest) creates a compensation arrangement, as defined in section 1877(h)(1)(A) of the Act, between the owner/investor and the owned/investment entity and can be part of a chain of persons or entities having financial relationships that create an indirect compensation arrangement.

Without this interpretation, unscrupulous physicians could evade section 1877 of the Act by simply interposing a shell entity, which they own, between themselves and the DHS entity (which they do not own) and taking out the compensation as dividends. In short, they would simply launder the compensation through the shell investment entity.

Comment: Another commenter suggested that a loan and any interest payments should be treated as either

ownership or compensation, but not both.

Response: We agree with the commenter. If a loan qualifies as a protected ownership or investment interest, the interest payments do not create a separate compensation arrangement. Accordingly, the interest payments need not satisfy a separate compensation exception.

Comment: A number of commenters asked that we clarify that an investment in a subsidiary that does not furnish DHS is not necessarily an ownership interest in the parent or a sibling corporation.

Response: An ownership or investment interest in a subsidiary company is neither an ownership or investment interest in the parent company, nor in any other subsidiary of the parent, unless the subsidiary company itself has an ownership or investment interest in the parent or such other subsidiaries. However, an owner of a subsidiary company may have an indirect financial relationship with the parent or sibling company that could trigger a violation of section 1877 of the Act.

Comment: One commenter objected to the suggestion in the preamble to the January 1998 proposed rule that an interest in a retirement plan might be treated as an ownership or investment interest. Another commenter stated that an unsecured loan that was subordinated to an entity's credit facility should not be treated as an ownership or investment interest.

Response: We are persuaded by the logic of the commenter and, accordingly, we withdraw the statement in the preamble to the January 1998 proposed rule that an interest in a retirement plan might be treated as an ownership or investment interest for purposes of section 1877 of the Act. We will consider contributions (including employer contributions) to retirement plans to be part of an employee's overall compensation arrangement with his or her employer. We also agree that an unsecured loan that is subordinated to a credit facility is a compensation arrangement and not an ownership or investment interest for purposes of section 1877 of the Act.

Comment: Another commenter stated that secured debt given by a not-for-profit hospital, as part of its acquisition of medical practices, should not be treated as an ownership or investment interest in the hospital, but as compensation.

Response: Section 1877(a)(2) of the Act provides that "an ownership or investment interest * * * may be through equity, debt or other means."

Accordingly, we believe that loans, bonds, or other financial instruments that are secured with an entity's property or revenue, or a portion thereof, constitute investment interests within the meaning of section 1877 of the Act. In addition, a contrary reading would result in disparate treatment of entities based on their organizational status.

Comment: One commenter asserted that stock options should be treated as either ownership or investment interests or compensation arrangements, but not both. Another commenter stated that stock options should be treated as compensation and not ownership since they do not carry voting rights or the right to dividends and must be sold upon conversion.

Response: In Phase I of this rulemaking, we are revising the rule to treat stock options as compensation at the time they are awarded. At the time they are exercised or converted, they create an ownership or investment interest and must meet an appropriate exception. Any dividends or profit distributions derived from an excepted stock ownership or investment interest would not have to meet a separate compensation exception.

Comment: Another commenter stated that stock options could be structured to discourage referrals for DHS.

Response: The fact that a particular financial arrangement might be structured to discourage referrals does not provide a basis for creating an exception. The statute is intended to remove incentives to overutilize by prohibiting certain financial relationships. If application of the statute required a case-by-case examination to determine the effect of the financial relationship, the statute's efficacy would be undermined.

Comment: One commenter suggested that the determination of whether a convertible security is a compensation arrangement or an ownership or investment interest should depend on which party has the right to convert the security. According to the commenter, if the DHS entity has the right to convert the security, the interest should be treated as compensation until conversion.

Response: We are applying the same approach to convertible securities as we are applying to stock options, and we will classify them as compensation until they are converted into equity. However, many convertible securities are bonds that can be converted into stock. Since bonds are typically secured debt, bonds will be treated as an ownership or investment interest.

B. When Does a Physician Make a Referral?

As defined by section 1877(h)(5) of the Act, a "referral" means a request by a physician for an item or service for which payment may be made under Medicare Part B, including a request for a consultation (including any tests or procedures ordered or performed by the consulting physician or under the supervision of the consulting physician), and the request or establishment of a plan of care by a physician that includes the furnishing of DHS, with certain exceptions for consultations by pathologists, diagnostic radiologists, and radiation oncologists. In the January 1998 proposed rule, we interpreted "referral" to mean any request by a physician for a service, including services subsequently performed by the physician. We proposed defining a "request" as any step taken after a physician performs an initial examination or a physician service on a patient that indicates that the physician believes the service is necessary. Under this broad definition, a referral could be either written or oral, made on medical charts or records, or indicated by a prescription or written order. We also proposed that a referral could be direct or indirect, meaning that a physician would be considered to have made a referral if he or she caused the referral to have been made by someone else (for example, an employee, a hospital discharge planner, or a staff member of a company that the physician owns or controls). As a general principle, we proposed that a physician may "cause" a referral to be made if he or she has the ability to control or influence the individual who selects the entity that furnishes the DHS.

In response to the public comments, we are making several significant changes to the definition of "referral" in Phase I of this rulemaking. These changes include the following:

- Revision of the definition of "referral" to exclude services performed personally by the referring physician. Simply stated, we are persuaded that a physician cannot make a "request" of himself or herself for services he or she personally performs. However, a physician can make a "request" of others, including, without limitation, his or her employees, co-workers, or independent contractors. These requests are "referrals" under section 1877 of the Act (although many of them will fit in an exception). We continue to believe that a referral can occur in a wide variety of formats, written, oral, or

electronic, depending on the particular service.

- Adding an exception using our regulatory authority under section 1877(b)(4) of the Act for certain referrals of DHS to an entity with which the referring physician has a prohibited financial relationship that are "indirect" referrals (for example, when a physician has caused a referral to be made by someone else or has directed or routed a referral through an intermediary) or are oral referrals (that is, no written request or other documentation that would identify the referring physician is required). A claim by the entity furnishing the DHS may be paid for purposes of section 1877 of the Act if the entity did not know or have reason to suspect the identity of the referring physician. In these circumstances, there is minimal risk of patient or program abuse by the entity submitting the claim (provided that the claim is otherwise valid).

- Clarification of the definition of a "consultation." In light of the clarifications relating to indirect and oral referrals described above, the practical significance of the definition of a "consultation" is substantially reduced.

We believe that these changes address many of the concerns expressed by commenters. In particular, we have endeavored to respond to the perceived harshness of section 1877 of the Act by creating a narrow exception under our section 1877(b)(4) authority. If the entity furnishing DHS knows of or has reason to suspect the identity of the physician who prescribed or ordered the DHS or made the referral, the DHS entity may not submit a claim for the services. If the physician who prescribes or orders a DHS is someone with whom the DHS entity has a prohibited financial relationship, we think a reasonable DHS entity should suspect that the physician referred the patient to the entity, absent some credible evidence to the contrary.

In the following paragraphs, we discuss and respond to the comments we received on the proposed interpretations of "referral" and "consultation" as published in the January 1998 proposed rule.

1. "Referral"

Comment: Many commenters objected to our interpretation in the January 1998 proposed rule that a service ordered and personally performed by a physician is a referral within the meaning of section 1877 of the Act. Commenters asked us to clarify that there is no referral if the referring physician personally performs the service. Similarly, some commenters sought clarification that there is no

referral if the services are "incident to" services personally performed by the referring physician.

Response: We are persuaded by the commenters that a physician does not make a "request," in the ordinary sense of that term, if he or she personally performs a designated health service. We agree it does not make sense to consider work that a referring physician initiates and personally performs as a referral to an entity. Thus, we are amending our definition of "referral" to exclude services that are personally performed by the referring physician (that is, the referring physician physically performs the service), and we are revising our definition of "entity" to clarify that the referring physician himself or herself is not an entity for purposes of section 1877 of the Act (although the physician's practice is an entity). All other Medicare-covered DHS performed at the request of a referring physician are "referrals" for purposes of section 1877 of the Act. A service performed by a hospital for which the hospital bills the technical or facility component of the charge would be a referred service. In such circumstances, however, the physician's service performed at the hospital for which the physician would bill Part B would not be a referred service.

With respect to services performed by others, including a physician's employees, we think the issue is more complicated. Services performed by others are reasonably considered to be performed as a result of a "request." Moreover, the statutory language in section 1877(h)(4)(B)(i) of the Act indicates that the Congress considered there to be a difference between personally performed services and services performed by others. On balance, we have chosen to include services performed by others, including a physician's employees, in the definition of referral. We are concerned that a blanket rule exempting services performed by a physician's employees from the definition of "referral" could, in some circumstances, undermine the intent of section 1877 of the Act. For example, by stationing employees in off-site DHS facilities, a physician practice could circumvent the statutory "building" requirements of the in-office ancillary services exception.

Even the more limited suggestion made by some commenters that there should be no "referral" if an employee's services are properly billable as "incident to" a physician's personally performed services could result in circumvention of the "building" requirements in some cases.

However, we believe the definition of "referral" we are adopting here—in conjunction with the in-office ancillary services exception—strikes an appropriate balance. Under the final rule, services performed by anyone other than the referring physician (whether an employee, a staff member, or a member of the physician's group practice) is a "referral" for purposes of section 1877 of the Act. Thus, services performed by a physician's employees will be considered "referrals". However, in most cases, such referrals will be permitted under the in-office ancillary services exception, which is substantially broader in this final rule than in the 1998 proposed rule. Services performed by employees that do not meet the "same building" or "centralized building" tests (as applicable, depending on whether the physician is a solo or group practitioner) will be prohibited unless another exception applies.

We recognize that, in many cases, services performed by a physician's employees are, for practical purposes, tantamount to services performed by the physician (for example, a physician's assistant applying a neck brace ordered by a physician for an individual who has been in an auto accident, when the face-to-face encounter with the patient, including the physical examination by the physician, indicates the need for a properly adjusted neck brace.) While such services are included in the definition of "referral" under this final rule, given the significance of this issue, we are soliciting comments as to whether, and under what conditions, services performed by a physician's employees could be treated as the physician's personally performed services under section 1877 of the Act.

Comment: A commenter asked that we clarify that a plan of care that includes the provision of DHS by the physician establishing the plan of care is not a referral. If not clarified as suggested, the commenter believes that the physician would effectively be barred from treating his or her own patients.

Response: If the DHS are personally performed by the physician who established the plan of care, there would be no referral as to those personally performed services.

Comment: Some commenters objected to our proposed presumption that a physician has referred his or her patient to an entity for the furnishing of DHS if the patient obtains the services from the entity with which the physician has a financial relationship. One commenter described the following scenario: A physician orally tells a patient or

another person that the patient needs a designated health service. The patient obtains the service from an entity with which the physician has a prohibited financial relationship. The entity does not know (and cannot know) that the physician orally told the patient (or other person) that the service was needed. The commenter sought clarification as to the application of section 1877 of the Act in these circumstances.

Response: We are establishing an exception for indirect and oral referrals. When there is no written order or other documentation of the referral, the issue is whether the DHS provider knows or has reason to suspect the identity of the physician who prescribed or ordered the DHS or made the referral.

Comment: Several commenters sought clarification that a physician's ordering, dispensing, or prescribing of drugs does not constitute a referral to the manufacturer of the drugs. The commenters noted that the manufacturers are not entities that furnish DHS (that is, outpatient prescription drugs) to patients. Rather, furnishing of DHS is performed by physicians, pharmacies, hospitals, and clinics.

Response: We agree that, in most cases, drug manufacturers are not entities that furnish DHS to patients for purposes of section 1877 of the Act, and, therefore, the ordering, dispensing, or prescribing of drugs would not constitute a referral to the manufacturer of the drugs. However, manufacturer-owned or -affiliated retail pharmacy operations, or other health care providers may be entities for purposes of section 1877 of the Act, if they furnish DHS to patients.

Comment: A commenter recommended that activities that a solo practitioner performs as a customary and integral part of patient treatment should not be considered a "referral."

Response: We find the commenter's proposed language too vague to be used in creating a standard. We believe our revised definition of "referral" that excludes personally performed services and our changes to the in-office ancillary services exception (see section VII.B.1 of this preamble) adequately address the commenter's concerns.

Comment: A commenter stated that referrals for DHS by a nonphysician professional employee of a group practice, such as a nurse practitioner or a physician assistant, should not be imputed to a physician member of the group practice, when the nonphysician is authorized and licensed to prescribe treatment on his or her own and can make independent decisions regarding

referrals. For example, if a nurse practitioner, staffing a group practice office without a physician member present, orders and performs a plain x-ray, the referral for the x-ray should not be imputed to a physician member of the group practice. If the referral is imputed, the service may not qualify under the in-office ancillary services exception, because it is not personally performed by the referring physician, another physician in the group practice, or a person who is directly supervised by the referring physician or another group practice physician. Alternatively, the commenter suggested that we modify the "direct supervision" standard to mirror our payment and coverage requirements to enable "imputed" referrals by a nurse practitioner and a physician assistant to fit in the in-office ancillary services exception.

Response: As previously stated, we are revising the "direct supervision" standard in the in-office ancillary services exception to mirror our payment and coverage requirements. (See discussion in section VI.B.2 of this preamble.) This change should address the concern identified by the commenter.

We believe that the question of whether a referral by a nurse practitioner or a physician assistant should be imputed to an employer physician will depend on the facts and circumstances of the referral. The inquiry is whether the physician controls or influences the nonphysician's referral. The Congress and HHS have recognized that many nurse practitioners and physician assistants are independent providers authorized and licensed to prescribe treatment and make independent decisions regarding referrals. However, these practitioners do not always act independently of their employers. For example, sometimes services of a nonphysician practitioner are billed "incident to" a physician service rather than directly under the nonphysician's independent billing number. In short, we are concerned that physicians could attempt to circumvent section 1877 of the Act by funneling referrals through nonphysician practitioners. We believe the change in the supervision requirement affords sufficient protection for legitimate arrangements.

Comment: Several commenters were confused by our discussion in the preamble to the January 1998 proposed rule at 63 FR 1710 of a situation in which a physician who owned a physical therapy (PT) company referred patients for treatment, including PT, to a skilled nursing facility (SNF) that

contracted with the physician's PT company. In the preamble, we indicated that we would analyze the arrangement as an indirect compensation arrangement and equate the physician with the PT provider.

Response: In the preamble of the January 1998 proposed rule, we suggested that the critical factor would be the degree of control the physician had over the PT provider and the extent of the PT provider's relationship with the SNF. We are abandoning that analysis. We think the proper focus is whether the physician is making a referral to the PT provider within the meaning of section 1877 of the Act. In other words, we believe that a physician can make a referral of DHS "to an entity" even though the referral is first directed or routed through another person or entity, provided the physician has reason to know the identity of the actual provider of the service. In the SNF/PT provider example, the relevant inquiry is whether the physician has made a referral, directly or indirectly, to the entity furnishing DHS, in other words, whether he or she is referring "to" that entity. Accordingly, if the physician referring the patient to the SNF knows that the PT company in which he or she has an investment interest will furnish DHS to the patient or could reasonably be expected to know that the PT company will actually furnish DHS to the patient, the referral is a referral "to the entity" and is prohibited, unless an exception applies. Similarly, where the PT company knows or has reason to suspect that the referral for DHS came from a referring physician with whom the PT company has a prohibited financial relationship, the PT company cannot submit the claim for the DHS. The PT/SNF example will be affected by the advent of full consolidated billing for SNFs, as described above in the responses to comments on indirect compensation arrangements.

To trigger section 1877 of the Act, the direction or steering of a patient "to an entity" does not need to be in writing, nor does it have to be absolute; it need only be reasonably intended to result in the patient receiving the service from the entity. Thus, for example, when a physician provides an order or prescription for a DHS to a patient that ostensibly can be filled by any of a number of entities and then suggests or informs the patient that the order can be serviced by a particular entity, there would be a referral "to" that entity. Given the administrative burden on entities presenting claims, in the context of an indirect financial relationship, we believe a claim for DHS should be

subject to nonpayment unless the entity does not know that, and does not have reason to suspect that, the referring physician had directed the patient to the entity.

2. Consultation

The Existing Law: Section 1877(h)(5)(C) of the Act excepts from the definition of a "referral" by a "referring physician" a request by a pathologist for clinical laboratory tests or pathological examination services, 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 specialist, pursuant to a consultation requested by another physician. Section 1877(h)(5)(C) creates a narrow exception from the definition of "referral" for a small subset of services provided or ordered by certain specialists pursuant to a consultation requested by another physician (the referring physician).

The Proposed Rule: In the preamble to the 1998 proposed rule, we referred to the interpretation of consultation that appeared in the March 1992 proposed rule for clinical laboratory services (57 FR 8595). There, we interpreted a consultation to be:

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. If, in the course of that consultation, the consulting physician deems it necessary to order clinical laboratory services, those services may not be ordered from a laboratory in which the referring [attending] physician has a financial interest. 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 [physician referral provision].

We did not add anything to this definition in the August 1995 final rule concerning referrals for clinical laboratory services.

Commenters to the 1998 proposed rule took issue with this interpretation for several reasons, including the requirement that the consulting physician examine and take a history of the patient, and the interpretation's failure to demarcate clearly when a consultant takes over treatment of the patient.

The Final Rule: The final rule adopts a very broad interpretation of a consultation. We want to make clear that this definition is only for the very

limited purpose of determining when a pathologist's, diagnostic radiologist's, or radiation oncologist's ordering of DHS from a facility with which he or she has an otherwise prohibited financial relationship will not prohibit submission of a claim to Medicare. *Most importantly, this definition is not intended to, and has no bearing on, coverage or payment rules relating to consultations.* Coverage and payment rules related to consultations raise many issues that are irrelevant for the very limited application of the term in section 1877 of the Act. Simply put, while there may be many difficult issues in determining when certain specialty services are consultations, as opposed to routine treatment, such difficulties are relatively rare in the context of the three exceptions in section 1877(h)(5)(C) of the Act (namely, a request by a pathologist for clinical laboratory services or pathological examination services, a request by a radiologist for diagnostic radiology services, or a request by a radiation oncologist for radiation therapy).

As a preliminary matter, we think it important to recognize that section 1877 of the Act defines referrals very broadly. Section 1877(h)(5) specifically includes referrals or requests for services made by the referring physician, as well as any DHS provided pursuant to a consultation with another physician, including DHS provided by the consulting physician or any DHS ordered by the consulting physician.

Section 1877(h)(5)(A) of the Act having established that a referral includes all DHS ordered by a consulting physician, section 1877(h)(5)(C) then carves out: (i) A request by a pathologist for clinical laboratory services or pathological examination services, (ii) a request by a radiologist for diagnostic radiology services, and (iii) 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 pursuant to a consultation requested by another physician.

The final rule adopts the following criteria to identify a consultation for purposes of section 1877:

(1) A consultation is provided by a physician whose opinion or advice regarding evaluation and/or management of a specific medical problem is requested by another physician.

(2) The request and need for the consultation is documented in the patient's medical record.

(3) After the consultation is provided, the consulting physician prepares a

written report of his or her findings, which is provided to the physician who requested the consultation.

(4) With respect to radiation therapy services provided by a radiation oncologist, a course of radiation treatments over a period of time will be considered to be pursuant to a consultation, provided the radiation oncologist communicates with the referring physician on a regular basis about the patient's course of treatment and progress.

Finally, we want to make clear that the exception in section 1877(h)(5)(C) of the Act only protects the referral of DHS from the pathologist, diagnostic radiologist, or radiation oncologist to the DHS provider. If the DHS provider—(1) knows or has reason to suspect that the referral originated from the referring physician, and (2) has a direct or indirect financial relationship with the referring physician, the DHS provider cannot submit a claim to Medicare for the DHS unless the financial relationship fits into an exception. Moreover, the referring physician may not make the referral to the consultant if he or she knows or has reason to suspect that the consultant will order DHS from an entity with which the referring physician has a direct or indirect financial relationship to which no exception applies.

Comment: A commenter suggested that the “diagnostic radiology” exception should be expanded to include other DHS performed or supervised by nonradiologist physicians to assure quality of care and access to a broad variety of services. The commenter asked that we broaden the consultation exception to include all DHS used to diagnose disease that are ordered pursuant to a consultation initiated by another physician.

Response: We agree that section 1877(h)(5)(C) of the Act creates an exception for the referrals of some specialists and not others. However, the Congress specifically excepted the requests of radiologists for diagnostic radiology services if the services are furnished by, or under the supervision of, the radiologist, pursuant to a consultation requested by another physician. It is our view that the Congress regarded most radiologists in this situation and the other excepted specialists as physicians who were not instigating a referral for services, but merely implementing the request of another physician who has already determined that the patient is likely to need radiology services. The Congress believes that, in general, a radiologist in this situation would not be likely to overutilize services.

We do not believe that we have the authority to extend this exception to other specialists, some of whom provide separate physician services to patients and would be in a position to instigate the referral for radiology.

Comment: One commenter was concerned about our willingness to exempt pathologists, radiologists, and radiation oncologists, yet require other arrangements and physicians to alter their referral methods. The commenter asserted that pathologists will order further stains or studies on specimens to aid in a diagnosis. Radiologists, not infrequently, recommend further studies as part of their interpretation, again to help make a diagnosis. The commenter stated that given the current medico-legal atmosphere, it is rare that he does not follow the suggestions of these consultants. In addition, the commenter stated that he has seen cancer patients with new or progressive diseases who are being treated by radiation oncologists without any direct input from attending or primary care physicians. In the commenter's view, these examples are standard medical practice and self-serving. Since radiologists often have an ownership interest in the diagnostic facility and pathologists in a laboratory facility, they are doubly benefitted by the referral.

Response: The statute clearly establishes special rules for diagnostic radiologists, pathologists, and radiation oncologists.

Comment: A number of commenters explained their problems with distinguishing a consultation from a referral based on their particular speciality area. For example, one commenter stated that during an active phase of an oncologic, hematologic, or pneumatologic illness, the care of the patient specific to that illness may be managed by the subspecialist and the overall care of the patient may be managed by the referring physician using the information obtained from the consultation. This commenter believes that a referral would occur only if the total care of the patient were transferred.

Another commenter asserted that rarely does a treating physician completely give up the care of a patient to another physician, and rarely does the treating physician completely retain responsibility for the care of the patient. Rather, a physician will send a patient to a specialist for testing, diagnosis, and initial treatment, and then the originating physician will take over the care of the patient.

Representing specialists who frequently perform consultations and assume the neurological care of patients at the request of referring physicians,

one commenter asserted that it is appropriate to bill for a consultation when care is transferred, rather than a lower-paying evaluation and management visit, because of the extra work for the consulting physician involved in preparing a report for the attending physician.

Response: We agree with the commenters that it can be difficult to determine whether a first physician initiating a visit to a second physician should constitute a referral to another physician or the request for a consultation with that physician. However, as discussed above, in the three specific instances identified in the statute, we think there will be little disagreement in determining when there is a consultation. In any event, for purposes of section 1877(h)(5)(C) of the Act, we are adopting a broader interpretation of a consultation than is in the coverage rules. Finally, payment and coverage for consultations are not addressed or affected by this rule.

Comment: One commenter, representing an association of radiologists, discussed the case of what happens when a patient is sent to a radiation oncologist for treatment of a tumor. The commenter stated that radiation oncology treatment occurs over a period of weeks or months, and is provided within a continuum of care involving the radiation oncologist, the referring physician, and even other physicians.

Response: We agree with the commenter and have clarified the definition to recognize that radiation therapy may extend over a prolonged period of time and still be considered to be pursuant to a consultation, provided the radiation oncologist regularly communicates with the referring physician as to the patient's care.

Comment: Commenters stated that when a referring physician sends a patient to a radiation oncologist for radiation therapy, the referring physician may not see the patient for some time. The radiation oncologist may decide during this time that the patient needs services other than radiation therapy services. The commenter asked whether the radiation oncologist's referrals for nonradiation therapy services falls within the scope of the consultation exception.

Response: Under section 1877(h)(5)(C) of the Act, for radiation oncology, only a request for radiation therapy by a radiation oncologist is not considered to be a referral. We understand that in some situations when a patient is undergoing radiation therapy, the patient's care is not supervised by a physician other than the radiation

oncologist. However, the radiation oncologist cannot send the patient for DHS other than radiation therapy services to an entity with which the radiation oncologist has a financial relationship without meeting an appropriate exception.

Comment: Section 1877(h)(5)(C) of the Act excepts DHS provided by consulting pathologists, diagnostic radiologists, and radiation oncologists if the services are furnished by, or under the supervision of, the consulting physician. A commenter inquired whether the required supervision could be delegated to a member of the consulting physician's group practice.

Response: The plain language of section 1877(h)(5)(C) of the Act does not allow for supervision by anyone other than the consulting physician. However, we are broadly interpreting the supervision requirement in this section to be consistent with the supervision requirements elsewhere in these regulations. Thus, the level of supervision required is whatever level is required under the applicable Medicare payment and coverage requirements. Furthermore, the in-office ancillary services exception may be available for services supervised by a physician in the consulting physician's group practice.

Comment: A commenter stated that neither diagnostic radiologists nor pathologists perform physical examinations on patients. An association representing certain specialists stated that the definition of a consultation should be modified so as *not to require* a patient history and physical examination except when appropriate; for example, diagnostic radiologists and nuclear medicine physicians generally do not take a patient's history or perform a medical examination. However, a nuclear medicine physician would perform a history and physical examination when a patient is referred for therapy. In addition, an association representing clinical laboratories declared that it is unlikely that a pathologist would ever see a patient or take a history from a patient. An association representing radiologists asserted that diagnostic radiologists generally do not take a patient's history or conduct a medical examination; therefore, we should clarify that a history and examination of the patient is not required as part of a radiologic consultation.

Response: For purposes of section 1877 of the Act, we agree that a consultation does not necessarily include either taking the history of a patient or performing a physical examination. Certainly, pathologists

would rarely see a patient. We do expect that, on occasion, a consulting physician, such as a radiologist, might interview a patient to gain additional information about the patient's condition, but this might not amount to a full scale history. Similarly, the radiologist might examine a patient, but focus only on a particular area of concern. We are amending our description of a "consultation" to clarify that there is no requirement that these steps be performed.

Comment: A commenter asked whether the prohibition under section 1877 of the Act is triggered when a physician, who has no financial relationship with a diagnostic imaging center, initiates a referral to the imaging center rather than to a particular radiologist.

Response: We understand the commenter to be asking whether the consultation exception set forth in section 1877(h)(5)(C) of the Act applies if the request for the consultation is made to the entity that employs or contracts with a consulting radiologist rather than to the consulting radiologist. The commenter's main concern seemed to be whether a subsequent request by the employed or contractor radiologist for diagnostic radiology services furnished by the imaging center would be protected under section 1877(h)(5)(C) of the Act. We believe that under section 1877(h)(5)(C) of the Act, the request for a consultation can be made to either a particular radiologist or an entity. Also, if the referring physician does not have a financial relationship with the diagnostic imaging center, the referral to the center is not prohibited under the general prohibition in section 1877(a) of the Act.

IV. Physician Compensation Under Section 1877 of the Act: An Overview

Many public comments addressed physician compensation issues. The statute touches on physician compensation in several places: the definition of group practice, the employee exception, and the personal services exception. The interplay of section 1877 of the Act and physician compensation is one of the most significant aspects of the self-referral law.

Obviously, the issue of physician compensation is of critical importance to the physician community. As a starting point, we do not believe that the Congress intended section 1877 of the Act to regulate physician compensation practices, except as necessary to minimize financial incentives to refer DHS to entities with which the physicians have financial relationships.

Having carefully studied the public comments and having reconsidered the statutory provisions, the legislative history, and our January 1998 regulatory proposals, we believe the following general principles govern the application of the statute to the manner in which physicians are paid:

- First, as explained in section III.B of this preamble, for purposes of section 1877 of the Act, the term "referral" does not include DHS that are personally performed by the physician. As a practical matter, the statutory language and structure indicate Congressional recognition that physicians are commonly compensated based on productivity with respect to services they personally perform.

- Second, with respect to group practices, the Congress intended to confer group practice status on *bona fide* group practices and not on loose confederations of physicians who come together as a "group" substantially in order to capture the profits of DHS under the in-office ancillary services exception to section 1877 of the Act. To that end, we proposed adding a "unified business" standard to the group practice definition, using the statutory authority the Congress conferred on the Secretary to impose additional standards on group practices. However, in response to comments, we have reconsidered the test for a "unified business"; the final regulations under Phase I of this rulemaking adopt a considerably more flexible approach to the same end. Under Phase I of this rulemaking, one of several characteristics of a "unified business" is that the group's physician compensation methodologies are established by the centralized management of the group practice. For the limited purposes of establishing that a group practice is a unified business, we think it is appropriate to look at physician compensation derived from all sources, not just from DHS. However, location- and specialty-based compensation practices are expressly permitted with respect to the distribution of revenues derived from services that are not DHS. Such practices may also be allowed for DHS, depending on the circumstances. (See the discussion of the group practice definition in section VI.C of this preamble.)

- Third, except for the limited purpose of determining whether a group practice is a unified business, the physician compensation provisions for group practices under section 1877 of the Act only affect the distribution of revenues derived from DHS. In general, these revenues are likely to comprise a relatively small portion of the total

revenues of most group practices. As we indicated in 1998, section 1877 of the Act does not affect the distribution of monies earned from other services. From a practical business standpoint, however, some group practices may find it impractical to segregate DHS revenues. These parties may find it more expedient to allocate compensation in accordance with the methods permitted for DHS revenues under section 1877 of the Act.

- Fourth, the statute implicitly recognizes that solo practitioners will keep all the profits from DHS that fit in the in-office ancillary services exception, whether performed personally or by others.

- Fifth, section 1877 of the Act contemplates that physicians—whether group practice members, independent contractors, or employees—can be paid in a manner that directly correlates to their own personal labor, including labor in the provision of DHS. In other words, “productivity,” as used in the statute, refers to the quantity and intensity of a physician’s own work, but does not include the physician’s fruitfulness in generating DHS performed by others (that is, the fruits of passive activity). “Incident to” services are not included in productivity bonuses under the statute unless the services are incident to services personally performed by a referring physician who is in a *bona fide* group practice. (“Incident to” services must meet the requirements of section 1861(s)(2)(A) of the Act and section 2050, “Services and Supplies,” of the Medicare Carriers Manual (HCFA Pub. 14–3), Part 3—Claims Process.) In the case of independent contractors under the personal service arrangements exception and employees under the *bona fide* employment exception, the amount of compensation for personal productivity is limited to fair market value for the services they personally perform. The fair market value standard in these exceptions acts as an additional check against inappropriate financial incentives. (The personal service arrangements exception, as well as several other exceptions, contains additional restrictions on compensation that varies based on the volume or value of referrals. The volume or value standard is discussed in section V of this preamble.)

- Sixth, the Congress recognized that in the case of group practices, revenues derived from DHS must be distributed to the group practice members in some fashion, even though the members generate the DHS revenue. However, the Congress wished to minimize the economic incentives to generate

unnecessary referrals of DHS.

Accordingly, the Congress permitted group practice members (and independent contractors who qualify as “physicians in the group practice”) to receive shares of the overall profits of the group, so long as those shares do not directly correlate to the volume or value of referrals generated by the member or “physician in the group practice” for DHS performed by someone else. In addition, the Congress permitted groups to pay their physicians productivity bonuses based directly on personal productivity (including services incident to personally performed services), but precluded groups from paying group practice physicians any productivity bonus based *directly* on referrals of DHS performed by someone else. As detailed below, we are establishing under Phase I of this rulemaking certain methodologies that describe compensation practices that will be deemed to be *indirectly* related to the volume or value of DHS referrals for purposes of section 1877(h)(4)(B)(i) of the Act and therefore allowable under section 1877 of the Act. Groups are free to develop their own indirect methodologies, but such methodologies are subject to case-by-case review.

V. “Volume or Value” of Referrals and “Other Business Generated” Standards: An Overview

Many of the exceptions in section 1877 of the Act covering specific kinds of compensation arrangements include as one element of the exception a requirement that the compensation not take into account the volume or value of any referrals and, in some of the exceptions, the further requirement that the compensation not take into account other business generated between the parties.

In the preamble to the January 1998 proposed regulation, we had interpreted this volume or value standard as follows:

- Compensation could be based on units of service (for example, “per use” equipment rentals) so long as the units of service did not include services provided to patients who were referred by the physician receiving the payment. For example, a physician who owned a lithotripter could rent it to a hospital on a per procedure basis, except for lithotripsies for patients referred by the physician-owner; payments for the use of the lithotripter for those patients would have to use a methodology that did not vary with referrals.

- The language “or other business generated between the parties” meant that the payment in an arrangement had to be fair market value for the services

expressly covered by the arrangement and could not include any payment for services not covered by the arrangement.

- Physician compensation arrangements that were fixed in amount but conditioned either expressly or implicitly on the physicians referring patients to a particular provider or supplier took into account the value or volume of referrals within the meaning of the statute.

After reviewing the comments received, we are substantially revising the regulation with respect to the scope of the volume or value standard. Most importantly, we are permitting time-based or unit-of-service-based payments, even when the physician receiving the payment has generated the payment through a DHS referral. We have reviewed the legislative history with respect to the exception for space and equipment leases and concluded that the Congress intended that time-based or unit-of-service-based payments be protected, so long as the payment per unit is at fair market value at inception and does not subsequently change during the lease term in any manner that takes into account DHS referrals. In the case of those exceptions that include the additional restriction that the payment not take into account “other business generated between the parties,” the per unit payment also may not take into account any other business, including non-Federal health care business, generated by the referring physician. We are interpreting the phrase “generated between the parties” to mean business generated by the referring physician for purposes of section 1877 of the Act.

Applying Phase I of this rulemaking to the lithotripter example noted above, the “per use” rental payments would be protected, even for lithotripsies performed on patients referred by the physician-owner, provided that the “per use” rental payment was at fair market value, did not vary over the lease term, and met the other requirements of the rental exception. In other words, if the “per use” payment is fair market value, we will not require a separate payment arrangement for use of the equipment on patients referred by the physician-owner. In determining whether the initial “per use” payment is at “fair market value,” we will generally look to the price a hospital would pay to rent the equipment from a company that did not have any physician ownership or investment (and thus was not in a position to generate referrals or other business—*DHS or otherwise*—for the hospital) in an arm’s-length transaction. In some cases, all the available

comparables or market values may involve transactions between entities that are in a position to refer or generate other business. In such situations, we would look to alternative valuation methodologies, including, but not limited to, cost plus reasonable rate of return on investment on leases of comparable medical equipment from disinterested lessors. (The definition of fair market value is discussed in more detail in section VII.B of this preamble.)

In the light of our interpretation of the volume or value standard as permitting unit of service or unit of time-based payments, we have determined that the additional limiting phrase "not taking into account * * * other business generated between the parties" means simply that the fixed, fair market value payment cannot take into account, or vary with, referrals of Medicare or Medicaid DHS or any other business generated by the referring physician, including other Federal and private pay business. Simply stated, section 1877 of the Act establishes a straightforward test that compensation arrangements should be at fair market value for the work or service performed or the equipment or space leased—not inflated to compensate for the physician's ability to generate other revenues.

In order to establish a "bright line" rule, we are applying this interpretation of the volume or value standard uniformly to all provisions under section 1877 of the Act and part 411 where the language appears (for example, the employee, personal service arrangements, rental of office space/equipment, fair market value, non-monetary compensation under \$300, hospital medical staff benefits, academic medical center exceptions, indirect compensation arrangements, and the group practice definition). The "other business generated" restriction applies only to those exceptions in which it expressly appears.

Consistent with this interpretation, we have determined that we will not consider the volume or value standard implicated by otherwise acceptable compensation arrangements for physician services solely because the arrangement requires the physician to refer to a particular provider as a condition of payment. So long as the payment is fixed in advance for the term of the agreement, is consistent with fair market value for the services performed (that is, the payment does not take into account the volume or value of the anticipated or required referrals), and otherwise complies with the requirements of the applicable exception, the fact that an employer or a managed care contract requires

referrals to certain providers will not vitiate the exception. Any such contract, however, must expressly provide exceptions (1) when the patient expresses a different choice, (2) when the patient's insurer determines the provider, or (3) when the referral is not in the best medical interest of the patient in the physician's judgment. We caution that these mandatory arrangements could still implicate the anti-kickback statute, depending on the facts and circumstances.

Finally, we want to clarify that ownership or investment interests that are not protected under sections 1877(b) through (d) of the Act (and are therefore compensation arrangements under section 1877(h)(1)(A) of the Act) are deemed to take into account the value or volume of referrals. We believe this view is consistent with the general prohibition on investment and ownership interests in the statute.

Our responses to comments follow below:

Comment: One commenter asked us to clarify the statement in the preamble of the January 1998 proposed rule at 63 FR 1780 that the volume or value standard that is in the compensation and other exceptions is uniformly meant to cover (and thus exclude from an exception) other business generated between the parties. Another commenter asked us to clarify that the requirement that the compensation not take into account the volume or value of referrals or other business generated between the parties refers only to referrals of DHS.

Response: The discussion of the phrase "other business generated between the parties" in the preamble to the January 1998 proposed rule caused confusion. Based on our review of the legislative history, we believe that the Congress intended the language to be a limitation on the compensation or payment formula parallel to the statutory and regulatory prohibition on taking into account referrals of DHS business. Simply stated, in the provisions in which the phrase appears, affected payments cannot be based or adjusted in any way on referrals of DHS or on any other business referred by the physician, including other Federal and private pay business.

Comment: One commenter urged us to amend the language of the regulation to correspond to the extensive discussion of the volume or value standard in the preamble.

Response: We are modifying the regulation to clarify the meaning of the volume or value standard.

Comment: One commenter asked us to clarify that a valuation of a

physician's practice could include the value of self-generated DHS in the purchase price as long as the purchase agreement was not contingent on future referrals.

Response: For purposes of section 1877 of the Act, the valuation of a physician practice could include the value of DHS in the purchase price if the DHS provided by the selling physician fit into an exception, such as the in-office ancillary services exception, and the purchase agreement (and purchase price) is not contingent on future referrals. Depending on the identity of the purchaser, however, the inclusion of the value of ancillary revenues could implicate the anti-kickback statute.

Comment: Several commenters asked us to clarify that the language requiring that the payment be fixed in advance and not be determined in a manner that takes into account the value or volume of referrals or other business generated between the parties does not require that the aggregate compensation be established in advance, but only that the methodology (for example, a rental per use, or payment per service) be fixed in advance.

Response: We are modifying the regulation to make it clear that the aggregate payment need not be specified in advance. However, if the aggregate amount is not specified, the amount of the payment on a "per use," "per service," or "per time period" basis must be fixed in advance. For example, a contract could include a fee schedule for services, provided the fee schedule is uniformly applied to all services provided to the contracting party. In addition, the payment must be fair market value compensation not taking into account the volume or value of referrals or other business generated by the referring physician either at inception or during the term of the agreement.

Comment: Commenters also wished us to clarify whether the following arrangements take into account the volume or value of referrals or other business generated between the parties: (1) Payments based on a percentage of gross revenues; (2) payments based on a percentage of collections; (3) payments based on a percentage of expenses; and (4) payments based on a percentage of a fee schedule.

Response: A compensation arrangement does not take into account the volume or value of referrals or other business generated between the parties if the compensation is fixed in advance and will result in fair market value compensation, and the compensation does not vary over the term of the

arrangement in any manner that takes into account referrals or other business generated. The first three arrangements described by the commenters are neither aggregate fixed compensation amounts, nor fixed "per service," "per use," or "per time period" payment amounts. Percentage compensation that is determined by calculating a percentage of a fluctuating or indeterminate amount, such as revenues, collections, or expenses, is not fixed in advance. Accordingly, the first three arrangements do not meet the requirement that compensation be fixed in advance. Whether the fourth arrangement mentioned by the commenters—a percentage of a fee schedule—is fixed in advance compensation depends on the circumstances. If the percentage payments are based on a single fee schedule, such that there is, in effect, a single fixed fee for each service, the arrangement meets the requirement that the compensation be fixed in advance. However, a percentage of fee schedule arrangement that bases payments on multiple fee schedules, such that there may be different fees for a particular service depending on the ultimate payer, is not fixed in advance. Thus, for example, if a physician has a contract for services with a hospital that has a chargemaster for all services, the physician can be paid a fixed percentage of that chargemaster fee schedule for each service. However, when the hospital accepts different payment amounts from different payers for a service, the physician cannot be paid a percentage of those varying amounts.

Comment: Several commenters requested that the final rule make clear that payments based on "per use" or "per service" meet the volume or value standard in the exceptions so long as the payments are at fair market value and the "per use" or "per service" amount does not change over the term of the contract based on the value or volume of referrals of DHS. The commenters stated that their position was consistent with the intent of the Congress and supported their position with language from the Conference Committee report.

Response: As described above, we are modifying the regulation to reflect the Conference Committee report, H. Rep. No. 213, 103rd Cong., 1st Sess. 814 (1993). The "per use," "per service," or "per time period" amount must reflect fair market value at inception not taking into account the volume or value of referrals and must not change over the term of the contract based on the volume or value of DHS referrals, or, when applicable, other business (that is,

other Federal or private pay business) generated by the referring physician.

Comment: One commenter specifically objected to our proposed interpretation that a "per use" payment was acceptable except when the payment was for a referral from a physician with an ownership or investment interest in the equipment. According to the commenter, the physician's ownership or investment interest should not matter so long as the physician does not have a controlling interest.

Response: We believe equipment rental arrangements are subject to abuse whether the payment received is only a small portion of the rental or the entire amount. Control is irrelevant; it is the financial incentive that has been shown repeatedly to result in overutilization. Despite the obvious potential for abuse, given the clearly expressed congressional intent in the legislative history, we are permitting "per use" payments even when the physician is generating the referrals. We wish to make clear that these arrangements may violate the anti-kickback statute.

Comment: A commenter asked that we clarify that a hospital can lease equipment on a "per use" basis to a physician for use in the physician's practice.

Response: A hospital can lease equipment to a physician for use in the physician's practice on a "per use" basis, provided the lease arrangement otherwise fits in the rental exception. As noted above, these arrangements may violate the anti-kickback statute.

Comment: Many commenters objected to our proposed interpretation in the preamble that fixed payments to a physician could be determined to take into account the volume or value of referrals if a condition or requirement for receiving the payment was that the physician refer DHS to a given entity, such as an employer or an affiliated entity. A number of commenters stated that we did not have statutory authority for our proposed interpretation. Some commenters said these arrangements were necessary to develop integrated networks and ensure quality control. Another commenter stated that the proposal would interfere with exclusive hospital-based physician relationships. One commenter argued that the proposed interpretation was inconsistent with the employee exception, while yet another stated the position was inconsistent with the common law duty of loyalty owed by an employee to his or her employer and the employer's right to set the terms and conditions of employment. Another commenter stated that the proposed

interpretation would adversely impact managed care arrangements by, in effect, requiring all managed care arrangements to meet the physician incentive plan regulations. Finally, a commenter proposed that we allow entities to require physicians to refer to a particular provider as part of a contract, except (1) when the patient expresses a different choice, (2) when the patient's insurer determines the provider, or (3) when the referral is against the physician's judgment.

Response: While we believe that payments tied to referral requirements can be abused, we agree that the proposed interpretation potentially would have had far-reaching effects, especially for managed care arrangements and group practices. We are adopting in modified form the one commenter's suggestion for appropriate conditions listed in the last sentence of the comment. We believe the suggested conditions will not impose a significant burden, since they are likely to be required anyway under existing laws, professional codes, and most contracts. Thus, so long as the referral requirement does not apply if a patient expresses a different choice, the patient's insurer determines the provider, or the referral is not in the best medical interest of the patient in the physician's judgment and the payment to the physician is fixed in advance at fair market value for the services actually rendered and does not vary based on referrals or, when applicable, other business generated by the physician, the fact that referrals may be required to be made to specific providers will not nullify an exception.

Comment: One commenter stated that the final rule should not prohibit primary care case management arrangements.

Response: As discussed in the preceding comment, we are no longer viewing these arrangements as violating the volume or value standard simply because referrals may be required to be made to certain providers. The arrangement would have to meet the other provisions of an exception.

Comment: According to two commenters, many covenants not to compete could be called into question by the proposed interpretation that fixed payments tied to referral requirements can violate the volume or value standard, a component of many of the exceptions. The commenters argued that these covenants are necessary adjuncts to many business acquisitions and personal services or management arrangements and urged us to affirm their legitimacy.

Response: The commenters were unclear as to how the proposed

interpretation would have adversely impacted covenants not to compete. A requirement to refer to a specific provider is different from an agreement not to establish a competing business. In other words, a covenant not to compete might prevent a physician from setting up a private practice or offering services that compete with the entity that purchased his or her practice. If an agreement also included the requirement that the physician refer business to the purchaser, the agreement would be suspect under the anti-kickback statute.

Comment: One commenter asked us to clarify that the discussion in the preamble about the volume or value standard applies not only to its interpretation in the context of the compensation exceptions, but also to its interpretation in the other exceptions in which the same language appears.

Response: The meaning of the volume or value standard as set forth in the preamble and regulations text under Phase I of this rulemaking applies to the standard wherever it appears in the statute and regulations.

Comment: One commenter stated that the interpretation of the volume or value standard in the January 1998 proposed rule at 63 FR 1701 would permit hospitals to pressure physicians to refer to network and other providers that the hospitals own or control.

Response: It is not clear from the comment what aspect of the proposed rule would lead the commenter to believe that this kind of coercion would occur. Nonetheless, section 1877 of the Act is limited in its application and does not address every abuse in the health care industry. The fact that a particular arrangement is not prohibited by section 1877 of the Act does not mean that the arrangement is not abusive; it simply means that a referral and submission of a claim for DHS is not prohibited under section 1877 of the Act.

VI. Exceptions Applicable to Ownership and Compensation Arrangements (Section 1877(b) of the Act)

A. Physician Services (Section 1877(b)(1) of the Act)

The Existing Law: Section 1877(b)(1) of the Act specifies that the general prohibition under section 1877 of the Act does not apply to services furnished on a referral basis, if the services are physician services, as defined in section 1861(q) of the Act, and are furnished (1) personally by another physician in the same group practice as the referring physician or (2) under the personal

supervision of another physician in the same group practice as the referring physician. Section 1861(q) defines “physicians’ services” as “professional services performed by physicians, including surgery, consultation, and home, office, and institutional calls (but not including services described in subsection (b)(6) [certain intern and resident services].” A physician is defined in the Act as a duly licensed and authorized doctor of medicine or osteopathy, doctor of dental surgery or dental medicine, doctor of podiatric medicine, doctor of optometry, or chiropractor who meets certain qualifications specified in the Act. (See section 1861(r) of the Act.)

The August 1995 final rule incorporated this provision in § 411.355 (General exceptions to the referral prohibition related to both ownership/investment and compensation), paragraph (a) (Physician services), covering physician services as defined in § 410.20 (Physicians’ services), paragraph (a) (Included services). The definition of a physician service in § 410.20(a) generally parallels the definition in section 1861(r) of the Act, with the addition of diagnosis and therapy services. Under the August 1995 final rule, physician services need not be performed in any specific location.

The Proposed Rule: The January 1998 proposed rule retained § 411.355(a) as set forth in the August 1995 final rule. In the preamble to the January 1998 proposed rule, we noted that the exception would apply to physician services that constitute DHS under section 1877 of the Act and regulations and that the exception in the Medicare context would not apply to services performed by nonphysicians, even though furnished under a physician’s supervision, such as ancillary or “incident to” services. We interpreted “personal supervision” to mean that the group practice physician must be legally responsible for monitoring the results of any test or other designated health service and must be available to assist the individual who is furnishing the service, even though the group practice physician need not be present while the service is being furnished.

The Final Rule: In general, we believe that the physician services exception is of limited application. However, the physician services exception does afford protection for referrals of the narrow class of physician services that are included in the definitions of DHS, especially in the area of radiology. (See discussion in section VIII.A of this preamble.) The physician services exception enables physicians in group practices to make referrals for physician

services that are DHS within their group practices. In addition, the in-office ancillary services exception may also apply, depending on the circumstances. We are interpreting the physician services exception to apply to referrals to (or referral services supervised by) a member of the group practice or an independent contractor who qualifies as a “physician in the group” as defined in § 411.351 (Definitions).

In particular, we are incorporating the physician services exception in § 411.355(a) as proposed in our January 1998 proposed rule, with the following modifications:

First, we are interpreting “personal supervision” to correspond with our revised interpretation of “direct supervision” in the context of the in-office ancillary services exception. (See discussion in section VI.B.2 of this preamble.) We can discern no compelling reason to have separate and potentially inconsistent supervision standards in the exceptions under section 1877 of the Act. Accordingly, the level of supervision required under the physician services exception is the level of supervision required under the payment and coverage rules applicable to the particular physician service at issue.

Second, as noted above, we are expressly interpreting the exception to apply to referrals to (or physician’s services supervised by) a member of the group practice or an independent contractor who qualifies as a “physician in the group” as defined in § 411.351.

Finally, as many have pointed out, the physician services exception (unlike the in-office ancillary services exception) does not cover referred services that are performed by the referring physician. We believe this narrower scope of the physician services exception is evidence that personally performed physician services fall outside the scope of section 1877 of the Act. For this and other reasons expressed elsewhere in this preamble, in § 411.351 of Phase I of this rulemaking, we are defining a “referral” for purposes of section 1877 of the Act to exclude referrals for work personally performed by the referring physician, and we have made clear that a referring physician is not himself or herself an entity to which he or she makes referrals.

Comment: A commenter asked that the regulations include a clear provision for providing compensation for professional reading fees within an outpatient group practice for diagnostic procedures such as EKG, pulmonary function testing, EEG, etc.

Response: To the extent that the professional reading fees mentioned by

the commenter are DHS (see § 411.351), the rules set forth in these regulations apply. (We note, however, that pulmonary function testing and EKGs and ECGs typically will not be DHS unless furnished in a hospital setting.) First, if the professional reading is performed personally by the referring physician, no referral occurs for purposes of section 1877 of the Act (though there may still be a referral of the technical component). Second, if the professional reading is performed by a physician other than the referring physician, the physician services and in-office ancillary services exceptions are available. In the case of a group practice, physician compensation will be governed by the rules in § 411.352 (Group practice). Subject to those rules, the physician performing the professional reading may be paid directly based on his or her personal performance of professional services.

Comment: A commenter expressed the view that all physician services are excluded from the scope of section 1877 of the Act. The commenter asserted that no evidence exists that the Congress intended to include in section 1877 of the Act physician services within the meaning of section 1861(s)(1) of the Act. The commenter, therefore, concluded that including professional components of services is beyond the scope of section 1877 and our regulatory authority.

Response: We disagree. A number of the DHS enumerated by the Congress in section 1877(h)(6) of the Act include substantial physician services components, and the Congress provided no exclusion or carve out. Indeed, we believe the physician services exception itself clearly evidences the Congress's recognition that the DHS categories set forth in section 1877(h)(6) of the Act include some physician services. At the very least, the Congress anticipated that there might be situations in which it would be difficult to demarcate clearly professional and technical components of the DHS. For those situations, the Congress provided an exception that makes clear that group practice physicians may refer physician services within their group practices when the conditions of the exception are satisfied.

Comment: A commenter inquired whether the physician services exception applies to services performed by a nonphysician. In the commenter's view, if the exception does not apply to these services, the exception would conflict directly with our other rules on the practice parameters applicable to nonphysician practitioners.

Response: We are cognizant of the expanding and evolving role of

nonphysician practitioners in the health care delivery system for Medicare beneficiaries. Notwithstanding, we are not persuaded that an expansion of the physicians' services exception is appropriate or, in the light of other interpretations set forth in these regulations, necessary to accommodate the commenter's concerns.

Section 1877(b)(1) expressly applies only to physicians' services as defined in section 1861(q) of the Act. Section 1861(q) of the Act provides that physician services are "professional services performed by physicians." The Act provides for Medicare coverage for certain services that would be physicians' services if furnished by a physician when such services are performed by a physician assistant (under the supervision of a physician) or a nurse practitioner or clinical nurse specialist (working in collaboration with a physician) (see sections 1861(s)(K)(i) and (s)(K)(ii) of the Act.) However, while such services may be identical to physicians' services, they are not physicians' services under section 1861(q) of the Act. Congress has provided for separate treatment of such services under the payment rules. To define nonphysician services as physician services for purposes of section 1877(b)(1) of the Act would distort Medicare's overall payment and coverage scheme.

We are also concerned that expanding the physicians' services exception, which has no building or billing requirements, to include nonphysician practitioners' services would permit group practices to circumvent the requirements of the in-office ancillary services exception.

However, while we are not including nonphysician services under section 1877(b)(1) of the Act, we have made other changes in the regulations that address the commenter's concerns. Specifically, we have interpreted the direct supervision requirement of the in-office ancillary services exception as requiring the level of supervision mandated under the relevant Medicare payment and coverage rules. See section VII.B.2 of this preamble. In other words, in the case of nonphysician practitioners, the supervision requirement of the in-office ancillary services exception corresponds to the supervision requirements applicable to such practitioners. Thus, the in-office ancillary services exception will cover most referral DHS provided by nonphysician practitioners in a group practice setting (provided the exception's building and billing requirements are also satisfied), without

imposing additional supervision requirements on such practitioners.

Moreover, referrals made by nonphysician practitioners generally do not implicate section 1877 of the Act, which focuses exclusively on referrals by physicians. However, if a referral made by a physician assistant or nurse practitioner (or other nonphysician) is directed or controlled by a physician, we are treating the referral as an indirect referral made by the directing or controlling physician, who is, in fact, the "referring physician." This interpretation is necessary to prevent the use of nonphysician practitioners to circumvent section 1877 of the Act.

We believe these interpretations adequately address the commenter's concerns and are consistent with the statutory language and structure. However, we invite public comments as to the need for a further exception for referred DHS performed by nonphysician practitioners in a group practice setting.

Comment: A commenter sought clarification as to the treatment of "incident to" services under the physicians' services exception. The commenter believed that unless "incident to" services are included in the exception, the exception would conflict with other payment and coverage rules.

Response: We are interpreting the physicians' services exception to apply only to "incident to" services (as defined in § 411.351) that are physician services under section 1861(q). All other "incident to" services would need to qualify under the in-office ancillary services or another exception.

Comment: A commenter suggested that the term "physician" should be defined in the regulations.

Response: The Act defines "physician" in section 1861(r). We agree that it would be helpful to incorporate this definition into these regulations and are doing so.

B. In-office Ancillary Services (Section 1877(b)(2) of the Act)

The Existing Law: We have divided our discussion of the in-office ancillary services exception into four subsections that correspond with the statutory structure: DHS included in the in-office ancillary services exception, supervision, building requirements, and billing requirements. The relevant provisions of the existing law are described in each subsection below.

The Proposed Rule: The relevant provisions of the proposed rule are described in each subsection below.

The Final Rule: Many commenters were highly critical of the January 1998

proposed rule's interpretation of the exception for in-office ancillary services, contending that the rule was arbitrary, inconsistent with our existing policies, and inefficient. We have revisited the premises of the January 1998 proposed rule, reexamined the statutory language and legislative history, and restructured the exception. The in-office ancillary services exception in Phase I of this rulemaking is consistent with the language of section 1877 of the Act and the organization and operation of many modern physicians' offices. While in most respects the exception is broader and administratively simpler than the proposed exception, we have substantially limited the ability of group practices to use part-time arrangements to provide DHS in buildings or facilities in which they do not routinely provide a wide range of services other than Federal or private pay DHS.

In revising the exception, we were cognizant of several key considerations. First, the Congress clearly was concerned with regulating physicians' ordering of DHS, even in the context of their own practices; otherwise, a detailed exception would not have been necessary. Second, the Congress intended to protect some in-office ancillary services provided they were truly ancillary to the medical services being provided by the physician or group; otherwise, the Congress would not have created the exception. Finally, we believe the boundaries of the exception as intended by the Congress are best expressed in the building requirement in section 1877(b)(2)(A)(ii) of the Act, which permits DHS to be provided in the same building where the physicians provide their regular medical services, or, in the case of a group practice, in a central DHS building.

Based on those considerations, we have revised the in-office ancillary services exception to permit the provision of DHS in the same building in which a group or a physician routinely provides the full range of the group's or physician's medical services with a minimum of restrictions. In general, the final exception will protect shared DHS facilities, so long as the physicians or groups that share the facility also routinely provide their full range of services in the same building. Moreover, in certain circumstances, part-time practitioners would be permitted to share the DHS facility, as long as they are also providing medical services they routinely provide that are not DHS (whether Federal or private pay). Coupled with a relaxation of the proposed supervision requirement

described below, we believe the final exception captures what the Congress intended to protect.

What will not be protected by Phase I of this rulemaking are a number of part-time, intermittent arrangements that functionally are nothing more than shared off-site facilities. Many of these part-time, off-site ancillary services arrangements are inconvenient for patients both as to location and time, and are created by physicians principally to capture revenue rather than to enhance patient care. To preclude such arrangements, and as a counter-balance to allowing certain shared facilities, we have interpreted the same building requirement as including a "full range of services" condition, and the centralized building requirement as requiring exclusivity. These interpretations are consistent with the statutory language and structure. To the extent the January 1998 proposed rule would have permitted these arrangements, it is no longer operative. To qualify under the "centralized building" standard, Phase I of this rulemaking will require, among other things, the group practice to own or lease and use the space exclusively on a full-time basis.

In addition to the changes to the "building" requirements, the exception for in-office ancillary services under Phase I of this rulemaking contains a number of other significant changes (all described in more detail in the relevant comments and responses sections that follow):

- Significantly expanding the scope of services potentially included in the in-office ancillary services exception by—(1) making clear that outpatient prescription drugs may be "furnished" in the office, even if they are used by the patient at home; (2) explicitly permitting external ambulatory infusion pumps that are DME to be provided under the in-office ancillary services exception; (3) making clear that chemotherapy infusion drugs may be provided under the in-office ancillary services exception through the administration or dispensing of the drugs to patients in the physician's office; and (4) creating a new exception for certain items of durable medical equipment (DME) furnished in a physician's office for the convenience of the physician's patients.

- Substantially modifying the "direct supervision" requirement to conform it to relevant Medicare and Medicaid payment and coverage rules for the specific service, in keeping with our premise that the Congress did not intend to revamp radically the provision

of ancillary services in physicians' offices.

- Allowing independent contractors to provide the requisite supervision, provided they are "physicians in the group practice," meaning that they have contracted with the group practice to treat group practice patients on group premises and have reassigned their claims to the group under § 424.80 of these regulations (as further explained in section 3060, "Reassignment," of the Medicare Carriers Manual (HCFA Pub. 14-3), Part 3—Claims Process).

Additional revisions and modifications to the rule are addressed in the discussion below. The discussion is divided into four subparts: the scope of DHS, supervision, building requirements, and billing requirements. The discussion of each subpart contains summaries of public comments and our responses to them.

1. Scope of Designated Health Services That Can Be In-Office Ancillary Services

The Existing Law: As a threshold matter, the DHS that are potentially protected by the in-office ancillary services exception are any of the DHS enumerated in section 1877(h)(6) of the Act, *except* DHS specifically excluded from the exception under section 1877(b)(2) of the Act. Excluded are all parenteral and enteral nutrients, equipment, and supplies (PEN) and DME (except for infusion pumps, which remain eligible for the exception). Referrals—in-office or otherwise—for services that are not DHS need not fit in the exception, since they do not implicate the statute. The scope of services that are considered to be DHS is discussed in section VIII.A of this preamble.

The Proposed Rule: We proposed that DHS would be considered furnished in the location where the service was actually performed or where a patient receives and begins using an item. We also proposed expanding the category of DHS included in the in-office ancillary services exception to include crutches, provided the physician does not mark up the cost of the crutches.

The Final Rule: First, we are revising the rule to provide that services will be considered "furnished" for purposes of the exception (1) in the location where the service is actually performed upon a patient or (2) when an item is dispensed to a patient in a manner that is sufficient to meet Medicare billing and coverage rules. This change will make application of the rule clearer in the case of outpatient prescription drugs and ambulatory infusion pumps that are DME. Second, in the interests of patient convenience, we are using our

regulatory authority under section 1877(b)(4) of the Act to expand the exception to include certain DME, including crutches, canes, walkers, and folding manual wheelchairs, that meet conditions set forth in the regulations. (Braces and collars are orthotics and, thus, may already qualify under the statute for the in-office ancillary services exception.) These conditions generally will require that—(1) the items are DME, such as canes, crutches, walkers, and folding wheelchairs, that a patient uses to ambulate in order to leave the physician's office; (2) the items are furnished in a building that meets the "same building" requirements of section 1877(b)(2) of the Act and § 411.355(b)(2)(i) as part of the treatment for the specific condition for which the physician-patient encounter occurred; (3) the items must be furnished personally by the physician who ordered the DME, by another physician in the group practice, or by an employee of the physician or the group practice; (4) the physician who furnishes the DME must meet all DME supplier standards; (5) the arrangement does not violate the anti-kickback statute; (6) the billing and claims submission for the DME complies with all applicable laws and regulations; and (7) all other requirements of the in-office ancillary services exception are satisfied. We are similarly excepting blood glucose monitors.

We are withdrawing our proposal that physicians not mark up these items when provided in-office to their patients; we believe the current DME Regional Carrier (DMERC) reimbursement provisions provide sufficient cost containment controls. We believe these limited modifications to the DME exclusion will promote quality of patient care without any significant increased risk of patient or program abuse.

Finally, with respect to infusion pumps (other than pumps that are PEN equipment or supplies), we are including, under Phase I of this rulemaking, the furnishing of external ambulatory infusion pumps as in-office ancillary services covered by the exception (which uses the generic term "infusion pumps"), provided all other conditions of the exception are satisfied. Because they are specifically included in the statutory exception, external ambulatory infusion pumps need not meet the added requirements for DME outlined in the preceding paragraph.

Comment: A hospital-based pathologist in a hospital with a full-service laboratory urged that the in-office ancillary services exception should not protect laboratories based in

physicians' offices. The pathologist asserted that these laboratories are merely enterprises that enable physicians to profit from referrals for laboratory tests and create unfair competition for pathology laboratories that are not owned by physicians. The pathologist expressed skepticism about the justification proffered by many physicians that in-office laboratories exist for the convenience of patients, noting that, in his case, his hospital laboratory is located directly across the street from the offices of physicians with in-office laboratories.

Response: Despite the fact that physician-owned or controlled laboratories and other DHS facilities may competitively disadvantage entities that do not have physician ownership or control, the Congress made a policy determination not to apply the prohibition under section 1877 of the Act to DHS referrals that occur within the parameters of a physician's or group practices' own medical practice, provided these referrals fit squarely in an exception under section 1877 of the Act.

Comment: The in-office ancillary services exception applies to DHS that are "furnished" in accordance with certain statutory conditions. A number of commenters objected to our interpretation that the term "furnished" excluded items provided to a patient (or delivered to a patient's home) that are meant to be used at home rather than in the physician's office. The commenters observed that such a rule does not make sense in the case of outpatient prescription drugs, which are commonly dispensed to patients for later consumption at home.

Response: In general, we believe the Congress intended to exclude from the reach of the statute only items and services provided (or used, as the case may be) in the physician's office. However, we believe that our definition of those circumstances can be simplified to accommodate the provision of outpatient prescription drugs, as well as ambulatory infusion pumps that are DME. Accordingly, we are revising the rule to provide that services will be considered "furnished," for purposes of the exception, in the location where the service is actually performed upon a patient or where an item is dispensed to a patient in a manner that is sufficient to meet the Medicare billing and coverage rules.

Comment: One commenter suggested that we should make clear that so long as the in-office ancillary services exception is met, discounts on drugs do not need to be passed on to Medicare.

Response: Nothing in section 1877 of the Act or these regulations is intended to require physicians to pass discounts on to the Medicare program. Whether a discount must be passed on to the program by physicians or others remains the subject of other statutory and regulatory provisions.

Comment: Commenters requested clarification that the furnishing of chemotherapy drugs can meet the in-office ancillary services exception. Commenters also sought clarification with respect to chemotherapy-related laboratory tests, x-rays, and prescription drugs that are secondary to the provision of chemotherapy.

Response: Chemotherapy infusion drugs and ancillary laboratory tests, x-rays, and prescription drugs are DHS for purposes of section 1877 of the Act that may be provided by physicians as in-office ancillary services if all of the conditions of the exception are satisfied. In light of the changes we are making in Phase I of this rulemaking—including revisions to the definition of "furnish" and to the supervision requirement in § 411.355(b)(5)—we believe the exception is sufficiently broad to accommodate virtually all existing arrangements for the provision of chemotherapy drugs and related services to patients in physicians' offices. Under Phase I of this rulemaking, referrals for chemotherapy infusion drugs may be protected by the in-office ancillary services exception if they are administered or dispensed to patients in the referring physician's office (or through the referring physician's group practice) in accordance with the supervision requirements already imposed by the Medicare program. We anticipate no appreciable disruption of chemotherapy services to Medicare or other patients as a result of Phase I of this rulemaking.

Comment: A commenter sought clarification whether the furnishing of allergen treatment sets would be protected under the in-office ancillary services exception.

Response: The provision of allergen treatment sets is protected by the in-office ancillary services exception so long as all of the conditions of the exception are satisfied. We believe that the changes in Phase I of this rulemaking to the definition of "furnish" in § 411.355(b)(5) and the supervision requirements make clear that allergen treatment sets may be furnished to patients under the in-office ancillary services exception.

Comment: A number of commenters questioned the scope of our proposed extension of the in-office ancillary services exception to include the

furnishing of crutches (DME being otherwise excluded by statute). The proposed extension would permit physicians to provide crutches if they make no profit on them and otherwise meet certain criteria. We proposed that the physician could bill only for the cost of acquiring and supplying the crutches. Commenters were confused as to how these costs would be determined and found the proposal to be unnecessarily restrictive. In addition, commenters wondered why crutches were included, but not canes, walkers, collars, splints, and the like. Other commenters variously sought inclusion of other DME, including DME for rheumatological conditions, orthopedic DME, and blood glucose monitors. Commenters suggested various measures for determining when DME should be permitted as an in-office ancillary service. One commenter proposed that whatever test we adopt should take into account the following: (1) the intended use of the item (that is, whether the item is an integral element in the customary continuum of patient care); (2) the cost of the item (that is, fair market value or a dollar cap); (3) the life-expectancy of the item (that is, whether items are limited to one-time prescriptions for 5 or 6 weeks); and (4) physician instruction (that is, whether some physician instruction in the use of the item is required). Other commenters proposed dollar caps as a means of excluding from the exception physician-directed sales of expensive wheelchairs, beds, and other pieces of equipment on which markups are significant.

Response: In the interest of patient convenience, we are using our regulatory authority under section 1877(b)(4) of the Act to expand the in-office ancillary services exception to include certain DME, including crutches, canes, walkers, and folding wheelchairs, that meet conditions set forth in the regulation (in our January 1998 proposed rule, we proposed a more limited exception for crutches only). (Braces and collars are classified as orthotics and already potentially qualify under the statute for the in-office ancillary services exception; splints are covered under section 1861(s)(5) of the Act and are not included in any category of DHS.) In doing so, we are concerned primarily with enabling the patient to depart from the physician's office. The narrow scope of this expansion and the fact that the need for ambulation equipment is objectively verifiable mitigate the potential for overutilization.

For somewhat different reasons, we are also creating an exception to permit blood glucose monitors (and one starter

set of testing strips and lancets, consisting of no more than 100 of each; this number is at least one month's supply) to be provided under the in-office ancillary services exception (under the authority granted in section 1877(b)(4) of the Act). In light of section 4105 of the BBA 1997, which added a Medicare benefit for diabetes self-management training services, we do not believe that the Congress intended the physician self-referral law to interfere with a physician's efforts to provide blood glucose monitors to patients. Therefore, the in-office ancillary services exception may be used by a physician or group practice to furnish a blood glucose monitor and a starter set of strips and lancets if the physician or group furnishes outpatient diabetes self-management training to patients for whom the blood glucose monitors are furnished.

While commenters sought the inclusion in this exception of various other items of DME, we decline to extend the in-office ancillary services exception further. To do so would, in essence, vitiate the congressional determination to exclude DME from the in-office ancillary services exception. We do not find—and we believe that the Congress did not find—that the in-office furnishing of other DME would pose no risk of fraud or abuse, as required under section 1877(b)(4) of the Act.

Having considered the various suggestions made by the commenters, we are adopting the following conditions for DME provided as an in-office ancillary service (these conditions being in addition to all other conditions of the exception):

- The item is one that a patient requires for the purposes of ambulating, uses in order to depart from the physician's office, or is a blood glucose monitor (including one starter set of test strips and lancets).
- The item is furnished in a building that meets the "same building" requirements in the in-office ancillary services exception as part of the treatment for the specific condition for which the physician-patient encounter occurred.
- The item is furnished personally by the physician who ordered the DME, by another physician in the group practice, or by an employee of the physician or the group practice.
- A physician or group practice that furnishes the DME meets all DME supplier standards located in paragraph (c) of § 424.57 (Special payment rules for items furnished by DMEPOS suppliers and issuance of DMEPOS supplier billing numbers).

- The arrangement does not violate the anti-kickback statute or any law or regulation governing billing and claims submission. (This condition is necessary to meet the "no risk of fraud or abuse" standard in 1877(b)(4) of the Act.)

- All other requirements of the in-office ancillary services exception are satisfied.

We agree with the commenters that our proposal with respect to not marking up costs was confusing and unnecessarily restrictive, and we are not adopting it. While we find the commenters' suggestions for dollar caps on DME items attractive, we have concluded that it is not feasible to devise dollar caps that would appropriately include low-value DME and exclude high-value DME in all cases (for example, a \$150 limit might be high for some types of DME and low for others). Upon further reflection, we believe the current DMERC reimbursement provisions provide sufficient cost containment controls, with respect to these items of DME we are including in the exception. We believe the modifications to the DME exclusion that we are making will promote quality of patient care without any significant increased risk of patient or program abuse.

Finally, we note with respect to DME furnished in physicians' offices that these arrangements remain subject to our conditions of participation for DME suppliers and other applicable payment and coverage rules.

Comment: A commenter asked that the final rule address whether the use of consignment closets as a means of providing DME in a physician's office implicates section 1877 of the Act. For example, a surgeon enters into an arrangement for a DME supplier to rent space (for example, a closet) in the surgeon's office at fair market value under a lease that meets the rental exception. The technician who measures for braces or DME supplies is a shared employee of the surgeon's practice and the supplier, with the supplier paying for the time the technician spends measuring the braces and supplying DME. The billing is done by the supplier. The commenter asserted that in this example, there is no financial relationship because the surgeon does not bill Medicare.

Response: If the lease fits squarely in the rental exception and the arrangement for the personal services of the technician fits squarely in the personal service arrangements exception, the "consignment closet" arrangement described in the preceding comment may not create a prohibited financial relationship under section

1877 of the Act. We wish to clarify that this result does not depend on whether the physician bills Medicare. To the contrary, the essential prohibition under section 1877 of the Act is on physicians making referrals to entities with which they have prohibited financial relationships and on those entities billing Medicare. Nothing in this rule is intended to, or should be interpreted as, legitimizing consignment closet arrangements. These arrangements raise significant questions under other legal authorities, including the anti-kickback statute and our supplier standards. Physicians and suppliers who are considering “consignment closet” arrangements would be well-advised to read the OIG’s Special Fraud Alert on the Rental of Physician Office Space by Persons or Entities to Which They Refer published in the **Federal Register** on February 24, 2000 (65 FR 9274).

Comment: One commenter expressed concern about the interaction of section 1877 of the Act and the proposed surety bond rule that would exempt physicians from the surety bond requirement if they provide DME incident to patient care. Specifically, the commenter asked whether we believe that physicians are allowed to disburse DME, orthotics, and prosthetics incident to patient care without violating the provisions of section 1877 of the Act and whether these provisions are applicable if a physician has a surety bond.

Response: Section 1877 requirements under the exception exist wholly apart from other requirements of law that may apply. In addition, the commenter is mistaken in asserting that we proposed to exempt physicians who furnish DME in their offices from the proposed surety bond requirements that would apply to all suppliers. We assume that the commenter is referring to our proposed rule concerning supplier standards that was published on January 20, 1998 (63 FR 2926). Such an exception is not included in the proposed rule.

Comment: Oncologists complained that the proposed regulations—which interpreted the in-office ancillary services exception as applying only to infusion pumps that are implanted in a physician’s office—would prohibit them from furnishing external ambulatory infusion pumps to their patients, contravening clear congressional intent and causing substantial inconvenience to patients. External ambulatory infusion pumps are used to administer chemotherapy agents and pain medication to cancer patients. The pumps are typically filled in the oncologist’s office, and the drug flow is ordinarily initiated before the patient leaves the office. The statutory in-office

ancillary services exception excludes DME (which typically is used by patients in their homes), but includes “infusion pumps.” Thus, the commenters asserted that the plain language of the exception indicates clear congressional intent to authorize physicians to furnish a certain category of DME—infusion pumps—to patients, even though those pumps will be used at home.

Response: We agree. The statute uses the general term “infusion pumps.” We are revising the regulation in § 411.355(b) to make clear that the in-office ancillary services exception protects external ambulatory infusion pumps (other than pumps that are PEN equipment or supplies) that are filled or serviced in the physician’s office, even though the patient uses them at home. However, the in-office ancillary services exception does not protect an infusion pump that is used to deliver PEN because that pump is not classified as DME, but is considered PEN. PEN is categorically excluded from the exception under section 1877(b)(2) of the Act. The statutory language addressing infusion pumps in the in-office ancillary services exception applies only to DME.

Comment: Two commenters requested clarification as to the application of the in-office ancillary services exception to home care physicians who primarily treat patients in their homes. These commenters asserted that home care physicians play an important role in the delivery of cost-effective, quality care to patients and provide services that, in some cases, preclude the need for more expensive hospitalizations. These commenters believe that section 1877 of the Act should not apply to home visits. In the alternative, these commenters requested clarification of the following issues:

- Are DHS performed in a patient’s home concurrently with the performance of a physician service included in the in-office ancillary services exception (for example, a physician uses a hand-held portable laboratory during a physician visit in the home)? Can a technician accompanying the physician perform the DHS during the home visit?
- What is the application of section 1877 of the Act to group practices that own home health agencies that in turn provide DHS to group patients?
- Are referrals from medical directors of home health agencies protected by the employee or another exception?

Response: We find nothing in the statute that excludes referrals for DHS by home care physicians from the reach of the statute. To the contrary, the

Congress expressly included home health services as a designated health service. That said, we generally agree with the commenters that the provision of DHS in a patient’s home should be protected by the in-office ancillary services exception, provided that all of the conditions of the exception are satisfied. However, in many cases, services provided by home care physicians will not fit neatly into the in-office ancillary services exception. For example, under the “same building” requirements, we are requiring that physicians provide substantial physician services unrelated to DHS in the building and that the services provided there be the full range of the physicians’ services. We believe that a home care physician meets these “same building” tests if his or her principal medical practice consists of treating patients in their private homes (for purposes of determining whether a physician is principally a home care physician, private homes do not include nursing, long term care, or other facilities), and the physician (or a staff member accompanying him or her) provides a designated health service in a private home contemporaneously with a physician service (provided by the referring physician) that is not a designated health service and the other exception requirements are met. (DHS provided in facilities, such as nursing homes, by home care or other physicians may qualify under the in-office ancillary services exception if all conditions of the exception are satisfied.) We have concluded that it may be appropriate to develop additional rules for home care physicians under the in-office ancillary services exception. We are expressly soliciting comments on this issue and will consider it further in Phase II of this rulemaking.

As to the commenter’s second question, section 1877 of the Act applies to a group practice’s ownership of a home health agency in the same manner it applies to the ownership by a group practice of any DHS entity. Referrals to the entity by the group practice or by members of the group must qualify under an ownership exception, such as the in-office ancillary services exception. In general, we do not believe that the furnishing of most home health services will meet the requirements of the in-office ancillary services exception. Unless a physician in the group personally conducts the home visit and provides a physician service unrelated to the furnishing of DHS, the “same building” requirements will not be satisfied (we see no plausible way for

home health services to qualify under the "centralized building" option under section 1877(b)(2)(A)(ii)(II) of the Act. In some cases, the "rural provider" exception may apply (that exception will be discussed in the Phase II rulemaking).

Finally, with respect to referrals from medical directors of home health agencies, these referrals may be protected by the employee exception or the personal service arrangements exception, depending on the facts and circumstances of the medical director's relationship with the home health agency. However, if the medical director is an owner of a group practice that owns the home health agency, an ownership exception would still need to apply.

Comment: A commenter sought clarification as to whether a referral to a physician spouse in another group practice, who subsequently orders a designated health service for the referred patient, could come within the in-office ancillary services exception. The commenter observed that there are many two-physician marriages in the health care industry and that many spouses engage in different specialties and practice in different group practices. The commenter argued that the referrals between physician spouses to each other's group practices should not constitute prohibited referrals, so long as either the referring physician or the physician spouse accepting the referral complies with an exception. In our January 1998 proposed rule, we took the position that a physician in one group practice will be prohibited from referring to his or her physician spouse in another group practice because the referring physician cannot meet the in-office ancillary services exception. The commenter found this interpretation overly restrictive and narrow. In the commenter's view, if the physician receiving the referral meets the in-office ancillary services exception, he or she should be able to accept the referral, because the accepting spouse and not the referring spouse is ordering the designated health service.

Response: On reconsideration, we generally agree with the commenter, with one important distinction. We believe that the referral to a spouse should be allowed, if the referral is for a physician service unrelated to the furnishing of a designated health service (that is, a designated health service is not the reason for the referral) and any subsequent DHS referrals by the spouse fit within the in-office ancillary services exception with respect to the spouse receiving the referral. We recognize that there may be some circumstances,

particularly in underserved areas, where a spouse may be the *only* qualified provider of a particular DHS. We are considering whether a limited additional exception is warranted and will address the issue further in Phase II of this rulemaking. We invite comments on this issue.

2. Direct Supervision

The Existing Law: Section 1877(b)(2) of the Act 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 member in the same group practice, or be furnished by individuals who are "directly supervised" by the referring physician or another physician in the group practice. The August 1995 final rule covering referrals for clinical laboratory services defined "direct supervision" in § 411.351 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.

The Proposed Rule: The January 1998 proposed rule retained this definition, with several clarifications and changes. In the preamble to the January 1998 proposed regulation, we expressed our view that the Congress intended the in-office ancillary services exception to apply to services that are closely attached to the activities of the referring physician. Consistent with this interpretation, we used the definition of "direct supervision" that appears in section 2050, "Services and Supplies," of the Medicare Carriers Manual (HCFA Pub. 14-3), Part 3—Claims Process, which describes services that are incident to a physician's professional services under section 1861(s)(2)(A) of the Act. Under this rule, supervision must be provided 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 who is immediately available to provide assistance and direction. The definition in the proposed rule also clarified the meaning of the term "present in the office suite" to mean that the physician is actually physically present. However, we would still have considered the physician "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.

The Final Rule: Our interpretation of the "direct supervision" standard produced the largest number of public comments about the in-office ancillary services exception, virtually all suggesting that our proposal would be overly burdensome, result in enigmatic technical rules, and require wasteful and inefficient practices.

We have revisited the direct supervision requirement and are now interpreting "directly supervised" in the statute to mean that the supervision meets the supervision requirements under applicable Medicare and Medicaid payment or coverage rules for the specific services at issue. Upon further review and consideration, we concluded that the Congress did not use the phrase "directly supervised" in any technical sense. Rather, the Congress sought to establish a nexus between the referring physician and the individual performing the ancillary services in order to limit the exception to services that are truly "ancillary" to the referring physician's medical practice. We believe that the Congress did not intend section 1877 of the Act to supersede or replicate existing statutory and regulatory structures that address supervision of services from the perspective of quality of care or patient safety. This interpretation is consistent with the often cited legislative history for section 1877 of the Act indicating that the Congress did not intend to require physicians to be present at all times that ancillary services were being performed. (*See* Conference Report for OBRA 1993, H. Rep. No. 213, 103d Congress 810 (1993).) Instead, we believe a sensible approach is to defer to existing Medicare and Medicaid supervision requirements. (Those rules are not addressed in Phase I of this rulemaking.)

In our January 1998 proposed rule with respect to the group practice definition, we proposed eliminating independent contractors as members of the group practice. This created the prospect that independent contractors would not be able to provide the supervision required under the in-office ancillary services exception. The statute provides that physicians "in the group practice" may supervise the furnishing of ancillary services to patients of a referring physician who is a member of the group practice. Under Phase I of this rulemaking, physicians "in the group practice" include owners of the group practice, employees of the group practice, and independent contractors who are "in the group practice." Owners and employees may also be

members of the group; independent contractors may not. We will consider an independent contractor physician to be "in the group practice" if he or she has a contractual arrangement to provide services to the group's patients in the group practice's facilities and the independent contractor's arrangement with the group complies with the reassignment rules in § 424.80(b)(3) of these regulations and in section 3060.3, "Payment to Health Care Delivery System," of the Medicare Carriers Manual (HCFA Pub. 14-3), Part 3—Claims Process. Independent contractors who qualify as physicians "in the group practice" may receive overall profit shares and productivity bonuses described in section 1877(h)(4)(B)(i) of the Act, as implemented by these regulations, and may provide the supervision required under the in-office ancillary services exception.

Comment: Many commenters raised concerns about the level of supervision required under the in-office ancillary services exception. Many commenters objected to our proposed interpretation of the direct supervision requirement, which would have adopted the supervision requirement applicable to "incident to" services in section 2050, "Services and Supplies," of the Medicare Carriers Manual (HCFA Pub. 14-3), Part 3—Claims Process, including a "present in the office suite" requirement, with an exception for brief absences by the physician. These commenters variously found the "presence" requirement overly burdensome, impractical, confusing, and unclear. Commenters believe that a general requirement of a physician's physical presence for all ancillary services would create unnecessary inefficiencies in the delivery of health care services, drive up costs, and inconvenience patients. For example, some commenters noted that tests are often scheduled in the mornings when physicians are making rounds or attending hospital meetings, with the physicians interpreting the tests when they arrive later at the office. Some commenters observed that they could discern no obvious connection between direct supervision and curtailing fraud and abuse. Others noted that a strict direct supervision requirement does not guarantee that DHS are medically appropriate and are not simply being performed for financial gain.

Commenters suggested various alternative standards, including "appropriate supervision," "professional responsibility," "general supervision," and "employee status." The vast majority of commenters, however, urged that the in-office

ancillary services exception "direct supervision" requirement be interpreted to comport with the applicable supervision requirements under our other payment and coverage rules. These commenters stressed that these rules adequately take into account quality concerns and the health and safety of patients and that there is no justification for imposing an additional layer of supervision requirements.

Response: Upon further review and consideration of the statute, the legislative history, and the public comments, we have concluded that the Congress did not use the phrase "directly supervised" in any technical sense in the statute. Rather, we believe the Congress sought to establish a nexus between the referring physician and the individual performing the ancillary services in order to limit the exception to services that are truly "ancillary" to the referring physician's medical practice. We believe that the Congress did not intend section 1877 of the Act to supersede or replicate existing statutory and regulatory structures that address supervision of services from the perspective of quality of care or patient safety. This interpretation is consistent with the often cited legislative history indicating that the Congress did not intend in the context of section 1877 of the Act to require physicians to be present at all times that ancillary services were being performed ("The conferees intend that the requirement for direct supervision by a physician would be met if the lab is in the physician's office which is personally supervised by a lab director, or a physician, even if the physician is not always on site" (H. Rep. No. 213, 103d Cong. 810 (1993)). We are persuaded that a more sensible approach is to defer to existing Medicare and Medicaid supervision requirements. (Those rules are not addressed in Phase I of this rulemaking.) Thus, the in-office ancillary services exception supervision requirements will be satisfied if the level of supervision provided meets all applicable Medicare or Medicaid payment and coverage requirements.

Comment: One commenter viewed the strict "direct supervision" standard established in the August 1995 final rule as an important check on inappropriate referrals and objected to any liberalization of the requirement, arguing that it would allow the connection between a physician's activities and DHS to "grow too thin." The commenter believes it is appropriate for us to impose higher standards of care to protect patients who are referred for DHS, because these services have been determined to

present a particularly high risk of inappropriate referrals. The commenter further noted that as the health and safety rationale for supervision declines (supervision being less necessary for certain low-risk services), the risk of unnecessary referrals and overutilization increases. The commenter recommended that we retain the "incident to" direct supervision standard. In the alternative, the commenter proposed a "sphere of service" test under which a physician would be allowed to refer a patient for services only if that physician, and not another licensed practitioner, normally would perform the services. According to the commenter, this approach would eliminate physician incentives to establish "backroom" practices to provide services that could be provided more efficiently elsewhere.

Response: We share this commenter's concerns about inappropriate financial incentives driving the provision of DHS. We are concerned that heightened downward pressure on physician incomes will generate increased upward pressure to expand in-office ancillary services as a means of offsetting income losses. However, we believe the Congress clearly articulated a policy determination to allow in-office ancillary services that meet certain statutory criteria. While the stricter "incident to" supervision standard might serve to reduce the risk of overutilization somewhat, on balance, we believe that using section 1877 of the Act to superimpose a separate supervision requirement on existing regulatory structures governing appropriate levels of supervision would be overly burdensome, inefficient, and inconsistent with the overall design of the statute. We note, however, that physicians wishing to bill DHS "incident to" (and group practice physicians wishing to obtain productivity bonuses for services incident to their personally performed physician services) must comply with the "incident to" supervision requirements, including the "present and available" requirement and the employee requirement, as set forth in section 2050, "Services and Supplies," of the Medicare Carriers Manual (HCFA Pub. 14-3), Part 3—Claims Process.

Comment: One commenter asked whether technicians must be directly supervised if a group practice provides technician services to a hospital. If so, the commenter requested that we clarify whether the group practice must follow self-referral supervision standards or hospital supervision standards.

Response: If a hospital is billing for the services, as this commenter implied,

the in-office ancillary services exception does not apply (along with its supervision requirement). Any hospital standards would always apply, since any requirement for supervision under section 1877 of the Act is separate and distinct from other supervision requirements under the Medicare and Medicaid statute and regulations.

Comment: While many commenters approved of our proposal to exclude independent contractors as members of a group practice for purposes of complying with the definitional tests for a group practice (making it easier for many groups, especially smaller groups, to qualify as a group practice for purposes of section 1877 of the Act), many commenters also urged that independent contractors be included as members of a group practice for purposes of the direct supervision requirement of the in-office ancillary services exception. Many commenters expressed concern that our bar on direct supervision by independent contractors would undercut the ability of group practices to deliver necessary health care services in situations in which employment of the physician is not possible or desirable. To support their claim that the statute does not require that the direct supervision be provided by a "member" of the group, commenters observed that section 1877(b)(2)(A)(i) of the Act only requires supervision "by the [referring] physician or by another physician in the group." One commenter noted that this language is consistent with section 3060.3, "Payment to the Health Care Delivery System," of the Medicare Carriers Manual (HCFA Pub. 14-3), Part 3—Claims Process, which treats independent contractors as "in the group" for reassignment purposes. Another commenter suggested that an independent contractor could properly be considered "in the group" if the physician provides services to the group practice's patients in the group practice's facility under a contract with the group, and the services are billed by the group.

Response: Having reviewed the comments and reconsidered the statutory language, we are persuaded that independent contractors may be physicians "in the group" for purposes of the in-office ancillary services exception. We are considering an independent contractor physician to be "in the group practice" if (1) he or she has a contractual arrangement to provide services to the group's patients in the group practice's facilities, (2) the contract contains compensation terms that are the same as those that apply to group members under section

1877(h)(4)(iv) of the Act or the contract fits in the personal services exception, and (3) the contract complies with the reassignment rules at § 424.80(b)(3) of these regulations and in section 3060.3, "Payment to the Health Care Delivery System," of the Medicare Carriers Manual (HCFA Pub. 14-3), Part 3—Claims Process, so that his or her services are billed by the group practice. We are codifying this new test in § 411.351 of the regulations. This latter requirement presents a technical problem under the plain language of the statute, which we address as follows. The billing requirements under section 1877(b)(2)(B) of the Act do not provide for billing by the group practice when a supervising physician is "a physician in the group practice," rather than a member of the group. Given the statutory structure and language, particularly the language of the direct supervision requirement under section 1877(b)(2)(A)(i) of the Act, we are interpreting the billing requirements to extend to billing by the group practice when the supervising physician is "in the group practice" in order to effectuate the direct supervision requirement. Independent contractors who qualify as "physicians in the group practice" may receive overall profit shares and productivity bonuses described in section 1877(h)(4)(B)(i) of the Act, as implemented by these regulations. As discussed in section VI.C.3 of this preamble, independent contractors are not "members" of the group.

Comment: Several commenters sought clarification with respect to the application of the in-office ancillary services exception to referrals for DHS from an independent contractor to the group practice with which he or she contracts (for example, referrals from an independent contractor to the group's in-office laboratory).

Response: Independent contractor physicians will have compensation relationships with the group practices with which they contract. In order for an independent contractor to refer DHS to the group practice, an exception must apply. Possible exceptions, depending on the circumstances, include the in-office ancillary services exception for independent contractors who are "physicians in the group", the physicians' services exception, the personal service arrangements exception, or the risk-sharing exception for services provided to certain managed care enrollees. We note that under the in-office ancillary services exception, the furnishing of DHS would have to take place in a "same building" location under section 1877(b)(2)(A)(ii)(I) of the

Act, as the "centralized building" provision (section 1877(b)(2)(A)(ii)(II) of the Act) only applies to referring physicians who are group members.

Comment: Several practitioners of ultrasonography commented that a direct supervision requirement that mandates physician presence for in-office ancillaries unfairly benefits radiologists, who are generally available on-site because they do not have "patients" to see or other responsibilities, while disadvantaging vascular laboratories that operate without physicians on-site. The commenters suggested that the rule require that ultrasound examinations and interpretations be performed in accordance with standards set by independent professional associations. However, another commenter—radiologist—urged us to retain the direct supervision requirement in the interest of patient health and safety.

Response: As noted above, we are modifying the direct supervision requirement under the in-office ancillary services exception to apply the requisite supervision requirements under Medicare and Medicaid payment and coverage rules.

3. The Building Requirements

The Existing Law: Under section 1877(b)(2)(A)(ii) of the Act, in-office ancillary services must be furnished in 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 DHS. Alternatively, in the case of a referring physician who is a member of a group practice, the in-office ancillary services can be furnished in another building that is used by the group practice for the provision of some or all of the group's clinical laboratory services, or for the centralized provision of the group's DHS (other than clinical laboratory services). (The existing regulations address the same and other building requirements only with respect to clinical laboratory services.)

The Proposed Rule: In our January 1998 proposed rule, we proposed defining the "same building" in § 411.355(b)(2)(i) as the same physical structure, with one address, and not multiple structures connected by tunnels or walkways.

The Final Rule: The building requirements are designed to ensure that the DHS qualifying for the exception are truly "in-office" (that is, part of the physician's routine medical office practice) and not provided as part of a separate business enterprise. The location requirements do not pertain to

the furnishing of DHS that are not payable by Medicare or Medicaid; these services may be furnished anywhere, subject to any restrictions in other applicable Federal, State, or local laws.

In general, the structure of the statutory language suggests that the Congress had two main objectives: permitting the provision of in-office ancillary services for the convenience of patients during their patient visits and, in the group practice context, permitting the provision of in-office ancillary services in a dedicated building used for these services (for example, a central clinical laboratory). By contrast, we believe the Congress did not intend to protect part-time rentals of ancillary services facilities under this exception.

Upon further consideration, we believe that the Congress did not intend the application of the in-office ancillary services exception to turn on the nuances of architectural design. Thus, for purposes of Phase I of this rulemaking, a "building" is defined as a structure with, or combination of structures that share, a single street address as assigned by the U.S. Postal Service. For purposes of this rule, the "same building" does not include exterior spaces, such as courtyards, lawns, driveways, or parking lots, or interior parking garages. The building could include a SNF or other facility or a patient's home, provided all other conditions of the exception are satisfied. A mobile van or trailer is not a building or a part of a building.

The statute implements congressional intent by offering two location options: the "same building" option, available to solo practitioners and group practices, and the "centralized building" option, available only to groups. (See section 1877(b)(2)(A)(i)(I) and (b)(2)(A)(ii)(II) of the Act.)

"Same Building"

Under section 1877(b)(2)(A)(i)(I) of the Act, services qualify for the in-office ancillary services exception if they are furnished "in 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." We believe the underlying intent of this provision is to allow physicians to furnish DHS that are ancillary to the physician's core medical practice in the location where the core medical services are routinely delivered. We believe the Congress did not intend to permit the wholesale provision of DHS in locations in which physicians perform only token services that are not related to the furnishing of DHS (that is, only token physician

services that are not Federal or private pay DHS). Simply stated, the DHS should be ancillary to physician services that are not DHS, and not the other way around. The exception was intended as an accommodation to physicians' customary practice of medicine and not as a loophole for physicians and group practices to operate DHS enterprises that are unconnected—or only marginally connected—to their medical practices. In addition, the significant easing of the "direct supervision" requirement described above necessitates a somewhat stricter interpretation of the location standards than we proposed in our January 1998 proposed rule, in order to ensure an adequate nexus between in-office ancillary DHS and the physician's core medical practice. Thus, we are making the following changes (except where noted) in the "same building" requirements:

- In our January 1998 proposed rule, we proposed interpreting the rule as allowing any quantity of services unrelated to DHS to be furnished in the same building. We are revising the rule to require that the referring physician (or another physician who is a member of the same group practice) must furnish in the same building *substantial* physician services unrelated to the furnishing of Federal or private pay DHS. We are defining the phrase "services unrelated to the furnishing of designated health services" to mean physician services that are neither Federal nor private pay DHS, even if the physician service leads to the ordering of DHS. In addition, to preclude single-service DHS enterprises from the in-office ancillary services exception, we are requiring that the unrelated physician services furnished in the building represent substantially the full range of physician services unrelated to the furnishing of DHS that the physician routinely provides (or, in the case of a member of a group practice, the full range of physician services that the physician routinely provides for the group practice).

- We are adding a requirement that the DHS furnished in the building be furnished to patients whose primary nexus with the referring physician (or his or her group practice) is the receipt of physician services unrelated to the furnishing of DHS. Simply stated, obtaining DHS should not be the main reason the patient has contact with the referring physician (or his or her group practice). Again, this standard will ensure that self-referred DHS are ancillary and not primary services for the patients who receive them. Thus, for example, a physician who provides

physician services and DHS for his or her patients in a nursing home may not also provide token physician services to other nursing home patients in order to provide DHS under the in-office ancillary services exception.

- The space in the building in which the DHS are provided need not be adjacent to the space in which services that are not DHS are provided (subject to the dictates of any Medicare or Medicaid payment or coverage supervision rules).

- Shared facilities in the same building are permitted to the extent they comply with the supervision, location, and billing requirements of the in-office ancillary services exception; we are not, however, creating a broader shared-facility exception.

- We believe that a home care physician whose principal medical practice consists of treating patients in their private homes meets the "same building" requirements if the physician (or a staff member accompanying the physician) provides a designated health service contemporaneously with a physician service (provided by the referring physician) that is not a designated health service in the patient's private home and the other exception requirements are met. Because the location requirements of the in-office ancillary services exception may disadvantage home care physicians, we are considering whether special rules should be developed under the "same building" requirements for physicians who primarily practice as home care physicians. We are soliciting comments on that issue and intend to address it further in Phase II of this rulemaking.

"Centralized Building"

Under section 1877(b)(2)(A)(ii)(II) of the Act, in the case of a referring physician who is a member of a group practice, services qualify for the in-office ancillary services exception if they are furnished "in another building which is used by the group practice * * * for the provision of some or all of the group's clinical laboratory services, or * * * for the centralized provision of the group's designated health services (other than clinical laboratory services)." We believe that this statutory provision—which allows group practices to have "off-site" DHS locations—was intended to accommodate the concerns of group practices with multiple office locations that wanted to consolidate DHS operations for cost containment purposes. However, in permitting group practices to provide centralized DHS, the Congress did not intend to

eviscerate the “in-office” element of the exception. We are therefore interpreting the “centralized building” standard as follows:

- The space (whether an entire building, subpart of a building, or mobile unit) used for the provision of the group practice’s clinical laboratory services or centralized DHS qualifies for the exception only if it is used *exclusively* by the group, that is, it is wholly owned by the group practice or leased by the group practice on a full-time basis (that is, 24 hours per day, 7 days per week). To preclude part-time arrangements in the form of one-day rentals, we are requiring that the centralized building be owned or leased exclusively by the group practice for at least 6 months. This rule precludes facilities shared by group practices in off-site buildings.

- Part-time “centralized” DHS arrangements are precluded. For example, a group practice may not rent a magnetic resonance imaging (MRI) facility 1 day per week and treat that facility as a “centralized” building under section 1877(b)(2)(A)(ii)(II) of the Act.

- Under the authority granted to the Secretary in the unnumbered paragraph that follows section 1877(b)(2)(A)(ii)(II)(bb) of the Act (that allows the Secretary to determine other terms and conditions related to section 1877(b)(2)(A)(ii)(II)(bb) under which the provision of DHS does not present a risk of program or patient abuse), we are determining that a mobile facility (for example, an x-ray van) owned and used *exclusively* by a group practice (24 hours per day, 7 days per week, for at least six months) will be considered to meet the “centralized building” standard, even though a mobile facility is not a building.

- Group practices may lease or sublease DHS facility space (including mobile units) to or from other group practices or solo practitioners on a part-time basis, but DHS provided to patients of part-time lessee or sublessee group practices will not fit in the in-office ancillary services exception, unless the “same building” requirements are met.

- Referrals for ancillary services from other physicians or group practices that are not affiliated with the group practice providing the DHS do not implicate section 1877 of the Act, provided there are no impermissible financial relationships between the parties. A referral for a designated health service does not create a financial relationship.

These building rules are designed to give physicians and group practices a meaningful opportunity to provide *bona fide* in-office ancillary DHS to their

patients, while preventing group practices from using the in-office ancillary services exception to operate enterprises that are functionally nothing more than self-referred DHS enterprises, providing minimal services that are not DHS so as to comply nominally with the exception and capture DHS profits. We believe the Congress did not intend the exception to include these operations. Far from promoting patient convenience and quality of care, these arrangements pose a significant risk of overutilization of services and shuttling of patients to DHS locations for the economic betterment of the physicians, without regard to the patient’s best interests.

Comment: Many commenters found the proposed regulations and interpretations of the “building” requirements to be confusing, over broad, potentially contradictory, and, in the words of one commenter, “metaphysical.” With respect to our proposed “physical structure” requirements, many commenters urged us not to place the agency or physicians into surveying real estate to determine whether a structure is one building. Commenters variously observed that while some walkways or tunnels between commercial medical office buildings may be sidewalks between distinct and separate buildings, other walkways or tunnels are part of the modern architecture of these buildings or are required to comply with zoning, land use, open space, or other real estate laws or to surmount natural barriers present on the site of the building.

There were a number of suggestions for revising the requirement. One group of commenters urged us to adopt a mailing address rule stating that a building would be considered as one building for all suites or room numbers located inside that are required by the U.S. Postal Service to use the same street address, regardless of suite number. Under this rule, suites operated by the same group practice or solo physician in buildings that use separate street addresses would be treated as separate buildings for the purposes of the in-office ancillary services exception. Other commenters objected to a street address test, noting that physicians have no control over the manner in which their buildings are assigned street addresses and that the parameters for assigning street addresses may vary by State and locality. One commenter expressed concern about buildings located on corner lots that might have two street addresses.

A second approach proposed by one commenter was to revise the regulations to allow connected buildings or portions of buildings that are owned or

controlled by the same group practice. Still other commenters claimed that the emphasis should be on the proximity of the supervising physician to the patient during the performance of DHS. Under this view, the location requirement of the in-office ancillary services exception should focus on whether the physician is “immediately available” to the support personnel and not on an artificially imposed physical design constraint. Along these lines, several commenters proposed that services be considered in the “same building” if the physician is within a certain number of minutes (for example, 10 minutes) from the patient or if the physician is “close at hand.”

Response: We regard the building requirement of the in-office ancillary services exception, in combination with the supervision and billing requirements, as the Congress’s attempt to circumscribe the exception so that it applies only to services provided within the referring physician’s actual sphere of practice. Without these requirements, physicians could refer to, and profit from, almost any entity, with the claim that somehow the referred services are “in-office” services that are being supervised from some remote place.

Notwithstanding, we realize that our proposed definition of a “building”—which attempted to define a building in architectural terms—could cause practical problems for some physicians and that a clearer, “bright line” rule would be preferable. Accordingly, having considered the various alternatives suggested by the commenters, we have concluded that for purposes of Phase I of this rulemaking, we are defining a “building” as a structure with, or combination of structures that share, a single street address as assigned by the U.S. Postal Service. A building will be considered as one building for all suites or room numbers located inside that are required by the U.S. Postal Service to use the same street address, regardless of the suite number. Under this rule, suites used by the same group practice or solo physician in buildings with separate street addresses will be treated as separate buildings for the purposes of the in-office ancillary services exception. While we recognize that this mailing address rule may result in an occasional anomaly, we are persuaded that it creates a “bright line” rule that will be easy to apply and will produce fair results in the vast majority of cases. Questionable cases may be appropriate candidates for an advisory opinion.

The space in the building in which the DHS are provided need not be adjacent to the space in which services

that are not DHS are provided (subject to the dictates of any Medicare or Medicaid payment or coverage supervision rules). Shared facilities in the same building are permitted under section 1877 of the Act to the extent they comply with the supervision, location, and billing requirements of the in-office ancillary services exception; we are not creating a broader shared facility exception.

Because of the increased risk of abuse, we do not intend to protect DHS provided by mobile vans or other mobile facilities under the in-office ancillary services exception, except in very limited circumstances described in section VI.B.3 of this preamble. Thus, we wish to make clear that for purposes of this rule, a "building" does not include exterior spaces, such as courtyards or parking lots, nor does it include interior parking garages. For purposes of the in-office ancillary services exception, a building consists of usable professional office space and common areas such as lobbies, corridors, elevator banks, and restrooms.

In light of the changes we are making in the supervision standard, we believe it is necessary to revisit the building standards in order to effectuate congressional intent to limit the scope of the in-office ancillary services exception to services that are truly ancillary to physician services and are not a primary business of the practice. Thus, we are revising the "same building" requirements to more definitively tie in-office ancillary services to the referring physician's core medical practice. Simply stated, we want to ensure that services covered by the exception are, in fact, furnished "in office." Under section 1877(b)(2)(A)(ii)(I) of the Act, services qualify for the in-office ancillary services exception if they are furnished "in a building in which the referring physician (or another physician who is a member of the same group practice) furnishes physicians' services unrelated to the furnishing of designated health services." We believe the underlying intent of this provision is to allow physicians to furnish DHS that are ancillary to the physician's core medical practice in the location where the core medical practice occurs. We believe the Congress did not intend to permit the wholesale provision of DHS in locations in which physicians perform only token services unrelated to the furnishing of DHS. Thus, we are interpreting the "same building" requirements as follows:

- The referring physician (or another physician who is a member of the same group practice) must furnish in the same

building *substantial* physician services unrelated to the furnishing of DHS. In addition, we are requiring that the unrelated physician services furnished in the building represent substantially the full range of physician services unrelated to the furnishing of DHS that the physician routinely provides (or, in the case of a member of a group practice, the full range of physician services that the physician routinely provides for the group practice). Independent contractors are not members of a group practice for purposes of section 1877 of the Act; thus, their activities do not count for purposes of compliance with the substantial physician services test or the full range of services test under the "same building" requirements, unless they are the referring physician. (See discussion in section VI.B.3 of this preamble.)

- For purposes of this exception, we are defining the phrase "services unrelated to the furnishing of designated health services" to mean physician services that are neither Federal nor private pay DHS, even if the services might generate orders or referrals of DHS. Thus, for example, a cardiologist who examines a patient and thereafter orders a diagnostic radiology test has performed a service unrelated to the furnishing of DHS. On the other hand, a cardiologist who reads the results of a diagnostic radiology test (such as, for example, a transthoracic echocardiography for congenital cardiac anomalies, CPT code 93303) (whether for a Federal or private pay patient) has performed a service that is related to the furnishing of DHS.

- The DHS furnished in the building are furnished to patients whose primary nexus with the referring physician (or the group practice of which the referring physician is a member) is the receipt of physician services unrelated to the furnishing of DHS. Thus, for example, a physician who provides physician services and DHS for his or her patients in a nursing home may not also provide token physician services to other nursing home patients in order to provide those services under the in-office ancillary services exception.

Comment: One commenter believes that our proposed interpretation of the "same building" requirements contradicts the purpose of section 1877(b)(2)(A)(ii) of the Act. The commenter focused on the part of this provision that requires that ancillary services be furnished in a building "in which the referring physician * * * furnishes physicians' services unrelated to the furnishing of designated health services." The proposed rule regarded a

physician's examination and diagnosis of a patient that leads to the physician requesting a designated health service as acts that are "unrelated to the furnishing of designated health services." The commenter is concerned that this interpretation would allow a physician's office to be a single specialty "mill" in which the physician could quickly generate a large quantity of referrals for profit. In other words, the exception could apply to a physician who does little more than conduct cursory evaluations and refer patients for a particular designated health service (for example, physical therapy). The commenter believes that, instead, the physician's office is meant to be a location in which the physician provides *bona fide* diagnostic and curative services to individuals presenting a variety of conditions.

Response: We share the commenter's general concern about inappropriate DHS arrangements, although we believe that the statute does not require us to include in the in-office ancillary services exception only services referred by physicians who treat a variety of conditions. The focus of the exception, in our view, is the requirement that the services be provided or performed in conjunction with a physician's own professional activities or as adjuncts to physician services, in a location in which the physician (or a member of his or her group practice) practices. If we were to limit this exception as the commenter suggested, some physician specialists might be prohibited from referring within their own practices. On the other hand, we agree that some restriction in the definition is appropriate to preclude physicians from providing virtually nothing more than referrals for DHS. Thus, as discussed above, in Phase I of this rulemaking, we are requiring that the unrelated physician services furnished in the building represent substantially the full range of physician services unrelated to the furnishing of DHS that the physician routinely provides (or, in the case of a member of a group practice, the full range of physician services that the physician routinely provides for the group practice).

Comment: Several commenters believe that our proposal to have our regional carriers determine whether the building requirements are satisfied was unworkable and impractical and would result in inequitable application of the law. Commenters noted that local carriers are often reluctant to express opinions on these issues and disinclined to provide written opinions. If the proposal survives, one commenter urged us, at a minimum, to give carriers

explicit authority and direction to issue these written opinions.

Response: We have endeavored to develop regulations that provide sufficiently clear rules so that parties can determine compliance without resorting to a regional carrier's determination.

Comment: A commenter expressed concern about DHS performed by physicians who travel to see patients. The commenter is a physician in a group practice of six physiatrists who perform electromyography and nerve conduction studies in a midwestern State. The group travels to rural counties in the State in which it practices to evaluate patients for musculoskeletal and neurologic problems. The patients often need nerve testing, and the group's physiatrists are often the only health care professionals in the county able to perform this testing. The commenter expressed concern that the regulations would prohibit the physiatrists from providing needed medical assessment and care to patients in these circumstances.

Response: Electromyography and nerve conduction studies are not physical therapy services under our definition in § 411.351; therefore, referrals for these services do not implicate section 1877 of the Act. Nonetheless, we wish to address the commenter's underlying question regarding traveling practitioners. Assuming that the physiatrist group meets the definition of a group practice under section 1877(h)(4) of the Act and the DHS are performed in the same building where the physiatrist (or a member of the group) also performs substantial physician services unrelated to the furnishing of Federal or private pay DHS, we believe the in-office ancillary services exception may apply in the situation described by the commenter. As noted elsewhere, we are soliciting comments on problems faced by physicians who principally practice in patients' homes and may be disadvantaged by the location requirements of the in-office ancillary services exception. We note also that the rural provider exception (to be addressed in Phase II of this rulemaking) may apply in the situation described by the commenter.

Comment: A commenter asked that we make clear that if a solo practitioner provides a designated health service for his or her own patients in the solo practitioner's own office, then the solo practitioner is not in violation of section 1877 of the Act.

Response: In the vast majority of situations we can envision, if a solo practitioner provides a designated

health service for his or her own patients in the solo practitioner's own office, then the solo practitioner will not violate section 1877 of the Act. First, we are revising the definition of a "referral" for purposes of section 1877 of the Act to exclude DHS personally performed by the referring physician. Second, with respect to DHS performed by employees of the solo practitioner (including "incident to" services), we believe the Congress intended for the in-office ancillary services exception to apply to solo practitioners as well as group practices. Thus, so long as a solo practitioner's provision of DHS meets the in-office ancillary services exception, section 1877 of the Act would not be violated.

Comment: Commenters were divided about the provision of ancillary services through mobile units. Some believe that the use of mobile units and equipment leads to abusive arrangements. Other commenters supported the use of mobile units as cost-efficient means of sharing expensive DHS resources, particularly in rural areas. One commenter noted that State certificate of necessity (CON) volume requirements would be nearly impossible to meet without mobile units. The same commenter argued that sharing equipment is a critical part of cost containment, because idle equipment may lead to overutilization. One commenter pointed out that Federal antitrust agencies approve joint ownership of high technology equipment and that Blue Cross/Blue Shield has many policy provisions requiring joint ownership. These commenters generally advocated that mobile units be permitted and that mobile units qualify as a centralized location for the provision of DHS. A commenter observed that under the January 1998 proposed rule, a group practice could move any piece of equipment from office to office and, applying the "same building" requirements, use that piece of equipment for the provision of DHS. In light of this, the commenter questioned whether it made sense for the group practice to be prohibited from transporting the piece of equipment in a mobile vehicle to the various practice sites and using the equipment in the vehicle, if the mobile unit were exclusively used by the group practice and is not leased to any other health care provider. The commenter requested clarification that in these circumstances, the mobile unit would meet either the "same building" requirements or "centralized building" standard. Other commenters urged a broader exception

for mobile units, for example, including them if they are parked in the parking lot of a physician's medical office building or treating the units themselves as buildings.

Response: The treatment of mobile units presents difficult questions under section 1877 of the Act. On the one hand, we have serious concerns about the potential for fraud and abuse when services are provided with mobile units. These are the same concerns we have (and believe the Congress shares) about all shared physician-owned or controlled ancillary services facilities. We believe that section 1877 of the Act is aimed at arrangements that enable physicians to profit from referrals to free-standing, money-making services ventures that are not central to their medical practices. On the other hand, we agree that the statute clearly permits services provided by mobile units that qualify under the "same building" requirements. Thus, we agree with the commenter that a group practice can move any piece of equipment from office to office and use that "in-office" piece of equipment for the provision of DHS in a location that meets the "same building" requirements. Because we are defining "building" narrowly to exclude parking lots and interior parking garages, services provided in mobile vans or trailers will not comply with the "same building" requirements. We believe it reasonable to conclude that these services are not "in-office" when a van circulates among various physicians' offices and is rented serially by each. These arrangements would seem to be calculated to enhance physician revenues, rather than patient convenience, since patients would likely be encouraged, if not required, to schedule appointments on the day that the physician stands to profit from the services.

That said, we believe that mobile services can constitute an important part of the health care delivery system for many patients. Nothing in the statute or these regulations precludes a physician or group practice from arranging for a mobile provider to treat the physician's patients at his or her office location, so long as the financial arrangement, if any, between the physician or group practice and the ancillary services provider fits in an exception under section 1877 of the Act. In addition, in rural areas, the "rural provider" exception (to be addressed in Phase II of this rulemaking) may apply to protect some physician-owned mobile service providers. Finally, we are persuaded that the risk is low if a group practice exclusively owns and uses its own mobile van or trailer that

circulates among its group practice locations. In that limited circumstance, we are treating the mobile unit as akin to a "centralized" building under section 1877(b)(2)(A)(ii)(II) of the Act.

Comment: Several commenters sought clarification in the regulations text that group practices can have more than one centralized location for the provision of DHS. However, one commenter offered a contrary view. This commenter expressed the view that the Congress intended that the in-office ancillary services exception be interpreted narrowly with respect to centralized, free-standing locations. Specifically, the commenter cites the Conference Report for OBRA 1993 in H. Rep. No. 213, 1st Sess., 810 (1993), which states: "The conference agreement includes an exception for clinical laboratory services provided by a group practice with multiple office locations. For all other DHS the exception for group practices applies only if the services are provided in a centralized location" (emphasis added). Based on this language, the commenter believes that the Congress intended to permit group practices to have a single centralized location to provide DHS, but not to permit group practices to establish multiple wholly owned locations or franchises for DHS.

Response: Under section 1877(b)(2)(A)(ii)(II) of the Act, in the case of a referring physician who is a member of a group practice, services qualify for the in-office ancillary services exception if they are furnished "in another building which is used by the group practice * * * for the provision of some or all of the group's clinical laboratory services, or * * * for the centralized provision of the group's designated health services (other than clinical laboratory services)." Neither the statute nor the legislative history for this provision specifically requires one single centralized location for a group to provide DHS. In addition, we see no compelling reason to impose such a requirement. We are interpreting the word "centralized" to apply when a group practice has established a separate facility for furnishing DHS to patients, without the requirement that it service all of the practice's offices or provide all of the practice's DHS. We are incorporating this interpretation into the regulations text.

If we were to require only one centralized facility for DHS, a group practice could be in the position of having to send patients from some offices to inconvenient locations or to house a variety of different kinds of ancillary services in one location, such as combining all physical therapy, laboratory services, and x-rays in one

building. It may be entirely impractical for a group practice to house the equipment and staff for such diverse services in one location. We believe the Congress meant to allow groups to use this kind of "central" or dedicated location in situations in which the facility is convenient to some of the different offices, but as a result may not be physically attached to any one of them. Thus, the facility is "central" to multiple offices, rather than attached to just one.

Comment: Several commenters sought clarification that a group practice with a single office location for the delivery of services that are not DHS can have a separate, centralized building for the delivery of DHS.

Response: While we believe that the "centralized building" provision—which allows group practices to have "off-site" DHS locations—was intended to accommodate the concerns of group practices with multiple office locations that wanted to consolidate DHS operations for cost containment purposes, we can discern nothing in the statute or legislative history that would prevent a group practice with only one office location from using a centralized building for the provision of DHS.

However, we are concerned that allowing single and multi-office group practices to have multiple off-site locations for DHS would effectively gut the in-office ancillary services exception without additional controls. Accordingly, we are modifying the "centralized building" standard to ensure that DHS referrals protected by the in-office ancillary services exception are truly part of the group practice's medical practice. First, we are requiring that the centralized office space (whether an entire building, subpart of a building, or mobile unit) used for the provision of the group practice's clinical laboratory services or DHS qualifies for the exception only if it is used *exclusively* by the group practice or group practice physicians, that is, it is wholly owned by the group practice (other than a security interest held by an unrelated lender or mortgagor) or is leased or subleased by the group practice on a full-time basis (that is, 24 hours per day, 7 days per week, for at least 6 months). This rule precludes group practice shared facilities in off-site buildings. Second, part-time "centralized" DHS arrangements are precluded. For example, a group practice may not rent an MRI facility one day per week and treat that facility as a "centralized" building. Third, a mobile facility (for example, an x-ray van) owned and used exclusively by the

group practice will be considered a "centralized building."

Notwithstanding, group practices may lease or sublease DHS facility space (including mobile units) to or from other group practices or solo practitioners on a part-time basis. However, DHS provided to patients of part-time lessee or sublessee group practices will not fit in the in-office ancillary services exception, unless the "same building" requirements are met. Finally, referrals for ancillary services to a group practice from physicians not in the group practice or other group practices do not implicate section 1877 of the Act, provided there are no impermissible financial relationships between the parties. A referral for a designated health service does not create a financial relationship.

Comment: Many commenters urged us to establish a separate exception for shared facilities. Several commenters argued that shared facilities pose no greater risk of overutilization than DHS furnished by solo practices or group practices. Moreover, commenters believe that shared facilities overseen by referring physicians are likely to be more convenient, efficient, and accountable than other facilities. A number of commenters suggested that failure to protect shared facilities would disrupt existing arrangements that are widespread in the industry (as one commenter stated, shared facilities are the "reality of what's going on"), leaving many solo practitioners with only two options: merge with others to form group practices or disband their shared facilities. One physician commenter believes that if his shared radiology and clinical laboratory facilities are not permitted, the result would be a shift of income to commercial laboratory ventures, pathologists, and radiologists, further "dichotomizing" the incomes of primary care physicians and specialists. The physician claimed that his income would drop by 25 percent and that he would have to fire employees and default on a lease. Commenters representing the interests of solo practitioners asserted that there is no meaningful distinction between DHS facilities shared by solo practitioners and group practice-owned DHS facilities.

A physician-oriented trade association and other commenters urged us to add a new exception to allow the legitimate use of shared office facilities by physicians modeled on language included in BBA 1997, but never enacted. Other commenters offered different formulations, including allowing shared facilities if they are in the same building or complex of

buildings as the solo practitioners' office practices.

Response: In the August 1995 final rule and the preamble to the January 1998 proposed regulation, we observed that the in-office ancillary services exception would allow certain shared facility arrangements among solo practitioners who do not wish to become a group practice. For example, we noted that two solo practitioners who share an office and jointly own a laboratory can continue to refer to that laboratory, as long as each physician (1) furnishes physician services unrelated to the furnishing of DHS in the office (that is, the arrangement meets the "same building" requirements), (2) directly supervises the laboratory services for his or her own Medicare or Medicaid patients while they are being furnished, and (3) bills for the services. We further noted that if only one of the solo practitioners owns the laboratory in a shared office, the nonowning physician can refer to the laboratory as long as he or she is not receiving compensation from the owner in exchange for referrals. We solicited comments on the effects of section 1877 of the Act on other shared facility arrangements.

After careful review of the public comments, we are persuaded that our original approach in the January 1998 proposed regulations is most consistent with the purposes of section 1877 of the Act. Under that approach, shared facilities are permitted if they comply with the supervision, location, and billing requirements of the in-office ancillary services exception. With respect to the location of the shared facility, Phase I of this rulemaking permits shared facilities that meet the "same building" requirements. (However, shared facilities do not qualify under the "centralized building" standard because they will not meet the *exclusively used* requirement). Thus, as noted above, two solo practitioners who share an office and jointly own a laboratory can continue to refer to that laboratory, as long as each physician furnishes substantial physician services unrelated to the furnishing of DHS in the building where the laboratory is located, provides (directly or through an independent contractor if permitted under applicable payment and coverage rules) the appropriate level of supervision for DHS for his or her own Medicare or Medicaid patients, and bills for the services. We believe the relaxation of the direct supervision requirement under these regulations will enable additional shared facilities to come within the exception. Additionally, if only one of the solo

practitioners owns the laboratory in a shared facility arrangement, the nonowning physician can refer to the laboratory as long as he or she is not compensated by the owner in exchange for referrals.

We are not persuaded, however, that a separate exception for shared facilities is warranted. The BBA 1997 language that several commenters proffered would apply to services that are furnished—

- Personally by the referring physician who is a shared facility physician or personally by an individual directly employed or under the general supervision of such a physician;
- By a shared facility in a building in which the referring physician furnishes substantially all of the services of the physician that are unrelated to the furnishing of shared facility services;
- To a patient of a shared facility physician; and
- That are billed by the referring physician or a group practice of which the physician is a member.

Given that we are revising the supervision standards under the in-office ancillary services exception, we believe that the in-office ancillary services exception will cover most, if not all, of the nonabusive shared facility arrangements that would have been protected by this commenter's proposed additional exception.

Comment: A commenter questioned the application of the proposed regulations if physicians who share a building, but for legal or personal reasons are not formally organized into a professional structure (that is, a "single legal entity"), form a joint venture to establish a clinical laboratory or other ancillary service provider.

Response: As explained above, solo practitioners may own and operate shared DHS facilities so long as they fit in the in-office ancillary services exception. If the practitioners form a separate joint venture to provide the services, they may run into problems complying with the billing requirements of the in-office ancillary services exception, if the joint venture does the billing (that is, the joint venture will not qualify as a wholly owned entity and, therefore, will not fit into any of the in-office ancillary billing requirements under section 1877(b)(2)(B) of the Act or § 411.355(b)).

4. The Billing Requirement

The Existing Law: To qualify for the in-office ancillary services exception under the statute, the DHS must be billed by one of the following:

- The physician performing or supervising the service;
- The group practice of which such physician is a member, under that group practice's billing number; or
- An entity that is wholly owned by the referring or supervising physician or the referring or supervising physician's group practice.

The Proposed Rule: In the proposed regulation, we interpreted the billing requirements to allow a single group to bill under more than one billing number assigned to the group and to allow an agent to bill for the group in the group's name, using the group's number, provided the billing arrangement meets the requirements in § 424.80(b)(6). We further interpreted the "wholly owned" entity provision to mean that a physician or group practice can establish a wholly owned provider of DHS that can bill Medicare or Medicaid on its own behalf, under its own billing number that is not a group billing number.

The Final Rule: As with the other requirements in this exception, the billing requirements serve to tie the ancillary services for which self-referrals will be permitted to the physician's routine medical practice. Phase I of this rulemaking incorporates the OBRA 1993 amendment clarifying that in-office ancillary services that are billed by a group practice of which the referring or supervising physician is a member must be billed under a billing number assigned to the group practice. However, group practices may have, and bill under, multiple group practice billing numbers, subject to any applicable Medicare or Medicaid program restrictions. Wholly owned entities that qualify to do the billing under the rule may use their own billing numbers and need not use a number assigned to the physician or group practice that owns them. The entities must be *wholly* owned either by the physician performing or supervising the services or by the group practice; joint ventures between group practices and individual group practice physicians or that include other providers or investors do not qualify as wholly owned entities.

Billing may be done by independent third party billing companies if they are acting as agents of a solo practitioner, group practice, or entity, but the billing must be done under billing numbers assigned to the solo practitioner, group practice, or entity, and the services may not be separately billed under a billing company's number. The billing arrangements must meet the requirements of § 424.80(b)(6).

The express billing requirements of section 1877(b)(2)(B) of the Act contain

no billing method applicable to supervising independent contractor physicians who are "physician in the group" under section 1877(b)(2)(A)(i) of the Act and § 411.351, but who are not members of the group under § 411.351 (these physicians cannot bill themselves as the supervising physician because they are required to reassign their billing rights to the group in order to qualify as "physicians in the group"). We believe the Congress intended the billing requirements of section 1877(b)(2)(B) of the Act to correspond with the supervision requirements of section 1877(b)(2)(a)(i) of the Act and that this omission was simply a legislative drafting oversight.

Accordingly, we are interpreting the billing requirements to be consistent with the supervision requirements, which permit supervision by a "physician in the group." Therefore, the billing conditions will be satisfied if the DHS are billed by the group practice when the supervising physician is a "physician in the group."

In summary, under the regulations in Phase I of this rulemaking, to qualify for the in-office ancillary services exception, DHS must be billed by one of the following:

- The physician performing or supervising the service.
- The group practice of which such physician is a member, under that group practice's billing number.
- The group practice if the physician is a "physician in the group practice," under that group practice's billing number.
- An entity that is wholly owned by the referring or supervising physician or the referring or supervising physician's group practice.

Comment: One commenter objected to our interpretation of the "wholly owned" entity provision as unsupported by the statute. The commenter believes that allowing separate and distinct entities to provide services and bill on their own behalf would frustrate efforts to detect fraud and abuse, because the provider numbers of the physician making the referral and the entity providing the DHS would not be clearly linked on a claim form. The commenter believes that the Congress likely intended to exempt only wholly owned entities that primarily provide administrative and billing services.

Response: We find nothing in the statutory language that would limit wholly owned entities under section 1877(b)(2)(B) of the Act to entities that provide only administrative and billing services. Rather, we believe the wholly owned entity provision can be read reasonably to permit group practices to

provide DHS and bill through these entities. A narrower interpretation would seem to imply that the group practices could only bill using third party billing companies if these companies were wholly owned by the group. We believe it unlikely that the Congress intended such an interpretation.

Comment: A commenter suggested that the billing provisions in the in-office ancillary services exception be changed to include billing by a hospital for physician services furnished under arrangements. This change would allow physician services for hospital patients to come within the in-office ancillary services exception.

Response: The in-office ancillary services exception is designed to exempt from the referral prohibition certain DHS that are provided within a group practice. As discussed in section VIII of this preamble, DHS provided under arrangements with a hospital are inpatient or outpatient hospital services for purposes of the statute. We believe the Congress did not intend to protect inpatient and outpatient hospital services under the in-office ancillary services exception. In fact, in describing the in-office ancillary services exception in H. Rep. No. 111, 103d Congress, 1st Sess. 546 (1993), the Congress pointed out that services provided by a hospital or other provider "under arrangement" with a group practice are not protected under the general exception for in-office ancillary services. "Under arrangements" issues are further discussed in section VIII.M of this preamble.

C. Group Practice Definition (Section 1877(h)(4) of the Act)

The Existing Law: As defined in section 1877(h)(4) of the Act, a "group practice" 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 certain conditions. Section 1877(h)(4) of the Act was promulgated as part of the original section 1877 law and later amended by OBRA 1993. The current law contains the following conditions applicable to "group practices" for purposes of section 1877 (those conditions added by OBRA 1993 are so noted):

- 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 (the "full range of services" test).

- 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") (revised by OBRA 1993).

- The overhead expenses of and the income from the practice are distributed in accordance with methods previously determined (modified by OBRA 1993).

- No physician member of the group directly or indirectly receives compensation based on the volume or value of referrals by the physician, with the exception of certain profits and productivity bonuses (added by OBRA 1993).

- Members of the group personally conduct at least 75 percent of the physician-patient encounters of the group practice (the "75 percent physician-patient encounters test") (added by OBRA 1993).

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

In addition, section 1877(h)(4)(B) of the Act establishes two "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 1993); and

- 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 covering clinical laboratory services referrals defined "group practice" at § 411.351 based on the statute as it read effective January 1, 1992. At that time, we interpreted the "substantially all test" to mean that at least 75 percent of the patient care services (defined as services addressing the medical needs of specific patients) of the group practice members must be furnished through the group. We interpreted members of the group to

include owners, employees, and independent contractors. We required that the group practice be “a single legal entity.” Finally, we stated that the “substantially all test” would not apply to any group practice that is located solely in a health professional shortage area (HPSA). For group practices located outside of a HPSA, the rule provided that any time spent by group practice members providing services in a HPSA would not be used to calculate whether the group practice located outside the HPSA had met the “substantially all test.”

The Proposed Rule: We proposed several changes to the definition of “group practice” in § 411.351 to incorporate OBRA 1993 changes. We also proposed several other significant changes. First, we proposed a “unified business test”—targeted at sham group practices—that would require group practices to exhibit “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.” Second, we proposed excluding independent contractors as members of the group to ease compliance with the “substantially all test.” Third, we proposed expanding our definition of “patient care services” to include any of a physician’s tasks that address the medical needs of specific patients or patients in general or that benefit the group practice.

Final Rule: As with the in-office ancillary services exception, we have been guided in developing the final definition of “group practice” by twin goals: (1) To minimize the regulatory intrusiveness of the definition while giving meaning to the statutory language and intent; and (2) to provide clear guidance as to what constitutes a “group practice” for purposes of section 1877 of the Act. We understand the importance of group practice status to physicians: simply stated, it allows group members to refer patients to one another (or to the group itself) for DHS payable by Medicare or Medicaid, and it allows group members to share in profits derived from such DHS. Section 1877 of the Act recognizes that referrals within groups are commonplace and may be appropriate adjuncts to a group’s core medical practice.

As an initial matter, the definition of “group practice” promulgated in the statute and these regulations applies only for purposes of section 1877 of the Act and may have little or no bearing for purposes of other Medicare or Medicaid provisions. For example, the definition of a “physician group” under the physician incentive plan rules is

broader than the definition of “group practice” under section 1877 of the Act.

A common complaint about our January 1998 proposed regulation was that it would exclude many *bona fide* group practices, intrude too far into the business and financial operations of physician practices, and chill group practice integration that is crucial in an increasingly managed care environment. We have been mindful of these concerns in developing Phase I of this rulemaking. It is not our intent to micro-manage group practices or dictate their organization or operation; rather, our intent is to define “group practice” so as to create, consistent with our understanding of the statutory intent, a meaningful exception to the general referral prohibition under section 1877 of the Act, an exception that permits certain traditional and commonplace referral patterns within group practices, without permitting the exception to swallow the rule. In general, Phase I of this rulemaking is more expansive than our January 1998 proposed rule and affords physicians substantial flexibility in designing and managing their medical practices (subject, of course, to any other legal impediments imposed by Federal or State law).

We believe the group practice definition set forth in section 1877(h)(4) of the Act is premised on two assumptions. First, internal group practice referrals should only be protected under the physician services or in-office ancillary services exceptions (both of which apply in specific ways to group practices) if the group practice is a *bona fide* group practice and not a loose confederation of individual physicians bound together primarily to profit from DHS referrals. We believe the Congress intended a true group practice to consist of physicians whose practices are fully integrated, medically and economically. In short, the physicians practice medicine together in a single group, not separately, and their financial prospects are interdependent. Thus, the Congress imposed certain tests that demonstrate the requisite integration and gave the Secretary regulatory authority to impose additional tests. If true integration is present, we do not believe the Congress otherwise intended to regulate the formal structure and operation of the group. Second, the financial incentives for group practice physicians to generate referrals of Medicare or Medicaid payable DHS for the group should be attenuated. Thus, the group practice definition provides that group practice physicians may not be paid directly or indirectly based on the volume or value of DHS referrals, unless the

compensation is a profit share or productivity bonus that is only indirectly related to those referrals.

With these precepts in mind, Phase I of this rulemaking incorporates the following significant revisions:

- Broadening of the types of arrangements that qualify as a “single legal entity” to include, among other things, multi-entity legal structures and structures owned by a single physician.
- Adoption of our proposal to exclude independent contractors from the definition of a “member of the group.” However, independent contractors who meet the conditions set forth at § 411.351 may qualify as “physicians in the group practice” who may receive profit shares and productivity bonuses under section 1877(h)(4)(B)(i) of the Act.
- Adoption of our proposed expanded definition of “patient care services” so that patient care services include all services a physician performs that address the medical needs of specific patients or patients in general or benefit the group practice (for example, administrative services for the group).
- Expansion of our 1998 proposal to gauge compliance with the “substantially all test” by measuring a physician’s actual time spent on patient care services by permitting groups to adopt other reasonable methods for determining compliance.
- Creation of a substantially more flexible definition of a “unified business” that will permit group practices to use cost- and location-based accounting with respect to services that are not DHS, and, in some cases, with respect to services that are DHS if the compensation method is not directly related to the volume or value of the physician’s referrals and other conditions are satisfied.
- Revision of the productivity bonus rules so that group practices may pay member physicians and independent contractors who qualify as “physicians in the group” productivity bonuses based directly on the physician’s personal productivity (including services incident to such personally performed services that meet the requirements of section 1861(s)(2)(A) of the Act and section 2050 of the Medicare Carriers Manual, Part 3), but may not pay such physicians any bonus based directly on their referrals of DHS that are performed by someone else.
- Promulgation of specific methods for ensuring that compensation for DHS is only indirectly related to referral income. In addition, parties may use other methods that are reasonable and documented.

- Elimination of the group practice attestation requirement.

These revisions and others are discussed in the comments and responses that follow. Each comment and response section begins with an overview of the relevant provision in the group practice definition and a summary of the final rule relating to that provision. The sections are divided as follows: General comments, the single legal entity requirement, members of the group, the "full range of services" test, the "substantially all" test, and the "75% physician-patient encounters" test.

1. General Comments

Comment: Many commenters, including a group practice trade association, criticized the proposed regulations for group practices as overly intrusive into the internal operations of physician practices, unnecessarily complex, and incapable of implementation in a fair and reasonable manner. The association and other commenters believe that the Congress intended the group practice provisions in the law predominately to regulate the external ownership, compensation, and referral arrangements of physicians and not the inner workings of group practices themselves. The association and other commenters protested that the rules create arbitrary distinctions among different types of physicians. These commenters contended that no tenable reason exists to treat group practices, pathologists, radiologists, and radiation oncologists—all of whom are permitted under the statute or various exceptions to make referrals to entities with which they have financial relationships under certain circumstances—differently than other physicians, since they have an equal incentive to self-refer.

Response: As indicated above, in preparing Phase I of this rulemaking, we have been mindful of the commenters' concerns about the intrusiveness of the proposed rule, and have sought to minimize the regulatory impact of the group practice definition and to provide clear guidance as to what constitutes a "group practice" for purposes of section 1877 of the Act. We do not intend to use these regulations to micro-manage group practices or to dictate their organization or operation, except as is necessary to give effect to the statutory intent of the Congress to create a limited exception to the general referral prohibition for DHS referrals by physicians within their own group practices. In general, Phase I of this rulemaking is broader than the January 1998 proposed rule and affords physicians substantial flexibility in

designing and managing their medical practices.

While we have endeavored to apply these rules as equally as possible to solo and group practitioners and among various types of practitioners, some differences in regulation and outcomes are unavoidable, and in some cases desired, given the wide array of arrangements to which the statute applies and the distinctions inherent in the statutory scheme. For example, the Congress included a specific exception for referrals by consulting pathologists, diagnostic radiologists, and radiation oncologists that does not apply in the case of other consulting physicians. The Congress intended disparate treatment of these consulting physicians, reasonably, we believe, because of the limited ability of pathologists, diagnostic radiologists, and radiation oncologists to generate patient referrals of services they either perform or supervise. Similarly, the Congress judged referrals within group practices (and solo practices) deserving of special consideration based, we believe, on a recognition of physicians' traditional practice of delivering DHS in their own offices to their own patients.

Comment: A commenter sought clarification as to whether a group practice was exempt from section 1877 of the Act. Several commenters observed that group practice status does not, by itself, protect against the risk of overutilization of ancillary services provided by the group.

Response: A group practice is not exempt from section 1877 of the Act by virtue of being a "group practice" under the definition in section 1877(h)(4) of the Act and § 411.352 of these regulations. A relevant exception, such as the in-office ancillary services or the physician services exceptions, must still apply.

Comment: Several commenters suggested that section 1877 of the Act and the regulations should focus on referrals of medically unnecessary tests to entities with which physicians have prohibited financial relationships. Some commenters suggested that we use our utilization data to develop norms for each physician specialty that could be the basis for measuring appropriate utilization and preventing inappropriate referrals.

Response: We disagree that section 1877 of the Act should apply only to referrals of unnecessary items and services. While overutilization is a principal concern of the statute, and a primary focus of this rule, nothing in the statute suggests that the Congress intended to limit the statute's reach to referrals of medically unnecessary tests

or procedures. Rather, the statute applies to all referrals of DHS to entities with which a referring physician has a prohibited financial relationship. The statute is designed to create a bright line that prohibits a high risk category of financial relationships and relieves the government from having to "look behind" every physician referral.

2. Single Legal Entity Requirement

The Existing Law: Under the statute, a group practice must consist of "two or more physicians who are legally organized as a partnership, professional corporation (PC), foundation, not-for-profit corporation, faculty practice plan, or similar association." The August 1995 final rule took the position that a group practice could consist of only one legal entity and that any individual or entity could organize, operate, or control a group practice, as long as two or more physicians had a role in providing services and the group met all of the other specific requirements for being a group practice under section 1877 of the Act. Thus, for example, a hospital could "own or operate" a group practice, provided no State law prohibited it.

The Proposed Rule: The January 1998 proposed regulations retained the interpretation of the single legal entity requirement from the August 1995 rule, requiring the legally organized group practice to consist of a "single legal entity", that is, one legal entity identified as the group practice that meets all of the group practice definitional tests. In addition, the January 1998 proposed regulations proposed allowing individual physicians who are incorporated as individual professional corporations to form a group practice, subject to meeting the remaining conditions of the group practice definition.

The Final Rule: We are retaining and incorporating into the regulations text the "bright line" rule that a group practice must be a single legal entity. The single legal entity can assume any form recognized by the State in which the entity achieves its legal status, including, but not limited to, a corporation (for-profit, professional, or nonprofit), partnership, foundation, faculty practice plan, or limited liability company. The single legal entity can be legally organized by any party or parties, including, but not limited to, physicians, health care facilities, or other persons or entities. The single legal entity must be formed primarily for the purpose of being a physician group practice. Hence, for example, a hospital that employs physicians is not a "group practice" for purposes of

section 1877 of the Act, although the hospital can form or acquire a group practice that is a separate single legal entity. The following structures are among those that may qualify under Phase I of this rulemaking, assuming all other requirements of the group practice definition are satisfied:

- A partnership between two or more physicians.

- A partnership between one physician and another party, provided that the partnership employs at least one other physician. (Similarly, a partnership between two nonphysician parties can qualify if it employs at least two physicians).

- A corporation or limited liability company with one or more physician shareholders or members, provided that a corporation or limited liability company with only one physician shareholder or member employs at least one other physician.

- A corporation or limited liability company owned by nonphysicians, provided it employs at least two physicians.

- A single legal entity owned by two or more physicians through their individual professional corporations.

- A solo practitioner who is organized as a legal entity (for example, a professional corporation) and employs at least one other full-time physician.

- A single legal entity (whether a corporation, limited liability company, or other form) owned by one or more other legal entities (that is, a multi-entity arrangement) that involves two or more physicians through employment or indirect ownership, provided that the “investing” or “owner” entities are not themselves functioning group practices. (In other words, existing groups may not band together to form a group practice primarily to share in-office ancillary referrals.) It is our understanding that the prevalent practice in these kinds of arrangements is for the physicians who own the investing entities to become employees of the new group practice, and for the investing entities themselves to cease functioning as group practices.

This list is illustrative only, and other variations are possible. What is essential is that there must be one identifiable legal entity that is a *bona fide* group practice of two or more physicians. The definition of group practice does not include a loose confederation of physicians, a substantial purpose of which is to share profits from referrals (sometimes referred to as a “group practice without walls”), or separate group practices under common ownership or control through a physician practice management

company, hospital, or health care system, or other entity or organization.

We have responded to public comments regarding problems faced by faculty practice plans under section 1877 of the Act by using our regulatory authority under section 1877(b)(4) of the Act to create a new exception applicable to faculty practice plans. This new exception is discussed in section VII.A of this preamble.

While several commenters requested accommodation in the group practice definition for bifurcated foundation-model group practices (that is, arrangements between a nonprofit entity that provides health care services and a physician group, typically used in States that restrict the corporate practice of medicine), we have determined that those arrangements are better addressed by the personal service arrangements exception. As noted elsewhere in this preamble, we intend to apply our uniform interpretation of the volume or value standard to all exceptions in which it appears. (See the discussion in section V of this preamble.)

Comment: Many commenters concurred with our position that a group practice can be organized by any individual or entity, but took issue with other aspects of our group practice organizational tests. As a threshold matter, a number of commenters maintained that the statute does not require a “single legal entity.” These commenters generally fell into three categories: (1) Commenters seeking protection for foundation model “groups” in States that follow the corporate practice of medicine doctrine, (2) commenters seeking protection for physician “groups” practicing in academic medical settings, and (3) commenters seeking protection for “groups” that are under common ownership or control, but that are not bound together in a single legal entity. Comments on the first two issues—foundation models and academic medical settings—are summarized and addressed elsewhere in this section and in section VII.A of this preamble.

As to the third category—common ownership and control—commenters generally requested that we recognize organizations under common control as a single unit or group practice, as we do in our definition of “hospital” in § 411.351 (Definitions) of the regulations. (Section 411.351 reads as follows: “*Hospital* * * * 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.”) Specifically, the commenters suggested

we interpret this portion of the group practice definition as covering a single legal entity that includes any separate, legally-organized operating entity plus any subsidiary, related entity, or other entities that perform services for the group practice’s patients and for which the group practice bills. Some commenters noted that the ability to have subsidiaries is important for groups for valid, nonabusive business reasons, such as to operate in more than one State when States have different corporate requirements, to organize components of the continuum of care such as home health or skilled nursing care, and to operate as multi-entity integrated delivery systems. Some commenters indicated that some State laws require physicians to practice in a different entity when working in a bordering State. Also noted was that complex corporate structures are sometimes required for a variety of other legitimate business reasons, such as allowing groups to meet State licensing requirements, to allocate the risk of liability, to comply with inconsistent State regulations, or to meet corporate practice of medicine requirements. Similarly, these commenters maintained that an aggregation of groups managed by the same physician practice management company or multiple groups owned by the same hospital should be considered a “group practice” for purposes of section 1877 of the Act.

Response: Having considered the comments, we iterate our view that a group practice must be a “single legal entity.” A standard that would allow entities under common ownership or control to be a group practice under section 1877(h)(4) of the Act does not sufficiently protect against sham group practice arrangements or loose confederations of physicians operating as a group practice substantially for purposes of profiting from DHS referrals. We find nothing in the statute that suggests that the Congress intended for a “group practice” to be so broadly construed as to include multiple group practices that happen to use the services of the same management company or that happen to be affiliated with the same health system. Single legal entities owned by multiple entities are permitted, as discussed in the response to the next comment. We address the special needs of foundation-based practices and faculty practice plans in this section and in section VII.A of this preamble, respectively.

Comment: Many commenters considered our proposed parameters for the composition of the “single legal entity” too restrictive, taking issue, in particular, with our statement that “the

statute specifically requires that a partnership consist of two or more physicians who are partners and that a PC consist of two or more physicians who are incorporated together.” While several commenters commended our proposal to allow group practices to include individual professional corporations that employ their own shareholders, commenters generally espoused expanding the group practice definition to include any physician group (regardless of its ownership) that is organized as a distinct legal entity and that employs more than one physician, provided that all of the other group practice definitional tests are met.

In these commenters’ view, prohibiting a sole practitioner from owning a group practice that employs multiple physicians is unfair, inconsistent, anticompetitive, and not supported by the statutory language. The commenters pointed out that, under our January 1998 proposed rule, a hospital could own a group practice, but an individual physician could not. Commenters believe that the other requirements for meeting the group practice definition prevent any sham practice arrangements and that an interpretation requiring direct ownership by two physicians does not further Federal fraud and abuse policy.

A number of commenters asked that we clarify that a group practice may be owned by any legal corporate structure or arrangement including, but not limited to, limited liability companies, multi-member professional corporations, sole physician shareholder companies that employ at least one physician, hospitals that employ physicians, entities owned jointly by physicians and a hospital (for example, a physician hospital organization (PHO)), or general corporations that employ two physicians without any physician ownership. This interpretation is consistent with the August 1995 final rule. In particular, several commenters observed that group practices commonly are formed through the merger of existing group practices. The merging practices typically contribute assets and transfer physicians and other employees to the new group practice entity, which bills for the physician services under a group billing number and treats amounts received as receipts of the new group practice, and which meets the other group practice definitional requirements. The commenter urged that the new group practice entity should qualify for group practice status, without having to dissolve the merging shareholder entities, which are often maintained for

tax or other purposes unrelated to Medicare or the fraud and abuse laws.

To prevent sham group practices, one commenter suggested that, in the case of a new group practice formed by the merger of existing group practices or professional corporations, we should require the new group practice to employ its members rather than allowing the multiple professional corporations (PCs) that formed the new group to continue employing practice members (except in the case of an individual professional corporation that employs a physician and owns a stake in a group practice). Similarly, another commenter recommended requiring all group practices (regardless of layers of composition) to be fully integrated into a single operating medical business at the top or “group” level. A group practice would be deemed fully integrated if it met the group practice definitional tests and presented itself as a single medical business whose equity holders operate as a single business by sharing such things as contracts, liability, facilities, equipment, support personnel, management, and a pension plan. A fully-integrated group would be required to employ or contract with all physicians at the group level so that physician compensation and accounts receivable of all members of the group would be “at risk” in the event of losses due to poor management of the group or in the event of a malpractice claim against any member of the group.

Response: We generally agree with the commenters. We have reconsidered the statutory language and believe that the provision requiring “a group of 2 or more physicians legally organized as a partnership, professional corporation, foundation, not-for-profit corporation, faculty practice plan, or similar association—” can be interpreted in several ways. It can reasonably be read to mean that a group must consist of some kind of legally organized entity, owned by virtually any combination of individuals or other entities, provided that there are at least two physicians providing services to patients as group practitioners. We have amended the definition of a group practice accordingly in § 411.351. We believe this interpretation allows us to treat all practices, regardless of who owns or operates them, more uniformly. The introduction to this section provides an illustrative list of possible group practice organizational structures.

We are adopting the commenters’ suggestion that no entity that owns all or part of a group practice (that is, no equity holder in the group) may itself function or qualify as a group practice (whether a group practice under section

1877(h)(4) of the Act or otherwise). Thus, for example, in the case of a new group practice formed through the merger of existing group practices, the merging or defunct group practices may not themselves operate as medical group practices (that is, they may not furnish or bill for health care services); however, the defunct practices are not required to dissolve. The merging group practices should transfer all medical assets to the new group practice, and the new group practice should employ the physicians and bill for their services, treating receipts as receipts of the new group practice.

We also generally agree that a group practice should consist of a single medical business whose equity holders operate as a single business by sharing such things as contracts, liability, facilities, equipment, support personnel, management, and a pension plan. This aspect of a group practice is addressed by the unified business test in § 411.352 of the regulations. (See section VI.C.7 of this preamble for additional information).

Comment: Commenters questioned whether a hospital could qualify as the “single legal entity” needed to establish group practice status. In the August 1995 regulations, we stated that “* * * if a clinic (or other facility) is legally organized to include two or more physicians and provides the services of physicians, it is a group practice, even if it is established, operated, and controlled by a nonphysician group or corporation. This would be so regardless of who employs the physicians (in the scenario presented by the commenter, the clinic physicians were employed by the hospital that established the clinic).” (60 FR 41937) One commenter interpreted this language to mean that a hospital, which is itself a legal entity, could employ physicians and, therefore, qualify as a group practice if the other requirements of the group practice definition were met. Thus, the hospital would not need to establish a separate legal entity for its employed physicians to be considered a group practice. A related concern was whether a single hospital could encompass multiple group practices. According to the commenter, the ability of hospitals to establish multiple groups is especially important for a hospital entity that may operate several campuses in different cities as unincorporated divisions, a situation likely to increase as providers consolidate into regional networks.

Response: We believe the commenter’s interpretation would stretch the meaning of a “group practice” too far. We do not believe that a hospital can reasonably be construed

as a "group practice." We find no basis to conclude that the Congress thought otherwise. The statement from the August 1995 regulations was made in response to a comment regarding an arrangement in which a tax-exempt hospital had affiliated group practices and established a separate tax-exempt physician-directed clinic as the group practice's operating entity, but employed the physicians in the affiliated groups directly. In responding to the comment, we attempted to make two points: (1) That a group practice need not be legally organized by physicians; and (2) that a physician-directed clinic could qualify as a group practice.

We iterate that a group practice may be legally organized by a hospital or other nonphysician person or entity; however, neither the hospital itself nor any other facility the primary purpose of which is something other than to operate a physician group medical practice, can be a group practice. A hospital may establish multiple group practices through subsidiaries or affiliated entities that are separate legal entities. Each entity may be a group practice for purposes of section 1877 of the Act, although the aggregation of groups will not be. Exceptions, such as the in-office ancillary services exception, would only apply to referrals within one of those groups and not across multiple groups within the same hospital entity.

Comment: A commenter noted that the August 1998 proposed rule clearly states that a hospital may own and operate a group practice (assuming there is no State law impediment to such ownership) and that physicians may own a group indirectly through individual professional corporations. In light of these statements, the commenter sought clarification on three points: (1) Whether a single legal entity owned jointly by physicians and the parent company of a hospital could qualify as a group practice, provided all of the other conditions in the definition were satisfied; (2) whether the "single legal entity" test could be met by a limited liability company; and (3) whether several physicians organized as a limited liability company could, in turn, own another entity (for example, a second limited liability company) that could qualify as a group practice.

Response: In responding to the commenter's questions, we apply the principles described above. First, a single legal entity owned jointly by physicians and the parent company of a hospital could qualify as a group practice, provided all of the other conditions in the definition were

satisfied. Second, a limited liability company duly organized under applicable State law could qualify as a "single legal entity." Third, several physicians organized as a limited liability company could, in turn, own another entity that could qualify as a group practice provided that the first limited liability company is not, and does not operate as, a group practice. In this last case, the physician members of the first limited liability company would be considered members of the group by virtue of their indirect ownership interest in the second entity.

Comment: Commenters note that health systems, management companies, hospitals, and other nonprofit and for-profit corporations must comply with State laws governing the corporate practice of medicine. In some States, these laws restrict or prohibit a corporation from directly employing physicians. In some cases, the corporations form a "captive" or "friendly" professional corporation with one physician owner who holds the ownership rights to the professional corporation in trust for the corporation. The friendly professional corporation directly employs physicians who then form the group practice. The corporation manages the business of the group practice, with the sole physician shareholder acting primarily as a "figurehead." The arrangement ensures that the corporation only indirectly employs the physicians and does not violate the corporate practice of medicine rules. Commenters noted that typically only one physician is a shareholder in the friendly professional corporation so that day-to-day transactions are less cumbersome.

Response: Since we have amended the group practice definition to cover groups that consist of one physician owner and one or more physician employees, we believe that the types of "captive" or "friendly" professional corporations described in the comment can both meet our definition and comply with corporate practice of medicine requirements. Groups must continue to meet all of the other criteria in the group practice definition in section 1877(h)(4) of the Act and § 411.351.

Comment: Several commenters asked that we clarify whether the "single legal entity" requirement precludes a group practice from having subsidiary entities that, for example, own real estate or equipment, provide billing services, or operate ancillary services.

Response: As we noted in the August 1995 final regulations, we believe that the statute does not preclude a single group practice from owning other legal

entities for the purposes of providing services to the group practice. Thus, to cite the example in the August 1995 final regulation at 60 FR 41936, a group practice could wholly own and separately incorporate a laboratory facility that provides laboratory services to a group practice or other patients. The physicians could qualify for the in-office ancillary services exception provided they meet the requirements for supervision, location, and billing. The billing requirement in section 1877(b)(2)(B) of the Act allows services to be billed by the referring or supervising physician, the group practice, or an entity wholly owned by the group practice. The exception appears to anticipate that a group practice may wholly own separate legal entities for billing or for providing ancillary services. Parties should be aware, however, that the group practice safe harbor under the anti-kickback statute (§ 1001.952(p) of this title), does not protect group practice ownership of ancillary services; for purposes of the anti-kickback statute, these arrangements are evaluated on a case-by-case basis.

3. Members of the Group

The Existing Law: Under the August 1995 final regulations, owners, employees, and independent contractors were all considered "members of a group" practice for purposes of the group practice definitional tests.

The Proposed Rule: The proposed regulations proposed modifying the definition of the term "members of the group" to include only physician partners, shareholders, and full-time and part-time physician employees. Independent contractors would no longer be considered members of the group. This change was proposed to aid group practices attempting to comply with the 75 percent "substantially all test." Physicians would be considered members of the group during the time that they furnish patient care services to the group.

The Final Rule: We are adopting our January 1998 proposal to define a member of a group practice as any physician who owns, or is employed by, the group practice. In the case of a group practice owned by professional corporations or defunct group practices, the physicians who own those entities will be considered members of the group practice. Also, those physicians who own all or part of the group practice through their own professional corporations and who are employed by their own professional corporations (which contract with the group practice to provide physician services) will be

considered members of the group. Physicians are members of the group during the time they furnish "patient care services" (as defined at § 411.351) to patients of the group or for the benefit of the group, even if those services cannot be billed by the group (for example, certain administrative services, *pro bono* services).

Independent contractors and leased employees will not be considered members of the group. The exclusion of independent contractors is intended to aid many group practices in complying with the "substantially all test" described below. Although not group practice members, under certain circumstances, independent contractors may provide the required supervision for the in-office ancillary services exception, as described in section VI.B.2 of this preamble.

While nonphysicians, such as nurse practitioners and physicians assistants, may be group practice "members" for general purposes under section 1877 of the Act, their membership will have no practical effect, since they are not "physicians" for purposes of the three group practice "tests" (the "full range of services," "substantially all," and "75 percent physician-patient encounters" test), nor for purposes of the profits and productivity bonuses provisions. While referrals by nurse practitioners and physician assistants generally do not trigger section 1877 of the Act, which applies only to physicians (as defined at section 1861(r) of the Act), referrals made by nonphysician health care professionals may implicate the statute if those referrals are directed or controlled by a physician. In other words, a physician or group practice cannot channel referrals through a nurse practitioner, physician assistant, or other nonphysician health care professional in order to circumvent the prohibition under section 1877, and any channeled referrals would be imputed to the responsible physician.

Comment: Many commenters supported our proposal to count owners and employees as members of the group, but not independent contractors. This change would facilitate compliance with the group practice definition by group practices that use part-time independent contractor physicians to supplement and expand the range of services the group offers to patients. Some commenters recommended that independent contractors be excluded only for purposes of the "substantially all test," but not for other purposes, including the direct supervision requirement of the in-office ancillary services exception and the 75 percent physician-patient encounters test. Some

commenters objected to excluding independent contractors from the definition of "members of the group" because they perceived that such exclusion would prevent group practices from paying independent contractors productivity bonuses for the work they personally perform under section 1877(h)(4)(B)(i) of the Act.

Response: We are retaining our proposal to exclude independent contractors from the definition of "members of the group practice." On balance, we believe this change will benefit many group practices that wish to qualify for group practice status. As to the other concerns raised by commenters, we believe those concerns have largely been addressed by other changes in these regulations. We have liberalized the direct supervision standard in the in-office ancillary services exception to permit supervision by independent contractors who meet certain conditions that establish that the independent contractors are "physicians in the group practice." (See discussion in section VI.B.2 of this preamble). As discussed below, in greater detail, we are permitting group practices to pay productivity bonuses to independent contractors who are "physicians in the group practice." (See discussion in section VI.C.8 of this preamble).

Comment: A number of commenters advocated a flexible approach to the definition of "member of the group," urging that groups be permitted to elect whether to include independent contractors as members on an annual or other basis. These elections would apply uniformly for purposes of qualifying under all of the group practice definitional tests and the in-office ancillary services exception, and would be reported to us.

Response: The election process described by the commenters strikes us as unnecessary given the significant changes in this final rule with respect to the treatment of independent contractors under the in-office ancillary services exception and the group practice productivity bonus provisions. In our view, an election process would impose an additional administrative burden on groups and the government, with minimal offsetting benefit.

Comment: To accommodate multi-entity group arrangements, a commenter suggested that "members of a group" should include owners of the group, employees of the group, and owners of any sole or multiple shareholder professional corporation that has an ownership interest in the group (that is, indirect owners).

Response: For purposes of the definition of "members of the group,"

we are including any physician owners of a sole or multiple shareholder PC or other entity that has an ownership interest in the group. In essence, we intend to "look through" any corporate or entity owners to the ultimate physician owners. Thus, members of the group include physicians who are owners (directly or indirectly) and *bona fide* employees of the group.

Comment: Several commenters suggested that independent contractors be permitted to qualify as group practice members on a *locum tenens* basis. Thus, for example, a group would be allowed to use independent contractors to provide coverage when a member of the group is ill and unable to practice medicine temporarily. Other reasons to use *locum tenens* physicians could include death or disability of a physician, resignation of a physician, accommodating seasonal increases in patient loads, and "trial runs" of physicians being recruited to join a practice. According to commenters, *locum tenens* providers are typically paid on a fee-for-time basis by the staffing organizations with which they are affiliated. Thus, they typically have no direct financial relationships with any of the health care entities to which they are assigned. The health care entities retain all patient receipts and, when possible, Medicare payments are reassigned to the health care entity.

Response: Nothing in section 1877 of the Act or these regulations prevents the use of *locum tenens* physicians in situations like those described in the comments. The issue raised, however, is how these physicians should be treated for purposes of a group practice's compliance with the group practice definition and how referrals by such physicians should be treated under the general prohibition under section 1877. As to the first issue, we believe an appropriate use of *locum tenens* physicians in exigent situations should not prevent a group practice that otherwise complies with the definition at section 1877(h)(4) and § 411.352 of these regulations from qualifying for group practice status. We are applying the rules at section 3060 "Reassignment," of the Medicare Carrier's Manual (HCFA Pub. 14-3), Part 3—Claims Process (the reassignment provisions) as the test for whether a physician is a *locum tenens* physician. A *locum tenens* physician will be considered as "standing in the shoes" of the regular physician (as defined in section 3060.7) if he or she replaces the regular physician in accordance with section 3060.7. We note that section 3060.7 does not treat a physician hired

on a "trial run" basis as a *locum tenens* physician.

Comment: One commenter sought clarification that on-call physicians who are independent contractors would be exempted from the group member and group practice requirements but would be able to provide and supervise care on behalf of a group member. On-call physicians for one group may be members of other group practices. They may or may not be compensated for their services or bill under the group practice billing number of the group for which they are serving in an on-call capacity. According to the commenter, on-call arrangements are commonplace, especially among groups that do not have sufficient numbers of specialists to cover for each other. The commenter requested a specific exemption under the statute so that on-call physicians do not impede groups from meeting the group practice definition and are not precluded from ordering DHS when they are serving in an on-call capacity. The commenter suggested an on-call physician be treated as "standing in the shoes" of the member while providing on-call services for purposes of the "substantially all test," the 75 percent physician-patient encounters test, and the supervision requirement of the in-office ancillary services exception.

Response: We agree that it is appropriate to treat on-call physicians as "standing in the shoes" of the member while providing on-call services for purposes of the "substantially all test," the 75 percent physician-patient encounters test, and the supervision requirement of the in-office ancillary services exception, provided that the services are billed by the practice for which the physician is serving on an on-call basis.

Comment: Several commenters questioned whether nurse practitioners, physician assistants, or other nonphysician providers could be group members, and if so, whether their services would count in the calculation of the 75 percent physician-patient encounters test.

Response: We perceive nothing in the statute that would prevent group practices from admitting nurse practitioners, physician assistants, or others as members of the group for purposes other than section 1877 of the Act. However, the definition of a "group practice" in section 1877(h)(4) of the Act contains several requirements that apply specifically to *physician* members of the group. Provisions of the in-office ancillary services exception and the physician services exception also refer specifically to physician members or physicians in the same group practice.

The term "physician" is specifically defined under the Medicare statute at section 1861(r) of the Act and does not include nurse practitioners or physician assistants. Any services that these individuals provide are not counted under the "substantially all test" or under any other part of the group practice requirements or exceptions that apply to physician members.

The referral prohibition in section 1877 of the Act applies only to referrals that are made by a physician to an entity with which that physician, or an immediate family member, has a financial relationship. If a nonphysician practitioner is referring a physician's patients at the physician's suggestion or in lieu of the treating physician, we would impute the referrals to the physician. Simply stated, physicians may not delegate their own referrals to avoid the referral prohibition. On the other hand, we would not impute the referrals if the nurse practitioner or the physician assistant is independently treating the patients and initiates the referrals on his or her own. We think the determination will depend on the specific facts and circumstances.

Comment: One commenter asked that we exclude from the definition of members of the group any employees who provide interpretation or supervision services only and are not otherwise involved in patient care.

Response: Given the revisions we have made in Phase I of this rulemaking to the in-office ancillary services exception and the group practice definition, we see no need for a special exclusion for physicians who provide interpretation or supervision services only. We recognize that these physicians may affect, among other things, a group practice's ability to comply with the 75 percent physician-patient encounters test because they generally do not see patients. But to exclude physicians who generally do not see patients would undermine the purpose of the test, which is to ensure that group practices are first, and foremost, joint medical practices for the provision of physician services to patients and not primarily designated health care services enterprises. The Congress addressed the special circumstances of pathologists, diagnostic radiologists, and radiation oncologists in a separate provision. (See discussion of section 1877(h)(5)(C) in section III.B of this preamble).

Comment: A commenter sought clarification that physicians who are employees of their own individual professional corporations instead of the group practice are considered "group members." The definition of a group

member in § 411.351 already includes physicians whose ownership interest in the group is held through an individual professional corporation. Many physicians wish to not only hold ownership interests in an individual professional corporation, but to be employees of these corporations for pension and tax reasons. To avoid potential abuse, the commenter suggested that we add the following parenthetical to the definition of "member of group" in § 411.351: "(including physicians who are employed by an individual professional corporation, as long as the group has legal authority over the terms of the physician's employment and is legally responsible for services provided by the physician on the group's behalf)."

Response: We agree with the commenter that these physicians are "members" of the group. If a physician already qualifies as an "owner" of the group through his or her individual professional corporation, then his or her status as an employee or contractor is irrelevant for purposes of qualifying for group practice status. The amendatory language proposed by the commenter is not necessary, although we are revising the regulations text to clarify that a physician who is employed by an individual professional corporation that has an ownership interest in the group practice is a "member of the group." Physicians who are employed by their own individual professional corporations and who have no ownership interest in the group (directly or through an individual professional corporation), but provide services to the group, are independent contractors and therefore not members of the group.

Comment: A commenter suggested that a physician who opts out of, and is not receiving any payments from, the Medicare program should not be bound by the limitations in section 1877 of the Act, and, thus, should be able to refer to entities with which he or she has a financial relationship. The commenter also asked that we clarify whether a physician who opts out of the Medicare program pursuant to the private contracting authority in the BBA 1997, but continues to practice with a particular group of physicians, is a group "member" for purposes of the physician self-referral law. The commenter reported that we have elsewhere stated that a group physician's opting out does not affect the ability of the rest of the group members to provide and bill for services they furnish to Medicare beneficiaries. The commenter stated that physicians who reassign benefits to organizations that participate in Medicare may not opt

out, and that consequently physicians who belong to groups that participate in Medicare and who opt out may not bill and accept payments from Medicare beneficiaries through the group practice unless the entire group practice opts out. Thus, a physician who opts out would have to bill under his or her own name instead of through the group.

The commenter also questioned whether a physician's time spent treating Medicare beneficiaries that is billed through the physician's own name must be counted against the amount of time the physician has spent treating other patients of the group practice. (We assume this means that, for the "substantially all test," the commenter wishes to know whether the physician's private billing constitutes "patient care services" provided outside the group context that would affect whether the physician provides substantially all of his or her services through the group and bills substantially all of his or her services under a billing number assigned to the group.)

The commenter urged that we consider physicians who have opted out as "members" of the group practice only for those services furnished through the group, but not count the physician services in calculating whether the group has met the "substantially all test."

Response: We agree with the commenter that a physician who opts out of the Medicare program and is not receiving any payments from the Medicare program is not bound by the limitations in section 1877 of the Act and, therefore, can refer to entities with which he or she has a financial relationship. Section 1877 prohibits only referrals for services "for which payment otherwise may be made under Medicare," and Medicare would not otherwise pay for services under a private contract. The commenter also is correct in stating that when a group physician has opted out, it does not affect the ability of the rest of the group members to furnish and bill for services they furnish to Medicare beneficiaries.

The commenter is not correct, however, that when a group physician has opted out, the group may not bill in its own name for services provided by the opt-out physician under a private contract. The Medicare statute does not prevent an opt-out physician's group—regardless of whether the group has a participation agreement with Medicare—from billing payers other than Medicare for services furnished under a private contract. Of course, neither the physician nor the group is allowed to bill Medicare for services

furnished under a private contract. Thus, a physician who opts out can remain a group member during the time he or she provides services to group patients, provided the services are billed through the group practice to payers other than Medicare. We believe the requirements in the group practice definition are meant to demonstrate that the physicians involved in the group are actually practicing medicine together. A physician can demonstrate a significant level of participation by treating either program or nonprogram patients, as long as they are group patients.

We also believe that any services the physician bills in his or her own name are not group services and, therefore, should be factored into the "substantially all test" as outside patient care services.

Comment: Several commenters were concerned about the proposed rule's effects on nonprofit medical foundations, particularly in light of our statement that a group practice can consist of only *one* legal entity. One commenter was specifically concerned about medical foundations in California, where such entities are established so that practices can comply with the corporate practice of medicine prohibition. One of the key exceptions to the prohibition allows nonphysician ("lay") participation in arranging for the delivery of physician services if the nonphysician is a qualified medical foundation. (These entities are nonprofit and exempt from Federal income taxation under section 501(c)(3) of the Internal Revenue Code). In California, for example, these foundations provide patient care through a separate, contracted medical group that is comprised of at least 40 physicians who collectively practice in at least 10 specialty areas. A chief concern was that our proposed rules would prevent the nonprofit foundation-model group practice from furnishing DHS under the in-office ancillary services exception because it has no employed physicians or physician owners who can qualify as "members of the group" for purposes of the group practices definitional tests.

The commenter considers the California nonprofit medical foundation to be, in essence, one bifurcated medical services provider that should be treated as a "single legal entity" for purposes of section 1877 of the Act. That is, under California law, the medical foundation is itself a health care provider; yet this can only work if the medical foundation encompasses the physicians who contract to provide the professional services. The IRS currently regards the physician-foundation relationship as comprising an integrated whole and

grants tax-exempt status to those truly integrated foundations as providers of professional medical care. The foundation operates and owns all elements of the practice, but cannot provide the physician services, and the physicians have agreed to furnish all patient care services through the foundation model; it is the foundation, and not the physicians, who own the medical practice.

The commenter stated that entities such as management service organizations do not merit tax-exempt status because they support the provision of services, but do not actually provide services, while the foundations actually provide services. The IRS scrutinizes the entire foundation relationship to assure that its interdependent functions and operations comply with the fundamental requirements for tax exemption.

Response: As an initial matter, that an arrangement is subject to IRS regulation is not determinative under section 1877 of the Act. The IRS's goals in regulating business structures do not necessarily take into account preventing fraud and abuse in the Medicare and Medicaid programs. As to foundation-model practices in corporate practice of medicine States, we recognize that they present special problems under section 1877 of the Act. On the one hand, section 1877(h)(4)(A) clearly authorizes group practices that are "foundations." On the other hand, in the typical foundation-model arrangement, the physicians are not legally organized as a "foundation."

In reviewing the statute and legislative history, we have reached the following conclusions. First, the Congress used the term "foundation" in the group practice definition in a generic sense to cover any situations in which the single legal entity, that is, the group practice, consists of a foundation; the reference was not necessarily intended to encompass bifurcated foundation-model arrangements. Second, the Congress intended for foundation-model arrangements to be excepted under the personal service arrangements exception. The OBRA 1993 Conference Report states that the "conferees intend that this exception [personal service arrangements] would apply to payments made by a nonprofit Medical Foundation under a contract with physicians to provide health care services and which conducts medical research." H. Rep. No. 213, 103d Cong., 1st Sess. 814 (1993).

The personal service arrangements exception should provide foundation-model arrangements with additional

flexibility in structuring their arrangements and that most foundation-model arrangements will be able to fit in the exception, in accordance with the congressional intent. The “volume or value of referrals” and “other business generated” standards will apply uniformly to all exceptions in which they are included. (See the discussion in section V of this preamble and the regulations at § 411.354(d).)

Comment: Several commenters noted that another arrangement commonly used in corporate practice of medicine States is the use of “friendly” or “captive” PCs to create hospital-affiliated group practices in States that prohibit hospitals from employing physicians directly. For example, a commenter explained that in Ohio, a single physician may own stock in a PC, but hold the stock in trust for a hospital or other nonprofit corporation. The PC itself employs physicians who operate as a group practice and would fulfill all of the other group practice requirements. The commenter suggested that this arrangement would satisfy section 1877 of the Act if the rule were changed to permit groups to be owned by a single physician owner.

Response: As noted in section VI.C.2 of this preamble, we have made the change suggested by the commenter. Group practices may be owned by a single physician provided that the group practice employs at least one other physician. Therefore, we believe that “friendly” or “captive” PCs can qualify as group practices if they meet all of the other conditions of the group practice definition.

Comment: Several commenters noted that the sole owner of the “captive” or “friendly” PC may be a hospital-based physician who does not practice medicine as part of the group. These commenters wondered whether a nonparticipating physician owner would be a member of the group for purposes of the group practice definitional tests, particularly the “substantially all test.”

Response: We believe that a hospital-based physician, who does not practice medicine as part of the group, is not a member of the group practice for purposes of the definitional tests. However, that means that the physician is not a member for any other purpose either. Thus, for example, a captive or friendly PC owned by such a physician would need to employ at least two physicians to qualify as a group practice. In addition, the sole physician owner described in the comment would not be eligible for sharing in overall profits or productivity bonuses under

section 1877(h)(4)(B)(i) of the Act and § 411.352(i) of the regulations.

Comment: Commenters generally supported our position in the proposed regulations that a physician’s financial relationship with an entity under section 1877 of the Act would not be imputed to his or her group practice. Thus, other members of the group practice could continue to make referrals to the entity, provided that the members did not have financial relationships with the entity and the physician with the financial relationship was not in a position to control the referrals of other group members. However, one commenter suggested that we include as members (who could continue to make referrals) physicians who are employed by their own PC (instead of the group) as long as the group has legal authority over the terms of the physician’s employment and is legally responsible for services provided by the physician on behalf of the group. This commenter noted that for tax and pension reasons, many physicians prefer to be employed by their PCs rather than the group practice entity.

Response: We are adopting the position we discussed in the proposed regulations, that is, that a physician’s financial relationship with an entity under section 1877 of the Act will not be imputed to his or her group practice. Thus, other members of the group practice can continue to make referrals to the entity, provided that the members do not have financial relationships with the entity and the physician with the financial relationship is not in a position to control the referrals of other group members. As we have indicated elsewhere in this preamble, physicians who are employed by their own individual PCs are considered members of the group if the PC has an ownership interest in the group. If not, the physician would be considered an independent contractor who is not a member of the group.

4. The “Full Range of Services Test”

Existing Law: The definition of a group practice in section 1877(h)(4)(A)(i) of the Act provides that, among other requirements, each physician who is a member of the group must provide substantially the full range of services that the physician routinely provides, including medical care, consultation, diagnosis, or treatment, through the joint use of shared office space, facilities, equipment, and personnel. In the August 1995 final rule covering referrals for clinical lab services, we required physician members to furnish the full range of

“patient care services,” defined as services addressing the medical needs of specific patients.

The Proposed Rule: In the January 1998 proposed rule, we proposed expanding “patient care services” to include any physician’s tasks that address the medical needs of specific patients or patients in general or that benefit the practice. These activities could include, for example, time spent training group staff members, arranging for equipment, or performing administrative or management tasks, as long as these activities benefit the operation of the group practice. Services wholly outside the group’s medical practice, such as teaching, do not count as patient care services. This proposed test was designed to ensure that a physician is actually practicing medicine as he or she ordinarily would as part of the group and has not simply joined the group in name only. It further ensures that physicians are practicing as part of the group and not simply using the group to profit from DHS referrals.

The Final Rule: We are promulgating the test as proposed in the January 1998 proposed rule.

Comment: Commenters generally favored our proposal to revise the definition of “patient care services” to include any physician task that addresses the medical needs of specific patients or patients in general, or that benefits the group practice. However, commenters requested clarification whether activities that are conducted outside the group practice, such as teaching, overseeing residents, or conducting medical research, but that nonetheless benefit patients in general, are covered within the definition. Other similar activities might include administrative positions within hospital systems or independent physicians’ associations that involve oversight of patients beyond those of the group practice.

Response: It does not appear to us that the activities listed by the commenter would particularly benefit group practice patients, except possibly in a very attenuated way. (The answer might change if the group itself was contracted to perform these “outside” tasks.) Therefore, we would generally not regard them as patient care services performed for the group. Instead, they might qualify as patient care services provided outside of the group. For example, the physician could be supervising residents in a hospital while the residents treat patients, the volunteer activities might involve treating indigent patients, or the administrative work could involve

overseeing the efficient delivery of care to patients.

If the physician furnishes patient care services exclusively within the group, then whatever services he or she furnishes should constitute the full range of that physician's routine patient care services. If the physician furnishes patient care services both inside and outside of the group, then the services for the group's patients should be comparable in scope to those provided outside of the group setting. Any of a physician's services that do not involve caring for patients should not affect this test. For example, if a physician teaches medicine outside of the practice, but does not oversee patient care, we would not expect that the physician would also be performing teaching services as part of his or her group services.

5. The "Substantially All Test"

The Existing Law: Under the definition of a "group practice" in section 1877(h)(4)(A)(ii) of the Act, substantially all of the services of the physician members must be provided through the group and billed under a billing number assigned to the group, and amounts so received must be treated as receipts of the group. In § 411.351, we interpreted "substantially all" to mean at least 75 percent of the total patient care services of the group practice's members. We promulgated special rules for group practices located solely in HPSAs and for physician members' time spent providing services in HPSAs.

The Proposed Rule: We proposed measuring patient care services (using the same definition of "patient care services" applied in the full range of services test described above) by the "total patient care time" each member spends on these services. We concluded that patient care time was the most straightforward and least burdensome method for measuring a physician's patient care services, but we solicited comments on other viable methodologies. Again, this test ensures that physicians who are members of the group practice are economically bound to the group for other than DHS referrals and are not just members of the group for purposes of profiting from DHS referrals.

The Final Rule: We are promulgating this test as proposed in our January 1998 proposed rule, except as discussed in this preamble. As proposed in our January 1998 proposed rule, the "substantially all test" could be measured based on the member physician's actual time spent performing patient care services, whether performed inside or outside the

group practice. Having reviewed the comments regarding alternative methods for meeting the test, we are amending the "substantially all test" to allow group practices greater flexibility. While "actual time spent" remains the default standard, group practices may adopt alternative measures, provided those measures are reasonable, fixed in advance of the performance of the services being measured (that is, no *ex post facto* methods), uniformly applied over time, verifiable, and documented. Independent contractors and leased employees are not defined under the final rule as members of the group; therefore, their services need not be counted for purposes of complying with the "substantially all test."

Comment: Many commenters appreciated our expansion of the definition of patient care services to include services that benefit group patients in general or the group practice itself, but suggested that group practices be allowed to adopt alternative methods for measuring compliance with the 75 percent "substantially all test," depending on the particular circumstances of the group and the most reasonable manner available for the group. These commenters pointed out that many physicians do not maintain time records and to do so would create an unnecessary administrative burden. Additionally, some commenters believe that it would be difficult or misleading to calculate the exact number of patient care hours as we suggested in the proposed regulations because many full-time physicians tend to work more than 40 hours per week. (Data submitted by a major physician trade association reflected that the "average" physician works 57.9 hours a week, with 53.2 hours spent on patient care activities). For example, one physician in a practice may work a full-time schedule of 40 hours per week for the group and another 60 hours per week; it would be inconsistent to count both as furnishing the same 100 percent of their time to the practice. Alternatively, a physician may work a full 40-hour week at his or her practice and then an additional 20 hours at a hospital or clinic. To count this physician as working only two-thirds time for the group, based on a straight calculation of hours, would be unreasonable. One commenter thought that the regulations should establish a presumption that 40 hours per week of patient care time for physicians equals 100 percent of such time for purposes of calculating the 75 percent "substantially all test"; any hours spent beyond 40 hours on professional patient care time would fall outside of the 75 percent

"substantially all test." Some groups expressed a preference for using relative value units (RVUs) to measure patient care services, while others preferred a revenue based calculation or a test based on patient encounters furnished and billed through the group. One commenter thought that the "patient care time" standard was ambiguous and not objectively verifiable, since physician timekeeping often does not account for time spent on activities not involving direct patient care.

Response: We are persuaded that it would be appropriate to permit group practices additional flexibility in measuring compliance with the "substantially all test" based on their unique circumstances. The "actual time spent" standard described in the preamble of the January 1998 proposed rule remains the default standard. Group practices that employ that standard can be assured that they are appropriately measuring "patient care services." As we noted in the January 1998 proposed rule, we are not requiring that physicians use detailed time sheets or time cards; in most cases, appointment calendars, personal schedules, billing records, or other existing sources will be sufficient to establish the time spent on patient care services. Group practices may adopt alternative means of satisfying the "substantially all test," provided the means used are (1) reasonable, (2) fixed in advance of the performance of the services being measured (that is, no *ex post facto* methods), (3) uniformly applied over time, and (4) verifiable. The data used to calculate compliance with the "substantially all test" and supporting documentation must be made available to the Secretary upon request.

Comment: Several commenters sought clarification whether the 75 percent "substantially all test" for patient care services is measured based on total patient services across all specialties in a group or whether it is measured on a specialty-by-specialty basis.

Response: Section 1877(h)(4)(A)(ii) of the Act provides that a group practice is a legally organized entity "for which substantially all of the services of the physicians who are members * * * are provided through the group * * * ." In § 411.351, we interpreted "substantially all" to mean at least 75 percent of the total patient care services of each of the group practice's members. It is our view that a group practice should aggregate all of the patient care services that each of its members provides, both inside and outside of the practice, including all varieties of patient care services, to determine whether 75 percent of those

services are furnished through the group. However, any services that are provided by a group through independent contractors would not be figured into the test. The test is designed to demonstrate that the activities of each member are conducted through the group. Services performed by independent contractors would have no bearing on this measure.

Comment: One commenter sought clarification in applying the 75 percent rule to new group practices that may be owned by, or employ, part-time physicians who are practicing elsewhere during the group's initial 12-month start-up period. In some cases, these groups will not meet the group practice definition during the start-up period.

Response: We agree with the commenter that some accommodation should be made for new group practices. Nothing in the statutory language precludes such accommodation. Accordingly, the final regulations provide that during the "start up" period for a new group practice (not to exceed 12 months), a group practice must make a reasonable, good faith effort to ensure that the group practice complies with the "substantially all test" as soon as practicable, but no later than 12 months from the date of the initial formation of the group practice. This "start up" provision does not apply when an existing group practice admits a new member or when an existing group practice reorganizes.

Comment: A commenter related the following scenario: A specialist provides professional services for a hospital outpatient under a contract with the hospital that allows a hospital employee to perform the technical component of the service. The specialist reassigns his or her payments for the professional services to the hospital. The hospital then bills Medicare for a global payment that includes the professional and technical components. Under this arrangement, the hospital pays the specialist a contractual amount for the professional component. The commenter requested that we explicitly permit the professional component of these types of services to be counted as part of the 75 percent requirement for purposes of the "substantially all test," even though the hospital and not the group practice bills Medicare for the specialist's services. Alternatively, commenters recommended that we change the two compensation exceptions that deal with hospitals (located in regulations in §§ 411.357(g) and (h)) to exclude compensation paid to a physician for professional services.

Response: We agree that a group practice should be able to count the

professional component of services provided by a member physician under a global payment when calculating the "75 percent of patient care services requirement" for purposes of the "substantially all test," even though the hospital actually bills Medicare directly for the physician services. We regard the "substantially all test" as designed to guarantee that a physician is providing a substantial amount of his or her own services through the group practice. If the group's business includes providing professional services to another entity, which, in turn, pays the group for those services, it is our view that these are services that should count as services a physician provides through the group. We are, therefore, interpreting the requirement that substantially all of a physician's services be provided through the group and be billed "under a billing number assigned to the group" and amounts so received treated as receipts of the group to include any physicians' professional services billed by a group under any group billing number regardless of the payer of the services, provided the receipts are treated as receipts of the group. In other words, the phrase "billed under a billing number assigned to the group" in section 1877(h)(4)(A)(ii) of the Act does not refer exclusively to Medicare or Medicaid billing numbers.

Comment: Several commenters objected to the proposed regulation because they believe it would require groups to bill under a group billing number and would force physicians in a group to bill individually when a patient has been seen in the hospital.

Response: While we are somewhat unclear as to the commenters' concern, we see nothing in these regulations that affects how group practice physicians bill for services provided to their own patients seen in a hospital.

6. The "Seventy-Five Percent Physician-Patient Encounters Test"

The Existing Law: Under section 1877(h)(4)(A)(v) of the Act, physician members of a group practice must personally conduct at least 75 percent of the group practice's patient encounters (measured per capita, not by time). The test ensures that the group practice is a legitimate medical practice and not primarily a business for the provision of lucrative ancillary services.

The Proposed Rule: The proposed rule would exclude independent contractors or leased employees from the test because they would not be considered members of the group.

The Final Rule: We are promulgating this test as proposed in our January 1998 proposed rule.

Comment: A commenter requested confirmation that *bona fide* employed physicians count for purposes of the 75 percent physician-patient encounters test.

Response: As discussed in section VI.C.3 of this preamble, members of a group practice include employed physicians. Thus, patient encounters by *bona fide* employed physicians count for purposes of the 75 percent physician-patient encounters test.

7. Unified Business Test

The Existing Law: For purposes of the group practice definition, section 1877(h)(4)(A)(iii) of the Act requires that "the overhead expenses of and the income from the group practice are distributed in accordance with methods previously determined."

The Proposed Rule: In our January 1998 proposed rule, we proposed exercising our discretion under section 1877(h)(4)(vi) of the Act to impose an additional standard under the definition of group practice that would require groups to be a "unified business." Our purpose was to ensure that group practices are substantially integrated business operations and that their allocation of group expenses and income to members reflect this. Absent a unified business test, we are concerned about the development of sham groups that are formed primarily for the purpose of profiting from self-referrals, but not for other, *bona fide* purposes. Thus, in the proposed regulations, we interpreted section 1877(h)(4)(A)(iii) of the Act as requiring that the group's overhead expenses and income be distributed according to methods that are—

- Determined prior to the time period during which the group has earned the income or incurred the costs, and
- Distributed according to methods indicating that the group practice is a unified business.

We indicated that 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."

The Final Rule: The statute requires that the overhead expenses of, and income from, the group practice be distributed in accordance with methods "previously determined." Unlike the January 1998 proposed rule, which interpreted "previously determined" as meaning before the group earned the income or incurred the cost, the final rule treats a distribution methodology as "previously determined" if it is determined prior to receipt of payment for the services giving rise to the

overhead expense or producing the income. Apart from this limitation, the rule does not prevent group practices from adjusting their compensation methodologies prospectively as frequently as they desire (subject to the restrictions on the distribution of DHS revenues in section 1877(h)(4)(B)(i) of the Act).

Commenters were nearly uniform in their criticism of the proposed unified business test, claiming that it invalidated many *bona fide* and common group practice compensation structures and discouraged beneficial integration of group practices. Reflecting these comments, Phase I of this rulemaking retains the general unified business test, but offers groups considerable additional flexibility in satisfying the requirement. Importantly, Phase I of this rulemaking permits many forms of cost center and location-based accounting, provided that compensation formulae with respect to DHS revenues otherwise meet the requirements of the law. To meet the unified business test, a group practice must be organized and operated on a *bona fide* basis as a single integrated business enterprise with legal and organizational integration. Essential elements are: (1) Centralized decision making by a body representative of the practice that maintains effective control over the group's assets and liabilities (including budgets, compensation, and salaries); (2) consolidated billing, accounting, and financial reporting; and (3) centralized utilization review (for example, utilization review conducted on a group-wide basis). We designed the rule to preclude group practice status for loose confederations of physicians that are group practices in name, but not operation. As adopted in Phase I of this rulemaking, the unified business test sets general parameters indicative of integration, but does not dictate specific compensation practices. Compensation, with respect to DHS, is subject to separate limitations described in these regulations.

Comment: Many commenters objected to our proposal to interpret the phrase "previously determined" to mean that the methodology for setting group members' compensation must be fixed before the group has earned the income or incurred the costs of providing the designated health care services. One commenter stated that this proposed interpretation would overly restrict a group practice's ability to adjust physician compensation periodically to reflect a physician's contribution to the group practice or to pay discretionary bonuses. Some commenters observed that groups have traditionally used ad hoc compensation systems that allow

groups to "wait and see how the year goes." These systems afford groups flexibility to deal with business realities as they occur without, in the commenters' view, increasing the risk of self-referral compensation. In lieu of our proposed "prior to incurrence" rule, a number of commenters favored a "prior to distribution" rule. One commenter recommended coupling a "prior to distribution" rule with a requirement that distributions not relate to the volume or value of Medicare or Medicaid DHS referrals and that distributions not be retroactively adjusted in a manner that establishes a relationship between compensation and referrals. Another commenter suggested that "previously determined" be interpreted to mean that the compensation formula must be reported at the same time groups report their financial relationships to us.

Response: It is a statutory requirement that a group's compensation methodology be determined in advance. Unrestricted ad hoc compensation systems would allow groups to compensate physicians directly based on the number of designated health care services referrals they generate—the very conduct the statute is intended to prohibit. A "prior to distribution" rule would be circular, since any distribution scheme would be determined prior to the distribution. We agree, however, that groups should have some flexibility in designing and implementing compensation systems that are responsive to changing circumstances. It is our understanding that most groups operate on a cash basis. In the final rule, we are requiring that group practices determine the methodology for distributing overhead expenses of, and income from, the provision of designated health care services prior to the receipt of payment for those services. The methodology may be determined at any time until payment has been received, even if the income has been earned or costs incurred. This rule permits groups to adjust their methodologies *prospectively* as often as they deem appropriate. We believe Phase I of this rulemaking provides groups with sufficient flexibility to respond to business realities, while complying with the statutory requirement that the distribution system be "previously determined."

Section 1877(h)(4)(A)(iv) of the Act prohibits a physician member of the group from being compensated in a manner that takes into account the volume or value of DHS referrals, except as provided in section 1877(h)(4)(B)(i) of the Act. Thus, a compensation method

that directly relates to the volume or value of Medicare referrals or is retroactively adjusted would violate section 1877(h)(4)(A)(iv) of the Act.

Comment: A commenter asked whether a group practice can distribute unexpected income which, by its nature, was not "previously" part of the group's distribution methodology. The commenter cited as an example a group practice opening a new site without specifically determining in advance how revenues or profits would be distributed to group members.

Response: We are unclear as to the circumstances under which a group practice would open a new office without considering distribution of the revenues or profits from that new office. We see no reason to deviate from the "prior to payment" rule established in these regulations for "unexpected income."

Comment: Although many commenters generally recognized the appropriateness of precluding group practice status for groups that are merely confederations of independent, unintegrated medical groups, many commenters expressed concerns about the unified business requirement promulgated in the proposed regulations. First, commenters questioned our legal authority to graft this new condition onto the statutory group practice definition. Second, commenters expressed the view that the unified business standard as proposed would have a chilling effect on legitimate group practices and discourage beneficial integration. Of particular concern was the perception that the regulations would completely prohibit or unduly complicate the group practices' use of profit and cost center or location-based accounting and distribution of expenses and income. In this regard, many commenters argued that site-specific or specialty-specific accountability encourages efficient management of expenses and practice patterns and eliminates a "free rider" problem that impedes cost effective integration, which groups find increasingly important with the growth of managed care. One commenter, representing a physician practice management company, noted that one reason groups prefer cost center accounting is that many physicians in newly-acquired group practices want to minimize changes in income levels they have historically realized; cost center accounting facilitates more absolute integration over time.

Instead of barring cost center or location-based accounting and distribution of expenses and income, commenters encouraged us to rely on

other indicators of integration. One commenter suggested that we could address our concern about loose confederations of groups by revising the rule to require that a group practice be organized and operated on a *bona fide* basis as a single business enterprise integrated legally and operationally. According to the commenters, while many legitimately integrated medical practices allow their satellite offices to make day-to-day, local practice decisions, almost all significant decisions, such as hiring and firing physicians and approval of annual operating budgets, are made by the entire practice's governing body. Moreover, the costs of central business activities such as billing, collections, managed care contracting, and purchasing of some products and services are, in most cases, shared by all practice sites, either per capita or based on a generally applied formula. Commenters offered numerous suggestions as to relevant criteria for ascertaining that a group practice is a unified business.

Response: Our statutory authority to impose a unified business test resides in section 1877(h)(4)(A)(vi) of the Act, which vests in the Secretary the ability to impose additional standards on group practices by regulation. Upon further consideration, we agree with the commenters that our proposed unified business test was too restrictive. The unified business test was designed to ensure that group practices are substantially integrated business operations and that their distribution of group expenses and income to members reflects this. The unified business test guards against the development of sham groups formed primarily for the purpose of profiting from self-referrals.

Phase I of this rulemaking, described in detail above, retains the general unified business test, but offers groups considerable flexibility in satisfying the requirement. Importantly, many forms of cost center and location-based accounting are permitted, provided that compensation formulae with respect to the distribution of DHS revenues otherwise meet the requirements of the law.

Comment: A physician trade association asked whether groups that compensate their physicians under more than one methodology can qualify as a "unified business." This issue is especially significant for larger groups that have expanded through the acquisition of other existing group practices, each of which may have negotiated different compensation arrangements. Typically, the methodology for compensating each

new physician who joins the group is set in advance, based on the negotiations between the parties and approved by the governing body of the acquiring group (or an authorized committee of the governing body).

Response: We see no impediment in the revised unified business test to groups like those described in the comment from qualifying as a unified business. In order to qualify for group practice status, the group would have to meet all of the other group practice tests, including the limitations on compensation based directly or indirectly on the volume or value of referrals and the restrictions on profit sharing and productivity bonuses. (See the discussion in section VI.C.8 of this preamble.)

Comment: One commenter expressed concern that the proposed unified business standard could be interpreted to prevent integrated medical practices from compensating their physicians on an individual collections minus expenses basis. A commenter urged that groups be allowed to compensate physicians based on their own productivity (excluding any revenue or expense related to the group's DHS), and that it be permissible to calculate the physician's compensation by allocating to the physician all of the physician's direct medical expenses of practice (including, but not limited to, for example, malpractice insurance, continuing medical education, space cost, supplies) and his or her pro rata share of general overhead not based on any volume or value of his or her referrals (for example, administrative and management costs). Similarly, another commenter stated that it is common practice for groups to compensate their members according to formulae that take into account "office profits," described as collected revenues attributable to a physician's medical services performed by that physician or personnel under his supervision, not including revenues for DHS or direct or indirect expenses of that physician.

Response: Distribution of group practice revenues derived from DHS is subject to the compensation rules set forth at § 411.352. With respect to income derived from other sources, groups are free to divide it in any manner they choose, provided they can demonstrate that they are a unified business under the three principles discussed in section VI.C.7 of this preamble. Depending on individual circumstances, we believe that most of the compensation methodologies described in the comment can be accommodated within the parameters of the revised unified business test.

Comment: One commenter questioned whether a total contingent revenue pool, distributed on an aggregate basis (after subtracting expenses that include allocated central practice or "home office" expenses) to the practitioners in a given branch or satellite office of a larger statewide PC according to a predetermined formula, would meet the requirements of the unified business test.

Response: Whether the described scheme fits in the exception would depend on whether the three factors described above are present. The scheme would also have to meet the requirements of sections 1877(h)(4)(A)(iv) (compensation for group members) and (h)(4)(B)(i) (profits and productivity bonuses) of the Act with respect to DHS. In particular, under the overall profit shares rule as set forth in Phase I of this rulemaking, as discussed in section VI.C.8, overall profit shares must be derived from aggregations of the entire practice or a component of the practice consisting of at least five physicians.

Comment: A commenter sought clarification as to whether the financial allocation requirements under the unified business standard apply solely to the DHS furnished by the group or whether they extend more broadly to all health care services furnished by the group. The commenter viewed the latter approach as beyond the statutory authority, which applies only to furnishing DHS, and as contrary to our own statements in the preamble to the proposed regulations that compensation arrangements for services that are not DHS are outside the scope of the statute and regulations.

Response: The Congress specifically conferred on the Secretary in section 1877(h)(4)(A)(vi) of the Act authority to impose additional standards in the definition of a group practice. For the limited purposes of establishing that a group practice is a unified business, we believe it is appropriate to consider the group practice's methods of distributing revenues derived from all sources, not just DHS. Group practices can distribute the revenues from services that are not Medicare-DHS in any manner they wish. However, if the payment methods do not indicate a unified business (or indicate a business that is unified solely with respect to the provision of DHS), the group may not qualify as a group practice under section 1877(h)(4) of the Act and § 411.352. Compensation paid to a physician creates a compensation arrangement within the meaning of § 411.354, even if the compensation relates only to services that are not DHS. Absent an applicable exception (for

example, the in-office ancillary services or employee exceptions), this compensation arrangement triggers the self-referral prohibition as to any of the physician's referrals of DHS.

8. Profit Shares and Productivity Bonuses

The Existing Law: In general, the statute provides that a physician who is a member of the group may not be compensated directly or indirectly based on the volume or value of his or her referrals of DHS. In addition, the statute provides that a "physician in a group practice" may receive shares of overall profits of the group or a productivity bonus based on services personally performed or incident to such personally performed services, provided the share or bonus is not determined in a manner that is directly related to the volume or value of referrals by such physician. In other words, group practice compensation formulae that are only indirectly related to the volume or value of referrals of DHS are permissible.

The Proposed Rule: We proposed to interpret the statute to mean that productivity bonuses could only relate to work personally performed by the physician that results from referrals from other physicians in the group, and could not relate (directly or indirectly) to work that results from self-referrals or DHS referrals to other physicians and other office personnel. Thus, we said that a physician could only receive compensation for his or her own DHS referrals through the aggregation that occurs as part of the overall sharing of group profits. As to the overall sharing of profits, we indicated that profits must be aggregated at the group level and not at a component level.

The Final Rule: In section IV of this preamble, we provide an overview of the physician compensation provisions of section 1877 of the Act. In general, a group practice can segregate its DHS revenues from its other revenues for purposes of compensating physicians; section 1877 of the Act applies only to a practice's DHS revenues. Generally, this income is likely to comprise a relatively small portion of the total revenues of most practices.

Under Phase I of this rulemaking, group practices may pay member physicians and independent contractors who qualify as "physicians in the group" productivity bonuses based directly on the physician's personal productivity (including services incident to such personally performed services that meet the requirements of section 1861(s)(2)(A) of the Act and section 2050 of the Medicare Carriers

Manual, Part 3), but may not pay these physicians any bonus based directly on their referrals of DHS that are performed by someone else. The statute also permits group practice members (and independent contractors who qualify as "physicians in the group") to receive shares of the overall profits of the group, so long as those shares do not directly correlate to the volume or value of DHS referrals generated by the physician that are provided by someone else. We are defining "share of overall profits" as meaning a share of the entire profits of the entire group or any component of the group that consists of at least 5 physicians derived from DHS.

Under the statutory scheme, revenues generated by DHS may be distributed to group practice members and physicians in the group in accordance with methods that indirectly take into account DHS referrals. In general, we believe a compensation structure does not directly take into account the volume or value of referrals if there is no direct correlation between the total amount of a physician's compensation and the volume or value of the physician's DHS referrals (regardless of whether the services are personally performed). Phase I of this rulemaking contains specific methodologies that describe compensation methods that are deemed to be indirect. In addition, Phase I of this rulemaking contains additional provisions that allow group practices to devise other reasonable indirect compensation methodologies.

The distribution methods for overall profit shares are as follows:

1. A per capita (that is, per physician) division of the overall profits.

2. A distribution of DHS revenues based on the distribution of the group practice's revenues attributable to services that are not DHS payable by Federal or private payers.

3. Any distribution of DHS revenues if the group practice's DHS revenues are less than 5 percent of the group practice's total revenues and no physician's allocated portion of those revenues is more than 5 percent of the physician's total compensation from the group practice.

The methods for productivity bonuses are as follows:

1. A productivity bonus based on the physician's total patient encounters or RVUs.

2. A productivity bonus based on the allocation of the physician's compensation that is attributable to services that are not DHS payable by Federal or private payers.

3. Any productivity bonus that includes DHS revenues if the group practice's DHS revenues are less than 5

percent of the group practice's total revenues and no physician's allocated portion of those revenues is more than 5 percent of the physician's total compensation from the group.

Comment: Many commenters objected to our proposed interpretation of the statute to mean that productivity bonuses can relate only to work personally performed that results from referrals from other physicians in the group, and cannot relate (directly or indirectly) to work that results from self-referrals. Commenters protested that this interpretation barred any compensation based on a physician's personal productivity for self-referred DHS and was, therefore, contrary to clear statutory intent. Several commenters explained that our interpretation would produce anomalous results in some circumstances. For example, an internist refers a patient with a gastrointestinal complaint to a gastrointestinal specialist, and the specialist evaluates the patient at an initial visit. The specialist subsequently performs an endoscopy on the patient. Under the proposed January 1998 regulations, the endoscopy would be a self-referral by the specialist, and the specialist could not receive a productivity bonus for performing the endoscopy. However, if the specialist referred the patient to another physician in the same group practice for the endoscopy, the specialist could receive compensation indirectly based on that endoscopy. Thus, in the commenter's view, the rule creates a disincentive to perform services and an incentive to refer (which may be contrary to good patient care and not cost effective). The commenter further noted that specialists who perform substantial amounts of DHS are disadvantaged by the proposed interpretation because they cannot be rewarded for personal productivity, while their counterparts, for whom the performance of DHS is a less significant part of their practices, can.

Commenters suggested an interpretation that would permit productivity bonuses for DHS personally performed by the referring physician, but not for DHS referred to others. The commenters generally requested that the final rule allow group practices to compensate members of the group based upon the volume or value of DHS, so long as the services are personally performed by the physician or are incident to the physician's personally performed services. One commenter noted that ancillary services (including "incident to" services) performed for one's own patients are more "personal" to the ordering or

supervising physician than are services he or she performs on colleagues' patients. Commenters also complained that our proposed interpretation would lead to disparate treatment of solo and group practitioners, since solo practitioners could receive the profits from personally performed DHS that they self-refer, whereas group practitioners could not. One commenter thought that this discrepancy would make solo practitioners reluctant to join group practices, thereby discouraging beneficial market integration.

Finally, some commenters noted that many group practices have insufficient information technology systems to track whether a service performed by a physician resulted from a self-referral or a referral from another physician. Commenters asserted that our proposed interpretation would impose a significant additional administrative burden on those groups.

Response: In light of the comments, the changes we have made to our interpretation of the definition of a "referral" and the volume or value standard, and our further review of the statutory language, we are persuaded that our proposed interpretation of the scope of productivity bonuses was unnecessarily restrictive. Accordingly, we have revised the regulation to make clear that group practices may pay member physicians (and independent contractors who qualify as "physicians in the group") productivity bonuses based directly on the physician's personal productivity (including services "incident to" such personally performed services that meet the requirements of section 1861(s)(2)(A) of the Act and section 2050, "Services and Supplies," of the Medicare Carrier's Manual (HCFA Pub. 14-3), Part 3—Claims Process), but may not pay these physicians any bonus based directly on their referrals of DHS that are performed by someone else.

Comment: Commenters sought clarification about the treatment of productivity bonuses for "incident to" services. One commenter observed that according to long-standing regulatory policies, "incident to" services are services that are an incidental although integral part of a physician's personal, professional service to a patient. Thus, in the commenter's view, there cannot be a referral for "incident to" services in any ordinary sense, since what the ancillary service provider does is part of the physician's service itself. Several commenters expressed their belief that one purpose of the productivity bonus provision was to allow physicians to receive "credit" for "incident to" services in their compensation. One

commenter pointed out that it would be hard to exclude "incident to" services in the calculation of productivity bonuses since claim forms typically do not indicate who performed the "incident to" service (that is, whether the service was performed by the supervising physician or someone else). Other commenters interpreted the statutory reference as equating "incident to" services with "in-office ancillary" services. Under this view, commenters asserted that the statutory language plainly allows productivity bonuses based indirectly on the volume or value of the physician's in-office ancillary services and opposed our proposed interpretation that prohibited any compensation based on referrals for in-office ancillary services.

Response: We agree with the essence of these comments with respect to group practices. Under the final regulation, group practice physicians can receive compensation directly related to the physician's personal productivity and to services incident to the physician's personally performed services, provided the "incident to" services comply with the requirements of section 1861(s)(2)(A) of the Act and section 2050, "Services and Supplies," of the Medicare Carrier's Manual (HCFA Pub. 14-3), Part 3—Claims Process, and any subsequent or additional HHS rules or regulations affecting "incident to" billing. This means that the "incident to" services must be directly supervised by the physician. In other words, the physician (or another clinic physician in the case of a physician-directed clinic) must be present in the office suite and immediately available to provide assistance and direction. Moreover, the person performing the "incident to" services must be an employee of the physician (or the physician-directed clinic). We believe that the heightened supervision requirement imposed by the "incident to" rules provides some assurance that the "incident to" DHS will not be the primary incentive for the self-referral. However, we may revisit the issue of compensation tied to "incident to" services if we find that abuses are occurring, especially in the area of physician-directed clinics.

Comment: We received a number of comments seeking clarification related to the methods of paying compensation that are not *directly* based on the volume or value of referrals. First, commenters urged that we allow pooling of revenues that are not DHS revenues, because such revenues are not governed by the statute. Second, a number of commenters objected to our position in the proposed regulations

that overall profits are not profits that "belong only to a particular specialty or subspecialty group" (even if the group is located in several States or has several locations in one State) because "the narrower the pooling, the more likely it will be that a physician will receive compensation for his or her own referrals." Commenters urged that pooling at practice sites with more than a few physicians should not result in any individual's compensation being directly related to the volume or value of his or her referrals, even if DHS revenues are included in the pool. Commenters generally advocated that we allow pooling if at least three physicians are included in the pool and the distribution formula is not related to DHS referrals. Third, commenters offered a variety of suggestions about how to calculate "indirect" compensation. For example, one commenter suggested that compensation be considered "indirect" if the referrals have no mathematical effect on compensation. Others suggested that compensation be considered "indirect" if it is based on per capita calculations, RVUs, patient encounters, hours worked, ownership shares in the practice, or seniority.

Response: First, we are persuaded that we should permit some additional flexibility related to the distribution of shares of overall profits by group practices. Thus, we are defining a "share of overall profits" to mean a share of the entire profits derived from DHS of the entire group practice or any component of the group that consists of at least five physicians. We believe a threshold of at least five physicians is likely to be broad enough to attenuate the ties between compensation and referrals. We are rejecting the suggestion to use a threshold of three physicians because we believe that the lesser threshold would result in pooling that would be too narrow and, therefore, potentially too closely related to DHS referrals. Second, we recognize the need for clear guidance as to appropriate indirect compensation methodologies. For that reason, we are including in Phase I of this rulemaking methodologies that describe compensation distribution systems that we deem to be indirect. In other words, if a group practice wants absolute assurance that its productivity bonuses or profit shares are not directly related to referrals, the group practice may employ one of the regulatory methodologies set forth in § 411.352 of the regulations. Group practices are not required, however, to use these methods. The regulations clarify that

other methods (including distributions based on ownership interests or seniority) are acceptable so long as they are reasonable, objectively verifiable, and indirectly related to referrals. These compensation methods should be adequately documented and supporting information must be made available to the Secretary upon request. Under this latter "catch-all" provision, the group practice essentially bears the risk of noncompliance.

Comment: Several commenters sought clarification as to whether an independent contractor could be compensated under the productivity bonus provision of the group practice definition as a "physician in the group", even though independent contractors are not members of the group.

Response: Independent contractors who qualify as "physicians in the group" under the provisions of § 411.351 can receive productivity bonuses under section 1877(h)(4)(B)(i) of the Act.

Comment: One commenter sought clarification as to how providers should treat capitation payments that cover more than one service for purposes of allocating profit shares and productivity bonuses.

Response: In general, we believe that capitation payments are not likely to lead to increased utilization. Parties may use any reasonable allocation method with respect to such payments.

Comment: On page 1691 of the preamble to the January 1998 proposed regulations, we explained our view that "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 complexity of the service)." A commenter objected to the parenthetical statement, asserting that barring consideration of the complexity of the service is contrary to other Medicare payment provisions, which take into consideration the level of training necessary to perform, and difficulty of, certain procedures.

Response: Given our revised interpretation, we believe the parenthetical statement ("such as value based on complexity of the service") is no longer relevant to these regulations. Group practice members can be compensated directly based on their personal productivity (that is, the fruits of their own labors), but not on their productivity in generating referrals. They may only be compensated based indirectly on DHS referrals to other physicians or providers. So long as the

compensation is only indirectly related to the volume or value of DHS referrals, we believe it makes little difference if the value of the DHS referrals reflects the complexity of the services.

Comment: A commenter sought clarification that when a physician is a member of a group practice and is also an employee of the group practice, his or her compensation may be determined under the group practice's rules without regard to the employee exception.

Response: We agree that when a physician is a member of a group practice, his or her compensation need only comply with the group practice rules. Meeting the group practice definition allows physicians in the group to refer within the group under the in-office ancillary services exception or the physicians' services exception. However, nothing prevents a physician and group practice from using the employee exception instead. It is important to remember that referrals of DHS are only permitted if an exception, such as the in-office ancillary services exception or employee exception, applies.

Comment: Several commenters were confused by our use of the terms "revenues" and "profits" throughout the preamble to the January 1998 proposed regulations. For example, on page 1691 we stated that "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." Similarly, on the same page we stated that 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 * * *." These commenters requested that the terms "profits" and "revenues" be used in a manner that is consistent with their generally accepted meanings or that definitions of the terms be provided in the regulations.

Response: We agree that the terms "revenues" and "profits" were used inconsistently in the January 1998 proposed regulation. In Phase I of this rulemaking, we have endeavored to use those terms consistent with their generally accepted meanings.

9. Group Practice Attestations

The Existing Law: In § 411.360 of the August 1995 final rule covering referrals for clinical laboratory services, we included the requirement that group practices provide their carriers with a written statement annually to attest that, during the most recent 12-month period, 75 percent of the total patient care services of group members was

furnished through the group. Any group that intended to meet the definition of a group practice in order to qualify for one of the exceptions provided in the regulations was required to submit the required attestation to its carrier by December 12, 1995. 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 could 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.

The Proposed Rule: The proposed rule retained § 411.360, as amended by the December 1995 final rule, with several minor changes.

The Final Rule: We have eliminated the attestation requirement.

Comment: One commenter suggested that group practice attestations not be required until 1 year after final regulations are published, while another recommended 1½ years after publication of the final rule. Otherwise, the commenter stated, a group practice would have to attest to membership requirements for the previous 12 months, without benefit of having had the membership requirements published in advance and an opportunity to comply with them.

One commenter also questioned whether we will actually use the information gained from group practice attestations. The commenter believes that imposing a civil money penalty for failing to submit an attestation is overly harsh when compared to the minimal benefit that may be derived from the attestations. The commenter recommended that we remove the requirement for attestations or, at least, reduce the related penalties.

Response: We agree with the commenters. After reviewing the attestation requirement, we have concluded that it would impose an unwarranted burden on group practices. We intend instead to allow groups to treat the information they need to establish that they are a group practice in the same manner as any information a furnishing entity must provide to us under the reporting requirements in § 411.361. In order to make 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 instead that entities should retain enough records to demonstrate, in the event of an audit, that particular relationships are excepted under the law. In the case of the in-office ancillary services exception and physician services exceptions in section 1877(b)(1) and (b)(2), an entity may need to establish that the services it provided were referred by members of a genuine group practice. Thus, a group should retain records that demonstrate that it meets the requirements in section 1877(h)(4) of the Act and § 411.351.

D. Prepaid Plans (Section 1877(b)(3) of the Act)

The Existing Law: In the August 1995 final rule, we interpreted the prepaid plan exception, section 1877(b)(3) of the Act, as creating an exception to the general prohibition on referrals for services furnished by certain prepaid health plans to their enrollees, including Federally qualified health maintenance organizations (HMOs) or prepaid health care organizations with a contract or agreement under sections 1876 or 1833(a)(1)(A) of the Act, or organizations participating in demonstration projects under section 402(a) of the Social Security Amendments of 1967 or section 222(a) of the Social Security Amendments of 1972. The August 1995 final rule incorporated section 1877(b)(3) into the regulations in § 411.355(c), concerning clinical laboratory services furnished by an organization (or its contractors or subcontractors) to enrollees of these prepaid health plans (not including services provided to enrollees in any other plan or line of business offered or administered by the same organization).

The Proposed Rule: The January 1998 proposed rule proposed an additional exception for services provided by organizations participating in the Medicaid program that are analogous to those cited in section 1877(b)(3) of the Act, including managed care organizations (MCOs) that contract with Medicaid under section 1903(m) of the Act, entities operating under a demonstration project under section 1115(a) of the Act, prepaid health plans contracting with a State, and health insuring organizations furnishing services as managed care contractors. (Although we proposed including demonstration projects under section 1115(a) of the Act in the preamble of the January 1998 proposed rule at 63 FR 1697, they were not listed in proposed § 435.1012 as the result of a drafting

error. We will include a technical correction for this section in Phase II of this rulemaking.) In addition, the rule proposed to extend the protection of section 1877(b)(3) of the Act to providers, suppliers, and other entities that provided services to enrollees of the protected organizations under contracts with these organizations, either directly or indirectly.

The January 1998 proposed rule also took a number of other positions that directly affected physicians' financial relationships with managed care entities and plans other than Medicare and Medicaid managed care plans. Most importantly, we proposed that MCOs would be deemed to be *entities "furnishing" DHS* provided by other entities if the MCOs billed Medicare for DHS provided to Medicare patients by providers and suppliers pursuant to a contractual arrangement with the MCOs (other than services under a plan protected under section 1877(b)(3) of the Act or other protected arrangement).

The preamble of the January 1998 proposed rule also discussed whether an MCO network physician could refer private fee-for-service patients to other physicians and providers that were participating in an MCO network. According to the preamble, a physician who had a contractual relationship with an MCO could refer a nonenrolled Medicare fee-for-service patient for a designated health service to another physician who also had a contract with the MCO provided that the physician to whom he or she referred the patient was not otherwise affiliated with the MCO. However, if the same physician referred the same patient to a laboratory owned by the MCO, the general prohibition would apply and the financial arrangement between the MCO and the physician would have to qualify for an exception. In other words, the referring physician would not have a financial relationship with the second physician, but he would have one with the laboratory. Of course, the arrangement could still be protected under the personal service arrangements exception.

The M+C interim final rule (63 FR 35066) amended § 411.355(c) of the regulations covering referrals for clinical laboratory services to include a new paragraph (5). This paragraph added to the list of prepaid plans coordinated care plans (within the meaning of section 1851(a)(2)(A) of the Act) offered by an organization in accordance with a contract with us under section 1857 of the Act. Section 1877(b)(3) of the Act was also amended by section 524(a) of the Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106-113, enacted

on November 29, 1999), which added a new paragraph (E). Paragraph (E) includes in the prepaid plans exception services referred by a physician to an organization that is an M+C organization under Part C that is offering a coordinated care plan described in section 1851 of the Act [42 U.S.C. 1395w-21(a)(2)(A)] to an individual enrolled with the organization.

The Final Rule: Virtually all commenters agreed with our decision to interpret the prepaid plan exception to protect any referrals by physicians for DHS covered by the listed Medicare managed care plans to an MCO that has a Medicare managed care contract or any entity, provider, or supplier furnishing these services under a contract or subcontract with the MCO, directly or indirectly ("downstream providers"). Several commenters asked that we amend the regulations text to reflect the interpretation. We are amending the text of § 411.355(c) to make clear that downstream providers are protected.

We are not finalizing at this time the proposed new § 435.1012 (Limitation on FFP related to prohibited referrals), paragraph (b) (Exception for services furnished to enrollees on a predetermined, capitated basis), which would have extended the protection to certain prepaid plans under Medicaid. A number of commenters agreed with our proposed exception for services provided by organizations analogous to those cited in section 1877(b)(3) of the Act. These and other commenters suggested that a number of other Medicare or Medicaid arrangements be included in the exception, including M+C coordinated care plans, Medicaid managed care plans under the BBA 1997, Medicaid managed care entities operating under a waiver pursuant to section 1115 of the Act, any demonstration project approved by us, including primary care case management programs (PCCMs) and managed long term care programs (MLTCs), programs of all-inclusive care for the elderly (PACE), capitated Medicare demonstration programs (including social health maintenance organizations (SHMOs), the Medicare subvention demonstration, and the Medicare prepaid competitive pricing demonstration). The commenters pointed out that although the preamble to the January 1998 proposed rule had proposed to include some of the above programs in the new exception, they had not been referenced in the regulations text. We agree with the commenters on adding the Medicaid organizations that are analogous to those

in section 1877(b)(3) of the Act as described in the January 1998 proposed rule and on some of the other listed areas; however, we will address Medicaid managed care, and potentially other suggestions related to Medicaid managed care raised by the commenters, in Phase II of this rulemaking.

We are also revising in Phase I of this rulemaking the proposed regulations in response to comments expressing concerns about the impact of the January 1998 proposed rule on commercial and employer-provided managed care arrangements. First, we are creating a new compensation exception for remuneration pursuant to a *bona fide* "risk-sharing arrangement" between a physician and a health plan for the provision of items or services to enrollees of the health plan, even when such an arrangement does not fall within existing statutory exceptions. (We note that the new risk-sharing arrangement exception differs from the shared risk exception to the anti-kickback statute at §§ 1001.952(t) and (u); for example, unlike the anti-kickback exception, the new exception under section 1877 of the Act contains no conditions related to the volume of Medicare beneficiaries enrolled in the health plan or the quantification of the financial risk.) Physicians generally are compensated for services to managed care enrollees in one of three ways, the first two of which do not vary based on the volume or value of referrals: (1) A salary in the case of a physician who is an employee, (2) a "fee-for-service" contractual arrangement under which the physician assumes no risk, or (3) a risk-sharing arrangement, under which the physician assumes risk for the costs of services, either through a capitation arrangement, or through a withhold, bonus, or risk-corridor approach. The first two compensation arrangements are eligible for the statutory exceptions for *bona fide* employment relationships and personal service arrangements, while the third is potentially eligible for the new risk-sharing arrangement exception we are creating in this final rule in § 411.357(n).

Second, we are revising the definition of "entity" in § 411.351 to permit physician ownership of network-type HMOs, MCOs, provider-sponsored organizations ("PSOs") and independent practice associations ("IPAs"). Specifically, we are clarifying the definition of *entity furnishing DHS*, to provide that a person or entity is considered to be furnishing DHS if it is the person or entity to which we make payment for the DHS, directly or upon assignment on the patient's behalf, except that if the person or entity has

reassigned its right to payment to (i) an employer pursuant to § 424.80(b)(1), (ii) a facility pursuant to § 424.80(b)(2), or (iii) a health care delivery system, including clinics, pursuant to § 424.80(b)(3) (other than a health care delivery system that is a health plan (as defined in § 1000.952(l)), and other than any MCO, PSO, or IPA with which a health plan contracts for services provided to plan enrollees), the person or entity furnishing DHS is the person or entity to which payment has been reassigned. We are providing further that a health plan, MCO, PSO, or IPA that employs a supplier or operates a facility that could accept reassignment from a supplier pursuant to §§ 424.80(b)(1) and (b)(2) is the entity furnishing DHS for any services provided by such supplier.

We believe these changes address the comments we received from the commercial and employer-sponsored managed care plans.

Comment: While commenters uniformly welcomed the broad protection given in the January 1998 proposed rule to referrals for services covered by Medicare prepaid health plans, several commenters stated that we interpreted several provisions of the statute in a manner that, taken together, would severely limit MCOs' use of physician incentive plans, whether under commercial or Medicare contracts. The commenters strongly objected to our statement that the prohibition on DHS referrals applies to referrals to entities that arrange for the furnishing of the DHS to Medicare or Medicaid patients by contracting with other providers, whenever the arranging entity also bills Medicare or Medicaid for the services. (See 63 FR 1706.) The commenters explained that this view, when joined with our interpretation of section 1877(e)(3)(B) of the Act (the physician incentive plan provision in the personal service arrangements exception), could effectively preclude the use of risk-sharing arrangements with physicians in any health plan, including commercial plans. The commenters explained the problem as follows:

- Physicians that participate in a managed care network will have a compensation arrangement with the MCO for payment for services to the MCO's enrollees. That payment arrangement will create a financial relationship for purposes of section 1877 of the Act. (Even participation in the network of an organization eligible for the Medicare prepaid plans exception would not entirely avoid this result, since the prepaid plans exception only protects referrals for DHS

furnished to beneficiaries enrolled under the Medicare contract). Many of these compensation arrangements use withholds, capitation, bonuses, or other methodologies that take into account, directly or indirectly, the volume or value of referrals or other business generated by the referring physician.

- Most, if not all, commercial or employer-provided group health plans offered by MCOs include some enrollees who are Medicare beneficiaries. Typically, these enrollees either are retired employees who have expanded benefits under an employer-provided plan (in which case Medicare is the primary insurer and the employer plan secondary) or are beneficiaries who have group health plan coverage based on current employment status (in which case the employer plan is the primary insurer and Medicare secondary). Even the MCOs that have Medicare managed care lines of business that are protected by the prepaid plans exception commonly have commercial lines of business that include some Medicare beneficiaries who are not enrolled under the organization's Medicare contract (that is, Medicare's payment is made on a fee-for-service basis under the traditional Medicare program).

- When a Medicare beneficiary is enrolled in a commercial or employer-provided group health plan, Medicare often pays for services provided by the plan to the beneficiary/enrollee on a fee-for-service basis. In such a case, if Medicare is the primary insurer, it will reimburse the provider according to the same provisions as any fee-for-service provider; if Medicare is the secondary insurer, it will pay based on a formula prescribed by law.

- Generally, if an enrollee of a commercial or employer-provided health plan has primary coverage under Medicare, the network physician or supplier (not the MCO) will submit the claim to Medicare directly, since Medicare is the primary insurance. However, many, if not all, such MCOs will occasionally bill Medicare for services provided by network providers to these Medicare beneficiaries. Most often, the purpose of the billing is to coordinate with Medicare when Medicare is the secondary payer. Occasionally, the MCOs may bill Medicare as the primary payer; for example, when there has been a recent change in beneficiary status, such as when a beneficiary's group health plan coverage ceases being based on current employment status because the beneficiary retires and Medicare becomes the primary insurer. Of course, MCOs may bill and be paid by Medicare only where the MCO meets the criteria

for direct payment, assignment of benefits or reassignment of benefits. (See §§ 424.73 and 424.80 of these regulations.)

- Accordingly, under the interpretation in the January 1998 proposed rule, a physician in the MCO network will be deemed to make a referral to the MCO for the provision of a DHS whenever the physician refers an enrollee of the MCO's commercial plan who also happens to be a Medicare beneficiary to another network provider for DHS. (Referrals of enrollees in any of the excepted prepaid plans would not be affected since they are not referrals of DHS by virtue of the prepaid plans exception.)

- As a result, unless all of the MCO's payment arrangements with network physicians, regardless of the line of business, fit in an exception under section 1877 of the Act, the referral of any enrollee with primary or secondary coverage under Medicare for a designated health service would be prohibited.

- The only kinds of physician compensation arrangements that are protected by the personal service arrangements exception in the proposed rule are (1) fixed per-service payments based on fair market value (for example, discounted fee-for-service arrangements) or (2) payment arrangements that incorporate risk-sharing elements, such as bonuses or withholds, provided they qualify as a physician incentive plan under section 1877(e)(3)(B) of the Act.

- However, many payment arrangements in commercial or employer-provided health plans contain risk-sharing elements that take into account a physician's referrals or the volume of services provided but that do not currently comply with the physician incentive plan regulations. These arrangements would have to be restructured. Moreover, even if restructured, the physician incentive plan regulations contain a number of requirements that would require revision if they are to be implemented with respect to non-M+C plans.

- Lastly, in the preamble to our January 1998 proposed rule, we stated that section 1877(e)(3)(B) of the Act only applied to compensation arrangements directly between the "entity" (that is, the MCO) and the physician; any compensation arrangements between a physician and party other than the MCO, such as an IPA or other subcontractor, would not qualify as a physician incentive plan.

The commenters asserted that the net effect of our interpretation in the January 1998 proposed rule of when an entity was furnishing DHS provided by

another entity would be the total disruption of commercial and employer-provided health plans. The only way an MCO could assure that its physician compensation arrangements were in compliance with section 1877 of the Act would be to restructure all its payment arrangements to pay all physicians for all lines of business on a discounted fee-for-service basis. Moreover, since the MCOs and, in many instances, subcontractors such as IPAs would also be entities furnishing DHS, any physician ownership of such entities would be a prohibited investment interest unless an appropriate exception applied.

Response: Nothing in the legislative history suggests that section 1877 of the Act was intended by the Congress to require the wholesale restructuring of commercial managed care arrangements with physicians. Accordingly, we are making two major changes to the January 1998 proposed rule that we believe will address the commenters' concerns. First, as noted above, we are creating a new compensation exception for *bona fide* risk-sharing arrangements between a health plan and providers for services provided to plan enrollees that do not otherwise qualify for an existing statutory exception. This exception will address concerns related to the prohibition on compensation arrangements in section 1877 of the Act. Second, we are revising our definition of "entity" to clarify that a person or entity is considered to be furnishing DHS if it is the person or entity to which we make payment for the DHS, directly or upon assignment on the patient's behalf, except that if the person or entity has reassigned its right to payment to (i) an employer pursuant to § 424.80(b)(1), (ii) a facility pursuant to § 424.80(b)(2), or (iii) a health care delivery system, including clinics, pursuant to § 424.80(b)(3) (other than a health care delivery system that is a health plan (as defined in § 1000.952(l)), and other than any MCO, PSO, or IPA with which a health plan contracts for services provided to plan enrollees), the person or entity furnishing DHS is the person or entity to which payment has been reassigned. We are providing further that a health plan, MCO, PSO, or IPA that employs a supplier or operates a facility that could accept reassignment from a supplier pursuant to §§ 424.80(b)(1) and (b)(2) is the entity furnishing DHS for any services provided by such supplier. We believe this change should address the possible adverse impact on physician ownership of MCOs and IPAs.

With respect to the first change, we are creating in § 411.357(n) a new

exception under section 1877(b)(4) of the Act for *bona fide* risk-sharing compensation arrangements between an MCO and a physician (either directly or indirectly through a subcontractor) for services to enrollees of a health plan. (For purposes of the new exception, we are incorporating the definitions of "health plan" and "enrollees" found in § 1001.952(l).) The vast majority of Medicare and Medicaid beneficiaries in managed care plans are either in M+C plans or Medicaid managed care plans, both of which are already required to comply with the physician incentive plan regulations. As to the relatively small number of Medicare beneficiaries in commercial or employer-sponsored plans that do not necessarily satisfy physician incentive plan requirements, or otherwise qualify for an existing exception under section 1877 of the Act, we are not currently aware of any fraud or abuse involving the Medicare program or Medicare beneficiaries arising from physician risk-sharing arrangements in these commercial or employer-provided health plans. Given the potential for the unintended disruption of these arrangements described by the commenters and the administrative need for "bright line" rules, we believe the new physician risk-sharing arrangements exception to section 1877 of the Act is needed. We will continue to monitor these arrangements for possible abuse and, if necessary, may revisit the issue in the future.

With respect to the second change, the potential impact of the January 1998 proposed rule on physician ownership of MCOs and IPAs was attributable to our interpretation that an MCO or IPA was an entity furnishing DHS provided by another entity whenever it billed for the services provided by another entity pursuant to a contract with the MCO or IPA. As noted above, in response to the above comment, we are amending the definition of "entity" in § 411.351 to clarify that a health plan, or an MCO, PSO, or IPA with which the plan contracts directly or indirectly for services to plan enrollees, will only be considered to be furnishing DHS when the health plan, MCO, PSO, or IPA furnishes the services directly (that is, through an employee), or otherwise is the entity to which we make payment for the DHS, either directly or upon assignment on the patient's behalf, or pursuant to a valid reassignment under the Medicare rules and regulations to (i) an employer pursuant to § 424.80(b)(1), (ii) a facility pursuant to § 424.80(b)(2), or (iii) a health care delivery system, including clinics, pursuant to

§ 424.80(b)(3) (other than a health care delivery system that is a health plan (as defined in § 1000.952(l)), and other than any MCO, PSO, or IPA with which a health plan contracts for services provided to plan enrollees). We are providing further that a health plan, MCO, PSO, or IPA that employs a supplier or operates a facility that could accept reassignment from a supplier pursuant to §§ 424.80(b)(1) and (b)(2) is the entity furnishing DHS for any services provided by such supplier.

We believe this change should allow for physician ownership of most types of network IPAs and MCOs. Ownership or investment interests in entities, including MCOs and IPAs, that provide DHS directly would still be prohibited (absent an applicable exception). Moreover, any indirect financial arrangements between physicians and the entities directly providing DHS would need to be analyzed to ensure there are no prohibited indirect financial relationships. For example, an MCO may have an investment interest in a lab, and a physician that contracts with that MCO may refer a Medicare beneficiary to that lab for DHS, for which Medicare is billed on a fee-for-service basis. While the MCO would not be considered to be furnishing the DHS for purposes of section 1877 of the Act, the lab in which the MCO has an investment interest would be furnishing DHS. Since the physician has a financial relationship with the MCO, and the MCO has an investment interest in the lab, there may be an indirect financial relationship that would then have to fit in an exception, most likely the indirect compensation arrangement exception or the risk-sharing arrangement exception. (See discussion in section III.A of this preamble.)

Finally, in Phase II of this rulemaking, we expect to amend the January 1998 proposed regulations for the personal service arrangements exception to reflect that risk-sharing compensation arrangements between entities downstream of a Medicare MCO can qualify as physician incentive plans within the meaning of section 1877(e)(3)(B) of the Act; this interpretation is consistent with our interpretation in the Medicare physician incentive plan regulations in §§ 422.208 and 422.210.

We believe these provisions will address the commenters' concerns.

Comment: One commenter stated that even if the MCO itself directly provided DHS pursuant to a physician referral, the MCO's compensation arrangement with the referring physician should not be deemed to take into account the volume or value of referrals for DHS

unless the risk-sharing arrangement was based in part on the utilization or cost of the DHS provided directly by the MCO.

Response: For purposes of the personal service arrangements exception, the compensation from the MCO does not take into account "the volume or value of referrals or other business generated between the parties" unless the compensation varies based on the volume or value of the MCO's business that is generated by the physician. (See the discussion of "volume or value" and "other business generated" in section V of this preamble.) We have addressed the issue of physician risk-sharing arrangements (including, but not limited to, capitation payments, bonuses, and withholdings) with commercial and employer-sponsored managed care plans by creating a new exception under section 1877(b)(4) of the Act for *bona fide* risk-sharing compensation arrangements between an MCO and a physician (either directly or indirectly through a subcontractor) for services to enrollees of a health plan.

Comment: Several commenters were unclear whether physicians who participate in a managed care network would be prohibited from referring Medicare fee-for-service patients who are not enrollees of a managed care plan for DHS to other providers in the managed care network simply because both providers had contractual relationships with the same MCO.

Response: Physicians who participate in a managed care network would not be prohibited from referring Federal fee-for-service patients who are not enrollees of a managed care plan for DHS to other providers with contractual relationships with the same MCO solely on the basis of the parallel contractual arrangement with the MCO. In other words, two physicians who contract with an MCO do not have a financial relationship with each other for purposes of section 1877 of the Act on that basis alone. However, they may have other financial relationships (including indirect financial relationships) that would bar their referrals (in the absence of an applicable exception).

Comment: Several commenters asked that we create an exception for nongovernment plans that include any significant cost-sharing elements. This exception would be similar to the exception in the Federal anti-kickback statute for risk-sharing arrangements.

Response: As discussed earlier, we have created a new exception for *bona fide* risk-sharing compensation arrangements between health plans and physicians. The exception we are

creating is substantially broader than the shared risk exception in the Federal anti-kickback statute.

Comment: Another commenter asked that we create an exception to permit public hospitals to enter into incentive arrangements with physician groups for the treatment of the public hospital's patients. One commenter also suggested that we create an exception for commercial managed care product lines that serve fewer than 20 percent Medicare patients as part of the group and that are not marketed directly to Medicare patients.

Response: As described above, we have created a risk-sharing arrangements exception in § 411.357(n) that should address the commenter's concern regarding commercial managed care arrangements. With respect to the request to create an exemption for public hospital patients, the commenter provided no explanation of the types of arrangements proposed to be exempted, and we see no reason why these arrangements could not be subject to abuse.

Comment: Two commenters asked us to clarify that the prepaid plan exception protects any DHS provided to any enrollee of any plan (including commercial or employer-sponsored plans) offered by an entity that either is a Federally-qualified HMO or has a contract under one of the programs cited in section 1877(b)(3) of the Act. One of the commenters asked us to clarify that services to persons covered under an employer self-funded health plan that is administered by an entity with a qualified contract under section 1877(b)(3) of the Act and uses the MCO's network of providers would also be exempt under the prepaid plan exception.

Response: We believe that the Congress intended that the exception in section 1877(b)(3) of the Act protect only the financial arrangements for services to enrollees of the prepaid plans identified in section 1877(b)(3). We see no basis for concluding that because an entity has one contract covering a specific population, there is any protection against abusive relationships in other product lines. Accordingly, we are clarifying the regulation to state that the protection extends only to financial arrangements for the services to enrollees of the plans specifically identified in the regulation and does not protect enrollees in any other plan or line of business furnished by the MCO or to which the MCO provides administrative services.

Comment: One commenter suggested that we use the definition of health plan and enrollee set forth in the managed

care safe harbor regulations to the Federal anti-kickback statute, § 1001.952 (Exceptions), paragraph (l) (Increased coverage, reduced cost-sharing amounts, or reduced premium amounts offered by health plans). The commenter stated that it was unclear from the preamble of the January 1998 proposed rule whether employees covered by an employer self-funded plan that utilized a commercial insurer to administer the plan would be considered “enrollees” of the commercial insurer for purposes of the prepaid plan exception and for application of the physician incentive plan provision of the personal service arrangements exception.

Response: We agree that employer self-funded plans should be able to qualify for protection of their physician compensation arrangements. We believe the new risk-sharing compensation exception will address the commenters’ concerns. For purposes of the new exception, we are incorporating the definitions of “health plan” and “enrollee” from the safe harbor regulations for certain health plans set forth in § 1001.952(l)(2). This definition would result in equal treatment for self-funded plans and insured plans.

Comment: One commenter requested that we interpret section 1877 of the Act to “grandfather” any pre-existing managed care arrangements. The same commenter asked that we broaden the exception for personal service arrangements to protect quality-related incentive plans that take into account the volume or value of DHS referrals.

Response: The statutory provisions clearly envision their application to managed care plans. Accordingly, a blanket “grandfather” provision for these plans is inappropriate. With respect to the request for protection of quality-related incentive plans, the commenter did not provide any details as to the kind of incentives being described. We do not perceive any impediment in the regulation that would preclude basing compensation on quality measures unrelated to the value or volume of DHS referrals or other business generated by the physician. However, absent further clarification, we are not inclined to protect any arrangement that takes into account referrals or business generated by the physician.

Comment: One commenter requested that we create a new exception for payer-directed services. According to the commenter, in managed care arrangements, the payer is the party that directs the referrals for DHS and not the physician who is contractually obligated to refer in the network. Another commenter stated that, in the managed

care environment, our proposed presumption in the January 1998 proposed rule that a physician has referred a patient to an entity with which he or she has a financial relationship if the patient, in fact, procures the services from this entity—even if there is no order or written plan of care—should not be applied.

Response: We believe the changes we have made to accommodate various financial relationships between managed care organizations and physicians should address the referral issues in the managed care environment.

Comment: Several commenters asked that the provision in the group practice definition permitting employees to receive productivity bonuses be expanded to permit remuneration based on volume or value of DHS referrals if the arrangement complies with the physician incentive plan regulations as permitted in the personal service arrangements exception. The commenters noted that in some arrangements, the employed physicians have separate contracts with the MCO, while in others the contract is between the MCO and the group, making it important to permit the group to incentivize its employed physicians. According to the commenters, employers should have at least as much latitude in structuring their compensation arrangements with employees as with independent contractors. The commenters suggested that the group practice definition already expressly permits productivity bonuses indirectly tied to referrals—a greater concern since overutilization is the primary concern of section 1877 of the Act. In light of that provision, one commenter believes it is incongruous to prohibit physician incentive plan arrangements that discourage utilization if they comply with the physician incentive plan regulations.

Response: We agree that, at least in the managed care environment, there is little reason to impose a more restrictive requirement on compensation arrangements between a group and its employees than on arrangements between the group and its independent contractors. However, this concern is only one aspect of the broader relationship between the group practice, personal service arrangement, and *bona fide* employment relationship exceptions that is discussed in sections IV and VI.C.8 of this preamble.

Comment: Several commenters asked that we clarify the reporting obligations of plans that are not technically subject to the physician incentive plan regulations, since they are not Medicare

or Medicaid managed care plans (or M+C plans), but that are complying with the regulations to qualify their financial arrangements with physicians for the personal service arrangements exception in section 1877 of the Act.

Response: The various reporting requirements associated with, or triggered by, the regulation will be addressed in Phase II of this rulemaking.

VII. New Regulatory Exceptions

This section describes new regulatory exceptions that are not in the statute, but which appeared in the January 1998 proposed rule or that we have created in response to comments and pursuant to statutory authority conferred on the Secretary. The new exceptions discussed here include: Academic medical centers, fair market value, and non-monetary compensation up to \$300 (and medical staff benefits). Other new exceptions described elsewhere in this preamble include: Implants in an ASC (§ 411.355(e); section VIII.J of this preamble); EPO and other dialysis-related drugs (§ 411.355(f); section VIII.L of this preamble); preventive screening tests, immunizations, and vaccines (§ 411.355(h); section VIII.L of this preamble); risk-sharing arrangements (§ 411.357(n); section VI.D of this preamble); compliance training programs (§ 411.357(o); section VII.C of this preamble); eyeglasses and contact lenses (§ 411.355(i); section VIII.J of this preamble); and indirect compensation arrangements (§ 411.354(c)(3); section III.A of this preamble).

A. Academic Medical Centers

The Existing Law: Section 1877(h)(4) of the Act contains a special rule for faculty practice plans. The rule provides that “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 provide a variety of different specialty services and provide professional services both within and outside the group, as well as perform other tasks such as research, subparagraph (A) [the definition of “group practice”] shall be applied only with respect to the services provided within the faculty practice plan.”

Several commenters to the August 1995 final rule suggested that we create a separate exception for faculty practice plans, since these plans are typically involved in complex organizational arrangements that do not fit comfortably—or at all—in the group practice definition. At the time of the August 1995 final rule, we rejected the suggestion for a new exception based on

our view that the personal service arrangements exception and the employment exception would provide physicians in academic medical settings with appropriate protection under section 1877 of the Act.

The Proposed Rule: We proposed no changes.

The Final Rule: We have revisited our prior position. The comments have persuaded us that academic medical practices raise numerous questions under section 1877 of the Act that are not adequately addressed by existing exceptions.

Though the relevant provision in the group practice definition is somewhat obscure, we believe it demonstrates congressional intent to address the circumstances of physicians practicing in academic medical settings. We do not believe, however, that the core problem of how to treat academic medical practices under section 1877 of the Act is amenable to resolution under the group practice definition; the problem lies elsewhere.

Academic medical settings often involve multiple affiliated entities that jointly deliver health care services to patients (for example, a faculty practice plan, medical school, teaching hospital, outpatient clinics). There are frequent referrals and monetary transfers between these various entities, and these relationships raise the possibility of indirect remuneration for referrals. The exceptions under section 1877 of the Act do not easily apply. For example, faculty practice plan physicians refer patients for ancillary services to entities that are outside of (and not wholly owned by) the single legal entity in which they conduct their medical practices (that is, the "group practice"), but with which they may have direct or indirect compensation relationships (for example, part of the physician's compensation may come from an affiliated medical school or teaching hospital). These referrals typically will not qualify under the in-office ancillary services exception, and it may be difficult to structure compensation relationships for faculty practice plan physicians that securely fit in the personal service arrangements exception because the physician's compensation often comes directly or indirectly from several separate sources.

Having reviewed the comment letters addressing the problems facing faculty practice plans under section 1877 of the Act, we believe the fundamental need of faculty practice plans is for a separate compensation exception for payments to faculty of academic medical centers that takes into account the unique circumstances of a faculty practice,

including the symbiotic relationship among faculty, medical centers, and teaching institutions, and the educational and research roles of faculty in these settings. Therefore, we are using our regulatory authority under section 1877(b)(4) of the Act to create a separate compensation exception for payments to faculty of academic medical centers that meet certain conditions that ensure that the arrangement poses essentially no risk of fraud or abuse. This exception is in addition to other exceptions that may apply in particular circumstances; an arrangement need only fit in one available exception.

The conditions applicable under the new exception in § 411.355(e)(1)(i) are that the referring physician is a *bona fide* employee of a component of an academic medical center on a full-time or substantial part-time basis, is licensed to practice medicine in the State, has a *bona fide* faculty appointment at the affiliated medical school, and provides either substantial academic or substantial clinical teaching services for which the faculty member receives compensation as part of his or her employment relationship with the academic medical center. The purpose of this condition is to ensure that protected physicians are truly engaged in an academic medical practice. The exception does not apply to payments to physicians who provide only occasional academic or clinical teaching services or who are principally community rather than academic medical center practitioners.

Under the new exception in § 411.355(e)(1)(i)(A), a "component" of an academic medical center means an affiliated medical school, faculty practice plan, hospital, teaching facility, institution of higher education, or departmental professional corporation. For purposes of this exception, an academic medical center may have some, but need not have all, of these components. As indicated in the preceding provision, however, the minimum requirements are a medical school, a faculty practice plan, and a hospital.

Under the new exception in § 411.355(e)(1)(ii), the total compensation paid for the previous 12-month period (or fiscal year or calendar year) from all academic medical center components to the referring physician is set in advance and, in the aggregate, does not exceed fair market value for the services provided, and is not determined in a manner that takes into account the volume or value of any referrals or other business generated within the academic medical center. As

with the corresponding provisions in the personal service arrangements, employee, and fair market value exceptions, this provision requires that remuneration to physicians be for *bona fide* services provided by the physicians and not for referrals. In determining fair market value for services in an academic medical practice, we believe the relevant comparison is aggregate compensation paid to physicians practicing in similar academic settings located in similar environments. Relevant factors include geographic location, size of the academic institutions, scope of clinical and academic programs offered, and the nature of the local health care marketplace. Nothing in this regulation is intended to preclude productivity bonuses paid to academic medical center physicians on the basis of services they *personally* perform.

Under the new exception in § 411.355(e)(2), the "academic medical center" for purposes of this section shall consist of—(1) an accredited medical school (including a university, when appropriate); (2) an affiliated faculty practice plan that is a nonprofit, tax-exempt organization under section 501(c)(3) or (c)(4) of the Internal Revenue Code (or is a part of such an organization under an umbrella designation); and (3) one or more affiliated hospital(s) in which a majority of the hospital medical staff consists of physicians who are faculty members, and where a majority of all hospital admissions are made by physicians who are faculty members. This provision ensures that the exception only protects physician compensation in genuine academic medical settings. This new exception reflects our view that the predominant purpose of an academic medical center is to teach new physicians and to run medical practices that support the teaching mission.

To fit within the new exception in § 411.355(e)(3), the academic medical center must meet the following conditions:

- All transfers of money between components of the academic medical center must directly or indirectly support the missions of teaching, indigent care, research, or community service. This provision ensures that the academic medical center is *bona fide* and that transfers of funds are not inappropriate payments of indirect compensation for referrals. We believe that patient care is integral to an academic medical center's community service mission.
- The relationship of the components of the academic medical center must be set forth in a written agreement that has

been adopted by the governing body of each component. This provision requires a *bona fide* affiliation between the medical center components.

- All money paid to a referring physician for research must be used solely to support *bona fide* research. We are concerned that research funding could be used to disguise additional payments for referrals. We are including this provision to ensure that money earmarked (intended or designated) for research is used solely for research purposes.

Under the new exception in § 411.355(e)(4), the referring physician's compensation arrangement must not violate the anti-kickback statute (section 1128B(b) of the Act) and billing and claims submission must be proper. As with all exceptions created under section 1877(b)(4) of the Act, this provision is necessary to ensure that the arrangement poses no risk of fraud or abuse.

Comment: As noted above, commenters pointed out that the structure of faculty practice plans can be very complicated; for example, physicians in a faculty practice plan may be compensated by one entity, but conduct their medical practice through a separate entity and order laboratory and other ancillary services from additional related entities (for example, the teaching hospital, the university's research laboratory for highly specialized testing, in-office laboratories within the faculty departments that may or may not be incorporated as professional corporations). As a result, arrangements between and among the various sub-entities of such faculty practice plans can raise a number of issues under section 1877 of the Act. In particular, the question arises whether each separate legal entity and relationship among legal entities must meet an exception under section 1877 of the Act.

Commenters appealed for a separate exception for faculty practice plans, insisting that faculty practice plans pose a minimal risk of abuse under section 1877 of the Act. First, they asserted that physicians in faculty practice plans are less likely to make abusive referrals than their more entrepreneurial counterparts in private practice because they practice in a setting that focuses on academic pursuits and patient care at affiliated teaching hospitals and clinics. Second, they stated that many faculty practice plans include not-for-profit organizations that are regulated under IRS rules that forbid private inurement and private benefit.

Response: As explained in the introduction to this section of the

preamble, we have revisited the issue of academic medical practices and are persuaded that academic medical practices present unique concerns under section 1877 of the Act that warrant a separate exception. Our new exception is described in the introduction. We believe that faculty practice plans will pose little risk of fraud or abuse under the conditions set forth in the new exception. We are not persuaded that physicians in faculty practice plans are necessarily less economically-motivated than their private practice counterparts or that regulation under IRS rules, though beneficial, is sufficient to prevent fraud or abuse.

Comment: A commenter suggested that the group practice definition and the requirements of the in-office ancillary services exception or personal service arrangements exception should be applied only at the level of the "umbrella" organization (that is, the organization that encompasses all the physicians within the faculty practice plan) for the entire faculty practice, thus obviating the need for each legal entity within the same academic setting to meet the provisions of section 1877 of the Act.

Response: In light of the new exception, we see no need to create new rules under existing exceptions for faculty practice plans. Parties may use the new exception or existing exceptions, depending on their individual circumstances.

Comment: As an alternative to a separate exception for faculty practice plans, one commenter urged that faculty practice plans be permitted to have independent contractors as "members" during the time they are providing services to the group. The commenter expressed the view that this solution would be preferable to requiring the faculty practice plan to employ such individuals.

Response: In light of the new compensation exception for physicians in faculty practice plans, we see no need to alter the definition of "member of the group" for academic medical practices. The definition of a "group practice" expressly includes a "faculty practice plan," and any faculty practice plan that fits in the definition is a "group practice" for purposes of section 1877 of the Act.

Comment: A commenter observed that under section 1877(b)(4)(B)(ii) of the Act a faculty practice plan qualifies as a group practice based solely on the services provided and revenue generated by the participating physicians within the faculty practice plan, regardless of the outside activities of those physicians. The commenter

sought clarification that the converse would also be true, that time and revenue allocable to a physician's faculty practice would not count against the "group practice" status of his outside medical group.

Response: The outside medical group must qualify for group practice status under the tests described in section 1877(h)(4) of the Act (§ 411.352 of the regulations) and in this preamble at V.I.C. Time and revenue allocable to a physician's faculty practice would be treated as all other outside time and revenue for purposes of those tests. In other words, such time and revenue would be treated no differently than time group practice physicians who are not in faculty practice plans spend supervising residents or conducting research.

B. Fair Market Value (§ 411.357(l))

The Proposed Rule. This proposed rule created an exception for compensation relationships that are based upon fair market value and meet certain other criteria. This exception is available for compensation arrangements between an entity and either a physician (or immediate family member) or any group of physicians (even if the group does not meet the definition of group practice set forth in § 411.351), as long as the compensation arrangement—

- Is in writing, is signed by the parties, and covers only identifiable items or services, all of which are specified in the agreement;
- Covers all of the items and services to be provided by the physician (or immediate family member) to the entity or, alternatively, cross refers to any other agreements for items or services between these parties;
- Specifies the time frame 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;
- Specifies 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), payment for referrals for medical services that are not covered under Medicare or Medicaid, or other business generated between the parties;

- Involves a transaction that is commercially reasonable and furthers the legitimate business purposes of the parties; and

- 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.

The Final Rule: Except for the revisions described below, Phase I of this rulemaking adopts the proposed regulation. The revisions include:

- Elimination of the requirement that the written document cross-reference other agreements between the parties.

- Revision of the “set in advance” language to conform the exception to other exceptions in which that language appears. “Set in advance,” as used in the fair market value exception, will have the uniform meaning described in section V of this preamble and § 411.354(d) of the regulations.

- Revision of § 411.357(l)(3) to conform to our uniform interpretation of the volume or value standard in § 411.354(d) (discussed at section V of this preamble).

- Revision of the proposal in § 411.357(l)(5) that required “compliance with” the anti-kickback statute. Under the final regulations, the compensation arrangement must—(1) not violate the anti-kickback statute, (2) comply with a statutory or regulatory anti-kickback safe harbor, or (3) have been approved by the OIG pursuant to a favorable advisory opinion issued in accordance with part 1008 (Advisory Opinions of the OIG) of this chapter. In addition, billing and claims submission must be proper.

- Addition of a provision to mirror section 1877(e)(3)(A)(vi) of the Act, which clarifies that the services performed under the agreement cannot involve the counseling or promotion of a business arrangement or other activity that violates Federal or State law. While we believe this condition is implied throughout the statute, we are conforming the new fair market value exception to the Congress’s inclusion of this same standard in the personal service arrangements exception.

Comment: Several commenters objected to the requirement that an arrangement must 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. First, commenters pointed out that the anti-kickback statute is an intent-based statute that prohibits certain knowing and willful conduct, whereas section 1877 of the Act is not based upon intent. In addition, one commenter was concerned

that a violation of the anti-kickback statute by one party would preclude both parties from using the fair market value exception. Thus, the innocent party who might be unaware of the other party’s violation of the anti-kickback statute and relying on the fair market value exception could unknowingly violate section 1877 of the Act. Second, several commenters stated that few arrangements would meet the requirements necessary to obtain safe harbor protection under the anti-kickback statute. Therefore, such arrangements would be excepted from section 1877 of the Act only if they met the standard of being “in compliance with the anti-kickback statute.” These commenters were concerned that “being in compliance with the anti-kickback statute” was a nebulous standard that could only be accomplished with certainty by obtaining an OIG advisory opinion.

Response: In response to the concerns of commenters, we have revised § 411.357(l)(5) of the regulations to make it clear that for a compensation arrangement to qualify for the fair market value exception, it must meet one of the following criteria:

- It must not violate the anti-kickback statute.

- It must comply with a statutory or regulatory anti-kickback safe harbor.

- It must have been approved by the OIG pursuant to a favorable advisory opinion issued in accordance with part 1008 of this title.

This revision is both a clarification of the text set forth in the January 1998 proposed rule and an expansion of the types of arrangements that may qualify for the fair market value exception. In particular, we are changing the requirement from “being in compliance with” the anti-kickback statute to requiring that the arrangement not violate the anti-kickback statute. The revised language is more appropriate with respect to a criminal statute, such as the anti-kickback statute. In addition, since the broad statutory language of the anti-kickback statute technically covers some relatively innocuous commercial arrangements, and since the OIG has promulgated regulations granting safe harbor protection for some of these arrangements (§ 1001.952 of this title), we are revising the criteria to permit compensation arrangements that comply fully with a regulatory safe harbor. Arrangements that comply with the statutory exceptions at section 1128B(b)(3) of the Act also satisfy the new criteria. Finally, any compensation arrangement that has been approved by the OIG pursuant to a favorable advisory

opinion issued in accordance with part 1008 of this title would meet the criteria of § 411.357(l)(5). (We caution, however, that only the requestor of an OIG advisory opinion may rely on the opinion for any purposes, including, without limitation, the fulfillment of this criteria. Therefore, all parties that intend to rely on the advisory opinion should be included as requestors.)

Finally, we address the scenario where only one party has the requisite intent (that is, acting knowingly and willfully) to violate the anti-kickback statute. In such a case, only the party with the requisite intent would have violated the anti-kickback statute. However, if both parties relied on meeting the “not in violation of the anti-kickback statute” standard to qualify for the fair market value exception, the anti-kickback statute violation would preclude the use of the fair market value exception to section 1877 of the Act and both parties would have violated section 1877 of the Act. Although we understand the dilemma, we believe that it would be unusual that only one party to a compensation arrangement would have the requisite intent for violation of the anti-kickback statute. If any *one* purpose of remuneration is to induce or reward referrals of Federal health care program business, the statute is violated. (See *United States v. Kats*, 871 F.2d 105 (9th Cir. 1989); *United States v. Greber*, 760 F.2d 68 (3d Cir.), *cert. denied*, 474 U.S. 988 (1985).) Also, if the “innocent” party knows that the compensation arrangement would violate the anti-kickback statute but for the lack of the requisite intent, that party should be aware of the risk he or she is facing and take action to ensure that prohibited payments are not made. In that situation, we would advise structuring the arrangement to fit within a safe harbor, if possible, or obtaining an OIG advisory opinion.

For a discussion on the differences between section 1877 of the Act and the anti-kickback statute, together with an analysis of the impact that the anti-kickback statute has on these regulatory exceptions, see section II of this preamble.

Comment: Some commenters requested clarification regarding whether services provided by an entity to a physician would fit within the fair market value exception. One commenter was confused by the fact that the preamble to the January 1998 proposed rule implied that the exception would cover any compensation arrangements based upon fair market value, but the rule itself implied that it only covered arrangements where the physician (or

immediate family member) provided items or services.

Response: This fair market value exception only covers items or services provided by a physician or any immediate family member to an entity. Depending on the facts, payments made by a physician to an entity for items or services furnished by the entity might qualify for the exception for payments by a physician which is set forth under § 411.357(i), provided that the compensation is consistent with fair market value and the payments are not specifically excepted under another provision in §§ 411.355 through 411.357.

Comment: One commenter requested clarification regarding whether this exception would be available if another exception could apply.

Response: In the preamble to the January 1998 proposed rule, we stated that parties involved in a compensation arrangement should use the fair market value exception if they have doubts about whether they meet the requirements in the other exceptions listed in § 411.357. We have reconsidered our position. The parties may use the fair market value exception even if another exception potentially applies. We believe that the safeguards against overutilization included in the fair market value exception are sufficient to cover various types of compensation arrangements, including some arrangements that are covered by other exceptions.

Comment: A couple of commenters expressed concern regarding the application of the fair market value exception to legitimate physician recruitment practices that do not otherwise qualify for exception under the physician recruitment exception set forth at § 411.357(e). One commenter was concerned that in order to meet the “commercially reasonable” and “legitimate business purposes” prerequisites, hospitals would be forced to obtain costly experts’ reports regarding recruiting incentives provided in comparable situations. Another commenter sought clarification regarding whether the “commercially reasonable” prerequisite was based upon the specific business in which the parties are involved or business in general. This commenter was concerned that some arrangements (for example, loan forgiveness programs) might be commercially reasonable in the context of hospital/physician relationships, but might not be commercially reasonable from a general business perspective.

Response: Physician recruitment arrangements might be covered by this fair market value exception or the

physician recruitment exception, depending on the specific facts involved. However, we recognize that many physician recruitment arrangements that offer “extra” payments to induce physicians to relocate will not be covered by the fair market value exception, because compensation offered for the physician’s services exceeds the fair market value for such services. We will consider the comments on the recruitment exception in Phase II of this final rule.

With respect to determining what is “commercially reasonable,” any reasonable method of valuation is acceptable, and the determination should be based upon the specific business in which the parties are involved, not business in general. In addition, we strongly suggest that the parties maintain good documentation supporting valuation. Finally, with respect to difficult cases, the parties could seek an advisory opinion under section 1877 of the Act. (See § 411.370.) However, we cannot express opinions on whether compensation represents fair market value. (See § 411.370(c)(1).) For further discussion of “fair market value”, see section VIII.B.3 of this preamble.

Comment: One commenter thought that it would be burdensome to require inclusion of all items and services provided by the physician (or immediate family member) or a cross reference to other pertinent agreements. First, the commenter noted that there may be no written agreement for certain *bona fide* employment arrangements. Therefore, if an immediate family member of a physician is employed by the entity and there is no written employment agreement, the physician’s compensation arrangement with the entity could not satisfy this requirement of the fair market value exception. Second, the commenter stated that arrangements between an entity and a physician (or immediate family member) may change from time to time as a result of new arrangements, terminations, renewals, etc. Therefore, the list of other agreements would become outdated quickly. Third, the commenter asserted that the requirement duplicated the information that was already required under the reporting requirements. To rectify the foregoing problems, the commenter suggested that the exception should only require a reference to a master list of contracts that could be updated periodically. Finally, the commenter requested clarification regarding what contracts must be cross-referenced when there is a compensation arrangement

between an entity and a member of a physician group practice. The commenter questioned, with respect to a contract between an entity and an immediate family member of a physician who is a member of a group practice, whether the contract must cross-reference arrangements between the entity and—(1) the group practice, (2) each member of that group practice, and (3) any family member of a member of the group practice.

Response: We agree that it is burdensome to require that the written agreement either cover all items and services to be provided by the physician or immediate family member to the entity, or cross refer to any other agreements for items or services between any of these parties. To alleviate this burden, we are eliminating the requirement that the agreement cross refer to any other agreements. Nevertheless, we note that cross-referencing other agreements and arrangements is a good practice and will enable contracting entities, as well as auditors, to review more efficiently the full scope of a physician’s relationship to the entity. In cases where a physician or an immediate family member of a physician is employed by the entity and there is no written employment agreement, the commenter’s conclusion that the physician’s compensation arrangement with the entity could not satisfy this requirement of the fair market value exception is correct. Another exception, such as the employment exception, may apply, since it does not require a written agreement.

Comment: Some commenters were concerned that by requiring that the compensation not be related to the volume or value of program referrals, non-program referrals, or other business generated between the parties, we had undermined the usefulness of the fair market value exception, as well as many other exceptions which are subject to the same restriction. One commenter suggested that an arrangement should not pose a risk of abuse as long as the compensation does not reflect the volume or value of the physician’s own referrals.

Response: For a discussion of the “value or volume of referrals” standard, refer to the discussion at section V of this preamble. We are conforming the language of the new fair market value exception to our uniform interpretation of the standard, which is discussed at section V of this preamble.

C. Non-Monetary Compensation up to \$300 (and Medical Staff Benefits (§§ 411.357(k) and (m))

The Proposed Rule. Physicians and their immediate family members are often given noncash items or services that have a relatively low value and are not part of a formal, written agreement. For example, a physician might receive free samples of certain drugs or chemicals from a laboratory or free coffee mugs or note pads from a hospital. Although these free or discounted items and services fall within the definition of "compensation arrangement," we believe that such compensation is unlikely to cause overutilization, if held within reasonable limits. Therefore, we proposed a new exception, titled *De Minimis Compensation*, for compensation from an entity in the form of items or services that would not exceed \$50 per gift and an aggregate of \$300 per year. In addition, to qualify for the proposed exception, the entity providing the compensation would have to make it available to all similarly situated individuals, regardless of whether these individuals refer patients to the entity for services, and the compensation could not be determined in any way that would take into account the volume or value of the physician's referrals to the entity.

The Final Rule. Except for the revisions discussed below, the regulations in Phase I of this rulemaking are the same as the proposed rule:

- Changing the name of this exception from "De Minimis Compensation" to "Non-Monetary Compensation Up To \$300" to avoid any unintentional implication that the dollar limits set forth in the exception are minimal or inconsequential in all circumstances. That is, although the \$300 dollar limit may be relatively low when compared to the average physician's annual income, we believe the amount could be sufficient to induce referrals. However, we believe that the dollar limit, together with the other conditions of the exception, are sufficient to protect against abuse.

- Elimination of the \$50 per gift limit. Therefore, if the other conditions of the exception are met, an entity can give a physician one noncash gift per year valued up to \$300 or two or more noncash gifts per year, as long as the annual aggregate value of the gifts does not exceed \$300.

- Addition of a provision that precludes protection for gifts solicited by physicians to prevent physicians from making such gifts a condition or expectation of doing business.

- Elimination of the "similarly situated" standard. This standard was designed to ensure that compensation was not paid primarily to reward high referrers. To ensure the same end, we are augmenting the standard that prohibits compensation that takes into account the volume or value of referrals by also prohibiting compensation that takes into account the volume or value of any other business generated between the parties.

- Addition of a new exception (§ 411.357(m)) to allow certain incidental benefits of low value provided by hospitals to their medical staffs.

Comment: Several commenters argued that section 1877 of the Act does not apply to relationships between physicians and drug manufacturers, because a drug manufacturer is not an "entity" that furnishes health services to which a physician purchasing drugs makes a "referral" under section 1877 of the Act. Applying this interpretation, commenters concluded that free drug samples, free training, and other gifts (for example, pens, notepads, and other items) provided to physicians by drug manufacturers are not prohibited by section 1877 of the Act, and, therefore, do not need to qualify for any of the exceptions. Also, many expressed concern that, if section 1877 of the Act is interpreted as applying to physicians' relationships with drug manufacturers, then free drug samples and training provided to physicians by pharmaceutical companies would be prohibited, because they would exceed the proposed per gift and annual dollar limits of the *de minimis* exception. They reasoned that free drug samples should be exempt from section 1877 of the Act, because they are extensively regulated by Federal law that restricts their use and prohibits their sale, and, therefore, free drug samples pose little risk of abuse. They also stressed that free training given in connection with free samples should be exempt, because it is part of the sales effort which benefits patients, as well as physicians.

Response: We agree that drug manufacturers typically are not "entities" that furnish health services to which physicians purchasing drugs make "referrals" under section 1877 of the Act. (See section VIII.B of this preamble.) Therefore, as a general rule, neither free drugs, free training, nor gifts provided to physicians by drug manufacturers are prohibited by section 1877 of the Act. We caution, however, that free or discounted items or services provided by drug manufacturers to physicians must be scrutinized to ensure compliance with other

applicable laws and regulations, including, without limitation, the anti-kickback statute and the Federal laws restricting the sale and distribution of drug samples, 21 U.S.C. § 353(c) through (d).

Comment: Many commenters expressed concern regarding the per gift and annual dollar limits. In particular, they stated that the dollar limits were so low that they precluded protection for many legitimate compensation arrangements. For example, many commenters were concerned that no protection would be provided for free or discounted benefits provided by a hospital for its medical staff. Commenters believe that free or discounted benefits (for example, free or discounted meals and refreshments, free or discounted parking, free continuing medical education or other training, free computer/Internet access, free laboratory coats, free or discounted malpractice insurance, free transcription of medical records, and free photocopying) would add up and exceed the dollar limits quickly. Concern was also expressed about the administrative burden of tracking the exact dollar amounts for benefits provided to each medical staff physician.

Finally, one commenter questioned whether, with respect to group practices, the dollar limit would apply to each individual member of the group or to the group as a whole. Another commenter suggested that the dollar limits should be indexed for inflation.

Response: First, we have added a new exception (§ 411.357(m)) for incidental benefits given to a hospital's medical staff members. The question of incidental benefits given by a hospital to members of its medical staff was addressed previously in the preamble to the January 1998 proposed rule at 63 FR 1713-1714. In particular, we noted that:

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 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 included 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.

We recognize that many of the incidental benefits that hospitals provide to medical staff members do not qualify for the employment exception because most members of a hospital's medical staff are not hospital employees, and do not qualify for the fair market value exception because, to the extent that the medical staff membership is the only relationship between the hospital and certain physicians, there is no written agreement between the parties to which these incidental benefits could be added. While we still believe that medical staff incidental benefits could be structured in a way that would reward physicians for referrals and, thereby, lead to overutilization, we also recognize that many medical staff incidental benefits are customary industry practices that are intended to benefit the hospital and its patients. For example, free computer/Internet access benefits the hospital and its patients by facilitating the maintenance of up-to-date, accurate medical records and the availability of cutting edge medical information. Consequently, we have added a new exception (§ 411.357(m)), which provides that medical staff incidental benefits are excepted from section 1877 of the Act, if the benefits in question are—

- Offered by a hospital to all members of the medical staff without regard to the volume or value of referrals or other business generated between the parties;
- Offered only during periods when the medical staff members are making rounds or performing other duties that benefit the hospital and its patients;
- Provided by the hospital and used by the medical staff members only on the hospital's campus;

- Reasonably related to the provision of, or designed to facilitate directly or indirectly the delivery of, medical services at the hospital;

- Consistent with the types of benefits offered to medical staff members by other hospitals within the same local region or, if no such hospitals exist, by comparable hospitals located in comparable regions; and

- Of low value (that is, less than \$25) with respect to each occurrence of the benefit (for example, each benefit must be of low value).

Regardless of compliance with the foregoing, we caution that medical staff incidental benefits should be reviewed to ensure compliance with other applicable laws and regulations, including, without limitation, the anti-kickback statute.

Medical staff incidental benefits that do not meet the foregoing conditions could constitute prohibited remuneration and, therefore, would be permitted under section 1877 of the Act only if an exception applies. For example, malpractice insurance offered by a hospital only to its emergency room physicians would not meet the foregoing conditions. Therefore, to be exempt from section 1877 of the Act, it would have to qualify for one of the exceptions. Malpractice insurance would not qualify for the exception for non-monetary compensation up to \$300, because it would exceed the applicable dollar limits. Nor would it qualify for the exception for remuneration unrelated to the provision of DHS, because such payments would be related to the provision of emergency services, which are included in the definition of inpatient hospital services and, therefore, are DHS. Malpractice insurance provided to emergency room physicians might qualify for the employee exception if the physician is employed by the hospital and the insurance is part of the employment agreement. Similarly, we do not believe medical transcription services are an incidental benefit of nominal value.

We are aware that some hospitals are offering compliance training programs for physicians on their medical staffs or in their local communities. Because we believe such programs are beneficial and do not pose a risk of fraud or abuse, we are creating a new exception for such compliance training programs.

We intentionally set the dollar limits in the proposed exception at a low level to decrease the likelihood that the items or services would influence utilization. However, in response to the comments, we have eliminated the \$50 per gift dollar limit. Therefore, under the final

rule, an entity could give a physician either one noncash gift per year of up to \$300 in value or two or more noncash gifts per year, as long as the annual aggregate value of the gifts does not exceed \$300. This change permits larger one-time gifts. For example, a noncash gift valued at \$150 would have exceeded the per gift dollar limit of the proposed rule, but would be permitted under the final rule, as long as the annual aggregate does not exceed \$300 and the other conditions of the exception are met.

The exception for non-monetary compensation up to \$300 only protects gifts to individual physicians. Thus, gifts given to a group practice would not qualify for this exception. Noncash gifts could, however, be given to one member, several individual members, or each member of a group practice, if each such gift meets all of the conditions of the exception for non-monetary compensation up to \$300. We caution, however, that the exception will not apply to gifts, such as holiday parties or office equipment or supplies, that are valued at not more than \$300 per physician in the group, but are, in effect, given or used as a group gift.

Notwithstanding the foregoing, we recognize that the aggregate dollar amount could be substantial for gifts to individual physician members of very large groups. For example, if a group consists of 50 physicians, each physician of the group could be given an aggregate of \$300 in non-cash gifts within a given year, equaling a total of \$15,000 from one entity. Such a large gift could provide an economic incentive for overutilization. Therefore, to counter-balance the removal of the \$50 per gift limit and to further guard against abuse, we have added a provision that excludes gifts solicited by the receiving physicians or their group practice. This change also serves to clarify that our use of the term "gift" refers to the ordinary meaning of the term; that is, a gift must involve a voluntary transfer made without consideration or compensation expected or received in return. This new provision prevents members of group practices, as well as solo practitioners, from making noncash gifts a condition of doing business with a particular entity. We intend to monitor the provision of gifts to group practice physicians under this exception and may revisit our position if abuses occur. Such gifts remain subject to the anti-kickback statute.

Finally, we have decided not to index the \$300 annual aggregate dollar limit for inflation. Removal of the per gift dollar limit gives entities much greater

flexibility with respect to the value of noncash gifts. That is, under the proposed rule, a single gift could not exceed \$50; whereas, under the final rule, the value of a single gift could be up to \$300, as long as the other conditions are met. We believe that this revision decreases the need for adjustment for inflation. In addition, we think it would create confusion as to the actual limit in succeeding years if we were to provide for an inflation adjuster. The rule as it stands creates an easy-to-follow bright line. However, we will continue to monitor the effect of the \$300 limit and may revisit the limit in the future.

Comment: One commenter asked for clarification regarding the relationship between the de minimis exception and the statute's exception for remuneration provided by a hospital to a physician "if such remuneration does not relate to the provision of designated health services." (See section 1877(e)(4) of the Act.)

Response: The exception for non-monetary compensation up to \$300 and the statutory exception for remuneration unrelated to the provision of DHS are totally separate exceptions with different criteria. The determination as to which of these exceptions, if any, is applicable depends on the facts and circumstances of the case involved.

Comment: One commenter questioned whether the requirement that compensation must be made available to all similarly situated individuals would prohibit hospitals from hosting meals on a person-to-person basis. Another commenter suggested that the similarly situated requirement should be eliminated because the type of promotional items that would be covered by the exception would probably be provided only to referrers or potential referrers, and such minimal gifts were unlikely to cause overutilization.

Response: We agree that, on balance, the "similarly situated" test does not add significantly to the protections of the exception. Accordingly, we have eliminated the "similarly situated" standard. This standard was designed to ensure that compensation was not paid primarily to reward high referrers. To ensure the same end, we are augmenting the standard that prohibits compensation that takes into account the volume or value of referrals by also prohibiting compensation that takes into account the volume or value of any other business generated by the referring physician.

Comment: Two commenters questioned how professional courtesy discounts (that is, free or discounted

services provided to physicians) would be handled under section 1877 of the Act. One of the commenters suggested that professional courtesy discounts should not violate section 1877 of the Act, because they fall within the non-monetary compensation up to \$300 exception or they do not constitute "remuneration."

Response: The term "professional courtesy" is used (or misused) to describe a number of analytically different practices, including the practice by a physician of waiving the *entire fee* for services provided to the physician's office staff, other physicians, and/or their families (the traditional meaning); the waiver of coinsurance obligations or other out-of-pocket expenses for physicians or their families (that is, insurance only billing); and similar payment arrangements by hospitals or other institutions for services provided to their medical staffs or employees. Therefore, we cannot generalize about the application of section 1877 of the Act to such arrangements. Some such arrangements may fit in an existing exception, depending on the circumstances (for example, the non-monetary compensation up to \$300 exception if the value of the courtesy services is less than \$300 and the other conditions of the exception are satisfied). However, some such arrangements may not fit in an exception. We are considering whether an exception could be developed for such arrangements and will address the matter further in Phase II of this rulemaking. We are soliciting comments about appropriate conditions for such an exception and an appropriate definition of "professional courtesy." In addition to conducting an analysis of professional courtesy arrangements under section 1877 of the Act, these arrangements must be analyzed with respect to other fraud and abuse, as well as payment, authorities, including the anti-kickback statute, the False Claims Act (31 U.S.C. § 3729 *et seq.*), and the prohibition of inducements to beneficiaries (section 1128A(a)(5) of the Act).

VIII. Definitions of the Designated Health Services

A. General Principles

Basis for the Definitions

As we pointed out in the preamble to the January 1998 proposed rule (63 FR 1673), section 1877(h)(6) of the Act lists the DHS, but does not define them. Moreover, the list in section 1877(h)(6) of the Act does not necessarily correspond to specific service categories as they are defined under either

Medicare or Medicaid. For example, section 1877(h)(6)(D) of the Act uses the phrase, "[r]adiology services, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services," although ultrasound is not usually considered a radiology service. In defining the DHS in § 411.351 of the January 1998 proposed rule, we stated that we chose, as much as possible, to base the definitions in section 1877 of the Act on existing definitions in the Medicare program. We also explained that in situations in which it was not clear whether a service was included, we would look to the intent of the statute. In general, we believe the Congress meant to include specific services that are or could be subject to abuse.

Because we had received a number of inquiries from individuals who were confused about whether a particular service fell under one of the DHS categories, we proposed defining the DHS whenever we could by cross-referencing existing definitions in the Medicare statute, regulations, or manuals or by including specific language whenever we believed the definitions should deviate from standard Medicare definitions.

Many of the comments we received on the proposed rule reflected that commenters were still unclear about which services fall under the DHS categories. Many commenters specifically requested that we establish a "bright line" test for identifying these services, and suggested that we base the services on an established list, such as the Current Procedural Terminology (CPT) codes. We agree that more precise definitions will make it much easier administratively for physicians and entities to comply with the law.

Accordingly, we have determined that we will define certain DHS (clinical laboratory services, physical therapy, occupational therapy, radiology and certain other imaging services, and radiation therapy services (sections 1877(h)(6)(A) through (h)(6)(E) of the Act) by publishing specific lists of CPT and HCFA Common Procedure Coding System (HCPCS) codes that physicians and providers most commonly associate with a given designated health service. The lists of codes will define the entire scope of the designated services category for purposes of section 1877 of the Act. While the definitions section of the regulations will contain a general explanation of the principles used to select the codes, in all cases the published list of codes will be controlling.

For services described in section 1877(h)(6) of the Act, paragraphs (F)

through (K), we will not be publishing a service-by-service list. The codes for these services may be just one component used for identifying the service; the codes may be all those that appear in a specific "level," such as all HCPCS level 2 codes, for a service; or the service is not defined using HCPCS codes at all. The definitions for the services in paragraphs (F) through (K) are explained in detail below under each service category.

The HCPCS is a collection of codes and descriptors that represent procedures, supplies, products, and services that may be provided to Medicare beneficiaries and to individuals enrolled in private health insurance programs. We believe that these codes will already be familiar to many in the health care industry. These codes must be used when billing Medicare for Part B services and supplies. The codes are divided into three levels, the first two of which are used in this final rule and are described below; they are listed in HCPCS 2001:

Level I: Codes and descriptors copyrighted by the American Medical Association in its Current Procedural Terminology, Fourth Edition (CPT-4). These are 5-position numeric codes primarily representing physician services.

Level II: These are 5-position alpha-numeric codes representing primarily items and nonphysician services that are not represented in the level I codes. Included are codes and descriptors copyrighted by the American Dental Association's Current Dental Terminology, Second Edition (CDT-2). These are 5-position alpha-numeric codes comprising the "D" series. All other level II codes and descriptors are approved and maintained jointly by the alpha-numeric editorial panel (consisting of HCFA, the Health Insurance Association of America, and the Blue Cross and Blue Shield Association).

Because these specific codes change and can quickly become out-of-date, we are not including the lists of DHS codes in the regulations text, but rather in an accompanying attachment. The definitions of specific services in the regulations text will cross refer to a comprehensive table that will appear initially in the **Federal Register** along with Phase I of this rulemaking and thereafter in an addendum to the annual final rule concerning payment policies under the physician fee schedule rule. This list titled, "List of CPT/HCPCS Codes Used to Describe Certain Designated Health Services Under the Physician Referral Provisions (Section 1877 of the Social Security Act)," will

also be posted on the HCFA web site at <http://www.hcfa.gov> on the date of **Federal Register** publication of this final rule. The table published each year will be a comprehensive listing of all codes for DHS and not merely a listing of changes to the prior year's table. The updates will also be posted on the HCFA web site. The physician fee schedule rule is generally published in late October or early November. We will consider comments on each year's revised list if we receive them during the applicable comment period for that rule. If any changes are made, we will then publish a revised table and respond to any public comments that we receive. This approach will provide an annual comprehensive list of codes for those DHS noted above (sections 1877(h)(6)(A) through (h)(6)(E) of the Act).

We are not providing lists of codes for the following categories of DHS (sections 1877(h)(6)(F) through (h)(6)(K) of the Act): 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; or inpatient and outpatient hospital services. We believe the definitions in Phase I of this rulemaking for these DHS provide sufficiently clear "bright line" rules.

In the preamble to the January 1998 proposed rule, we had stated that we believed the Congress intended to include specific services that are or could be subject to abuse and that we would attempt to define the services accordingly. In the January 1998 proposed rule preamble and regulations text, we then attempted in some cases to include or exclude services or types of services based on our view as to their potential for abuse. Many commenters disagreed with our views about particular services (for example, lithotripsy), and many more argued that the particular service they provided should also be excluded because it was not overutilized. In light of these comments and upon further review of the statutory scheme, we have decided that the Congress did not intend that we categorize DHS by determining the potential for overutilization or abuse on a service-by-service basis. Accordingly, in Phase I of this rulemaking, we are including all services that we believe come within the general categories; we have created limited exceptions for a few specific cases (that is, implants in ambulatory surgical centers, legislatively mandated preventive screening tests and immunizations subject to frequency limits, eyeglasses

and contact lenses subject to frequency limits, and erythropoietin (EPO) provided by end-stage renal disease (ESRD) facilities) for which we believe an exception poses a limited risk of abuse and is necessary to avoid needless disruption of patient care. However, even for those rare exceptions, we will continue to monitor the services for abuse and, if necessary, revisit the exclusions.

We also stated in the preamble to the January 1998 proposed rule (63 FR 1673) that we consider a service to be a designated health service, even if it is billed as something else or is subsumed within another service category by being bundled with other services for billing purposes. We gave as an example skilled nursing facility (SNF) services, which can encompass a variety of DHS, such as physical therapy (PT), occupational therapy (OT), or laboratory services. Commenters complained that this interpretation would result in an expansion of the DHS beyond the services specifically listed in the law. According to the commenters, when the Congress intended to cover specific Medicare services (including composite rate services, such as hospital or home health services), it did so expressly. Upon review, we agree with the commenters. Under the final rule, services that would otherwise constitute DHS, but that are paid by Medicare as part of a composite payment for a group of services as a separate benefit (for example, ambulatory surgical center (ASC) or SNF rate), are not DHS for purposes of section 1877 of the Act. (As expressly provided in section 1877(h)(6) of the Act, hospital and home health services remain DHS although they are paid through a composite rate.) We note, however, that because of SNF consolidated billing, most, if not all, SNFs will also be considered entities providing DHS (for example, PT or OT) under Part B to SNF patients who have exhausted their Part A benefit or to other nursing home residents (that is, patients for whom the services are not covered as part of a composite rate). The consolidated billing requirement places with the SNF the Medicare billing responsibility for most of the services that a SNF resident receives (except for certain practitioner services and a limited number of other services) under Part A and under Part B. (Presently, consolidated billing is in effect only for patients in a covered Part A stay, but will become effective for Part B services in the near future.) Accordingly, a physician will not be able to refer Medicare patients who will require DHS to a SNF in which he or she has an

ownership or investment interest, unless the interest is protected under an exception to section 1877 of the Act.

In the August 1995 final rule relating to clinical laboratory services, we created an exception for laboratory services furnished in an ASC or ESRD facility or by a hospice if the services were included in a composite rate or per diem hospice charge. (See § 411.355(d)). In the January 1998 proposed rule, we had proposed extending this composite rate exception to include all DHS furnished in an ASC or ESRD facility or by a hospice if payment is included in the ASC payment rate, the ESRD composite payment rate, or as part of the hospice payment rate. This proposal was intended to address problems faced by ASCs, ESRD facilities, and hospices in the light of our proposed stance on DHS subsumed by bundled payments. However, since under the final rule DHS that are subsumed by a bundled payment do not implicate section 1877 of the Act, we have not adopted our proposal to extend § 411.355(d) beyond clinical laboratory services. Moreover, given our final interpretation, we are reconsidering the need for § 411.355(d) as applied to clinical laboratory services and intend to address the matter further in Phase II of this rulemaking. We are soliciting comments on this issue.

B. General Comment: Professional Services as Designated Health Services

Comment: Many commenters expressed the view that the professional component of DHS (particularly clinical laboratory and radiology services) should not implicate section 1877 of the Act. Commenters asserted that the Congress did not intend for professional services to come within the physician self-referral law prohibition and that we exceeded our authority to promulgate regulations by including them. Commenters also contended that limiting DHS under section 1877 of the Act solely to the technical components of services would sufficiently control the risk of program or patient abuse. Other commenters stated that if we included professional components of some DHS, we should do so for all DHS. The commenters pointed out that our proposed position on productivity bonuses (that is, that they may not reflect the volume or value of any DHS referrals) would require special bookkeeping to segregate professional fees when calculating bonuses that will burden practices, without serving a public policy purpose.

Response: We believe that it was not the intent of the statute to exclude all professional services from the list of DHS. Many of the DHS, such as

radiology and radiation therapy, have substantial physician service components. If the Congress intended to exclude them, we would expect the statute to specifically do so. While some services are not viewed as having a professional component that is paid separately, Medicare still requires professional supervision of them to qualify for Medicare payment.

We agree to some extent that limiting referrals for the technical component of a service should greatly reduce the number of unnecessary referrals. Nonetheless, there are some DHS that consist only of a professional component (for example, some radiation therapy services) or are primarily professional in nature, and these would not otherwise be subject to the law if we carved out all professional components.

We agree with the commenters that we should include professional components when relevant in all DHS categories. Therefore, we have revised the definitions of each of the DHS to include the professional components in each case in which a professional component is included in the CPT or HCPCS codes that represent one of those services.

We understand that these rules may impose an administrative burden on some group practices, depending on how they choose to comply with section 1877 of the Act. We think Phase I of this rulemaking has a number of substantive changes that will ease the administrative burden of compliance, including the exception from the definition of "referral" for personally performed services and the greater flexibility afforded group practices over their distribution of revenues. As a practical matter, the professional component of many of these services will be excluded from the definition of a referral as services personally performed by the referring physician.

Individual Designated Health Services

We discuss below each designated health service category in the order in which it appears in section 1877(h)(6) of the Act. Each discussion includes a general summary of the category, summaries of the relevant public comments, and our responses.

C. Clinical Laboratory Services

In the August 1995 final rule covering a physician's referrals for clinical laboratory services, we defined these services in § 411.351 as—

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.

We had stated in the August 1995 final rule, in response to a commenter who requested a definition of clinical laboratory services, that we believed the most appropriate way for a physician or clinical laboratory to determine if a diagnostic test is a clinical laboratory test subject to the requirements of section 1877 of the Act, is to find out if the test is subject to categorization under the Clinical Laboratory Improvement Act (CLIA). We pointed out that there is a list of clinical laboratory test systems, assays, and examinations categorized by complexity and published by the Center for Disease Control (CDC). We also stated that, given this definition, CPT codes would not be the sole references to identify clinical laboratory services for physician referral purposes.

Commenters also had asked about the professional components of laboratory services. We stated that we believed that CLIA covers the actual examination of materials, their analysis, and any interpretation and reporting of the results that are performed by a facility that qualifies as a laboratory, as defined in § 493.2 (Definitions). However, if a laboratory sent test results to an independent physician, any interpretation performed by the physician would not be performed by the laboratory facility. As a result, the services would not constitute part of the clinical laboratory test.

We stated in the January 1998 proposed rule covering referrals for the other DHS that we would retain the definition of clinical laboratory services that was incorporated into our regulations by the August 1995 final rule. However, in line with our revised approach for identifying the DHS in this final rule, we have amended the rule to refer specifically to CPT and HCPCS codes. We have included as DHS the professional components of laboratory tests when they are listed as such in the codes. It is our belief that the specification of the codes in the attachment to this final rule is consistent with, although not identical to, the definition of clinical laboratory services in our January 1998 proposed rule.

D. Physical Therapy Services

We proposed to define physical therapy services in § 411.351 as those

outpatient physical therapy services (including speech-language pathology services) described at section 1861(p) of the Act and in § 410.100 (Included services), paragraphs (b) and (d). Under section 1861(p) of the Act, the term "outpatient physical therapy services" specifically includes speech-language pathology services. Because section 1877(h)(6) of the Act lists physical therapy services in general, and not just *outpatient* services, we also included in the definition any other services with the characteristics described in § 410.100(b) and (d) that are covered under Medicare Part A or Part B, regardless of who provides them, the location in which they are provided, or how they are billed.

We pointed out that services that are essentially the same as "outpatient physical therapy services" are also covered by Medicare in other contexts and in different settings, and may be billed under different categories. For example, we have a longstanding policy of covering physical therapy and occupational therapy as diagnostic or therapeutic inpatient hospital services. Similarly, these services can also be covered as SNF services, and can be furnished as "incident to" physician services under section 1861(s)(2)(A) of the Act. (Section 1877 implications for DHS provided by SNFs are discussed earlier in this section.)

It was our view in the January 1998 proposed rule that covered outpatient physical therapy services basically included three types of services, which were best described in § 410.100(b) (which specifically concerns services provided by a comprehensive rehabilitation facility (CORF)). This definition covers the 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; and the establishment of a maintenance therapy program for an individual whose restoration has been reached. Many commenters asserted that the proposed definition was imprecise or improperly included some procedures that are not generally considered physical therapy services.

We have responded to these concerns by redefining physical therapy services, as some commenters suggested, by using a list of HCPCS codes. We believe the list is limited to services that are more traditionally regarded as physical therapy. In general, these services are described in the "Physical Medicine

and Rehabilitation" section (the 97000 series) of the CPT and in other relevant sections of the HCPCS.

In the January 1998 proposed rule, we also included speech-language pathology services as a designated health service since section 1861(p) of the Act includes "speech-language pathology services" in the definition of "outpatient physical therapy services." These services are defined in section 1861(l)(1) of the Act as 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 1861(l)(3) of the Act defines a "qualified speech-language pathologist."

We used in the proposed rule the brief description of speech-language pathology services in § 410.100(d), which applies to services provided in CORFs, as those services that are necessary for the diagnosis and treatment of speech and language disorders that create difficulties in communication. In an effort to furnish a "bright line" test, we are defining the services in Phase I of this rulemaking by the specific codes that correspond to the services that we consider to be speech-language pathology services.

As we developed the list of CPT and HCPCS codes relevant to speech-language pathology, we realized that our proposed definition, which cross-refers to the CORF definition in § 410.100(d), did not encompass the full range of services that are commonly considered to be speech-language pathology services. It failed to recognize that speech-language difficulties can be caused by cognitive disorders and failed to recognize that speech-language pathology may be used to treat swallowing and other oral-motor dysfunctions. Therefore, in developing the list of codes for speech pathology in Phase I of this rulemaking, we included the diagnosis and treatment of cognitive disorders including swallowing and other oral-motor dysfunctions.

Finally, because of the overlap between physical therapy, occupational therapy, and speech-language pathology services, we are listing the codes for all three services together. We believe that this set of HCPCS codes represents what most clinicians would define as PT/OT/speech therapy services that are covered by the Medicare program. The list is set out in the attachment to this final rule.

Comment: A number of commenters were particularly concerned that the

proposed definition of physical therapy services implies that physical therapists can perform diagnostic testing and measurements, such as electromyography tests (EMGs). These tests are used primarily to provide medical diagnostic information regarding neuromuscular diseases and occasionally to measure neuromuscular function. Although some States permit physical therapists to perform these tests, the commenters believe that EMGs are typically performed by a physician as part of a physical examination to determine whether a patient is a surgical candidate or if some other course of treatment is warranted.

In addition, other commenters stated that the proposed definition of physical therapy services could be interpreted to include therapeutic procedures such as nerve blocks and arthrocentesis that the commenters believe are physician services. One commenter, a physician who practices physical medicine and rehabilitation, asserted that our proposed definition of physical therapy included services that could be administered by physicians and physical therapists. He feared that this could prohibit him from treating patients he diagnoses. Several commenters responded to the inclusion in the definition of physical therapy of any "assessment and treatment" designed to alleviate pain or disability. The commenters asserted that this phrase captures a large portion of modern medicine, given that pain is the most common presenting symptom in a physician's office, and virtually any assessment or treatment following therefrom would have as its purpose the alleviation of that pain.

Response: Nothing in the proposed definition affected the scope of any practitioner's practice. We agree with the commenters that only in certain States are physical therapists licensed to perform EMGs. Additionally, we agree that therapeutic procedures such as nerve blocks and arthrocentesis are typically performed by a physician and are not generally considered to be a part of physical therapy. These procedures are not included on the list of codes that defines the scope of physical therapy for purposes of section 1877(h)(6)(B) of the Act. In the January 1998 proposed rule, we did not intend to convey the message that what is generally considered physical therapy would change. We proposed to use an existing definition of physical therapy (in § 410.100(b), which covers physical therapy services in CORFs) precisely because we did not want to change the existing perception of physical therapy.

In order to avoid confusion, we are revising our proposed definition by providing a list of CPT and HCPCS codes that are, collectively, the PT/OT/speech-language therapy DHS. This list of codes defines the entire scope of PT/OT/speech-language therapy services for purposes of section 1877 of the Act. Finally, we note that under Phase I of this rulemaking, if a physician personally provides a designated health service to his or her patient, there is no "referral" for purposes of section 1877(a)(1) of the Act. See section III.B of this preamble.

Comment: One commenter asserted that pulmonary function tests are for the measurement of the function of the respiratory system and have nothing to do with physical therapy. However, another commenter recommended that the definition of physical therapy include the neuromuscular and pulmonary function tests that test for functional capacity ratings and that are usually performed by a physical therapist without the direct supervision of a physician.

Response: We agree with the commenter that pulmonary function tests for the measurement of the function of the respiratory system are not physical therapy. The only pulmonary function test that may be considered to be a physical therapy service is pulse oximetry testing, CPT code 94762, when it is used to test for functional capacity ratings. A pulse oximetry test that is performed to determine whether a patient has enough oxygen to perform certain activities of daily living is, for example, a physical therapy service.

Comment: One commenter recommended that we define physical therapy as those therapeutic exercises and physical medicine modalities described in the 97000 series of the CPT codes, included in the patient's written plan of physical therapy treatment, and provided by a physical therapist or physical therapy aide.

Response: We agree with the commenter that PT services should be based on the CPT codes and have modified the rule accordingly. With respect to which professionals can provide a given service, we defer in this rule to existing Medicare policy. Many of these DHS can be provided by physicians.

Comment: A number of commenters opposed the inclusion of speech-language pathology services in the definition of physical therapy services. The commenters stated that the Congress did not intend to include these services within the ban on physician referrals and asserted that including

these services as DHS is unnecessary (although they did not state why this would be the case). One commenter asserted that when the Congress intended to include outpatient speech-language pathology services within the category of outpatient physical therapy services, the Congress enacted explicit language that made that intention clear. The commenter pointed to section 4541(a)(1) of the BBA 1997, which added paragraph (8)(A) to section 1833(a) of the Act. That provision states that, for covered individuals, amounts will be paid from the Medicare Trust Fund for "outpatient physical therapy services (which includes outpatient speech-language pathology services) and outpatient occupational therapy services furnished—" * * * by certain entities.

Response: The definition of "outpatient physical therapy services" in section 1861(p) of the Act specifically states that "the term 'outpatient physical therapy services' also includes speech-language pathology services furnished by a provider of services, a clinic, rehabilitation agency, or by a public health agency, or by others. * * *" Thus, by definition, speech-language pathology services are a subset of outpatient physical therapy services under the Medicare statute. We believe that the parenthetical language under the BBA 1997 simply confirms our interpretation.

E. Occupational Therapy Services

In the January 1998 proposed regulations text, we proposed to include those OT services described in section 1861(g) of the Act and the CORF regulations in § 410.100(c). We proposed that occupational therapy services would also include any other services with the characteristics described in § 410.100(c) that are covered under Medicare Part A or Part B, regardless of who furnishes them, the location in which they are furnished, or how they are billed. In proposed § 411.351, OT services included 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 discussed in the preceding section, we are revising our proposed definition by providing a list of CPT and HCPCS

codes that collectively are the PT/OT/speech therapy DHS. Also, as described above, we are excluding from the definition of DHS any designated health service that is paid for as part of a "bundled" payment (for example, services covered by the SNF Part A rate or the ASC rate), unless the statute otherwise provides that a "bundled" set of services is itself a designated health service (for example, home health services and inpatient and outpatient hospital services).

Comment: A major OT association asserted that the definition of OT is too narrow because it does not adequately capture the scope of the OT benefit. For example, OT is furnished to patients with cognitive impairments as well as to patients with physical impairments and limitations. As another example, OT may also be furnished in partial hospitalization programs for patients with a psychiatric illness. The commenter believes that it is important for the definition in § 411.351 to be as complete and accurate as possible to assure appropriate compliance with the law, and that § 410.100(c) is too narrow to be used as the complete definition of OT services for purposes of these regulations. The commenter suggested that we broaden the definition by adding to it the coverage guidelines stated in section 3101.9, "Occupational Therapy Furnished by the Hospital or by Others under Arrangements with the Hospital and under its Supervision," of the Medicare Intermediary Manual (HCFA Pub. 13-3), Part 3—Claims Process, and section 2217, "Covered Occupational Therapy," of the Medicare Carriers Manual (HCFA Pub. 14-3), Part 3—Claims Process. The commenter recommended that we use the following definition for OT in § 411.351:

Occupational therapy services means those services described at section 1861(g) of the Act, § 410.100(c) of this chapter, and in the occupational therapy coverage guidelines contained in section 3101.9 of the Medicare Intermediary Manual and section 2217 of the Medicare Carriers Manual. Occupational therapy services also include any other services with the characteristics described in § 410.100(c) and the occupational therapy coverage guidelines 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.

Response: We agree with the commenter that the proposed definition does not clearly recognize that OT is furnished to patients with cognitive impairments. As we have stated previously in this preamble, we did not intend to change what is commonly regarded as OT. We referred to the existing definition in § 410.100(c) so

that we would not be proposing any change. However, as the commenter pointed out, the existing definition at § 410.100(c) is not complete. Therefore, we are expanding the proposed definition by including codes for the “teaching of compensatory techniques to permit an individual with a physical or cognitive impairment or limitation to engage in daily activities.”

However, the commenter is correct that a partial hospitalization program may provide OT services. This is in accordance with section 1861(ff) of the Act, which defines “partial hospitalization services” and specifically includes OT as a partial hospitalization service. However, with respect to partial hospitalization, we have determined that services provided as part of a group of services paid under a bundled rate are not DHS. Partial hospitalization services are paid under a bundled rate. Therefore, partial hospitalization services (including OT services provided as part of the partial hospitalization benefit) furnished by a community mental health center are not DHS. However, partial hospitalization services furnished by a hospital are outpatient hospital services, which is a category of DHS.

In order to eliminate any confusion the January 1998 proposed regulations may have caused and to make Phase I of this rulemaking clear, we are defining OT by a list of specific HCPCS/CPT codes. In light of the changes we have made in Phase I of this rulemaking, it is not necessary for us to include the references to the intermediary and carrier manuals that the commenter suggested.

Occupational therapy services may be furnished by an occupational therapist, an occupational therapy aide who is supervised by an occupational therapist, or by a physician. Section 1861(r) of the Act allows a physician to furnish any medical service that his or her State allows the physician to furnish.

F. Radiology and Certain Other Imaging Services

In the January 1998 proposed rule, we combined the DHS in section 1877(h)(6)(D) of the Act—“radiology services, including magnetic resonance imaging, computerized axial tomography, and ultrasound services”—and 1877(h)(6)(E) of the Act—“radiation therapy services and supplies” into the following definition:

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.

Commenters found the proposed definition to be confusing in two main respects:

- The definition both combined two different categories of radiology-related services (that is, radiology and radiation therapy and supplies) and included other services not commonly considered to be radiology-related (ultrasound and nuclear medicine). Many commenters thought that all services not strictly considered radiology should be excluded.

- At different places in the January 1998 proposed regulation preamble, we stated that we were excluding DHS that were peripheral, incidental, or secondary to a nondesignated health service. In the proposed definition, however, we only excluded imaging modalities used to “guide a needle, probe, or catheter.” Many commenters thought the scope of excluded radiology and other imaging services should be broader than just guidance, while others thought the distinction between primary and secondary services would be difficult to apply in practice.

Based on the comments, we have redefined this category of DHS in a manner that should provide greater clarity. First, we have segregated radiation therapy and supplies from radiology and other imaging services and returned them to a separate category, as in the statute. (We discuss comments relating to radiation therapy services in section VIII.G of this preamble). Second, we are excluding nuclear medicine since those services are not commonly considered to be radiology. Third, for purposes of these regulations we have renamed the category of services covered by section 1877(h)(6)(D) of the Act “Radiology and Certain Other Imaging Services” to make clear the Congress’s intent to include in subsection (D) some imaging services other than radiology. Fourth, consistent with the approach we are following with several other of the DHS categories, we are defining the entire scope of covered services under section 1877(h)(6)(D) of the Act by using lists of CPT and HCPCS codes, which lists control in all circumstances. The lists include those services typically considered as radiology or ultrasound services, or as constituting an MRI or a computerized axial tomography (CAT)

scan. Fifth, we have excluded certain covered preventive screening procedures, such as screening mammography, that are subject to HCFA-imposed frequency limits that mitigate the potential for abuse. In these circumstances, we believe the Congress did not intend the physician self-referral law to interfere with a physician’s or entity’s attempts to provide these preventive procedures to Medicare patients.

Sixth, based on the comments we received, we concluded that the terms “invasive” radiology and radiology “incidental” or “secondary” to a non-DHS procedure used in our proposed definition of “radiology services” created confusion and uncertainty. We agree with commenters that “invasive” radiology includes more than just those procedures used to “guide a needle, probe or catheter.” Consequently, we are revising our definition of radiology and certain other imaging services to exclude from the definitional list of codes x-ray, fluoroscopy, and ultrasound services that are themselves invasive procedures that require the insertion of a needle, catheter, tube, or probe. Thus, cardiac catheterizations and endoscopies will not fall within the scope of “radiology services” for purposes of section 1877 of the Act. All MRIs or CAT scans, however, are within the scope of the DHS because excluding some on the basis that they are “invasive” tests would have the effect of excluding all MRIs and CAT scans that use contrast injection. The use of contrast is not mandatory for the performance of a scan, as it is for the performance of a barium enema, excretory urogram, or traditional vascular angiography. Thus, an exclusion from the DHS definition of contrast for MRIs and CAT scans could have the effect of encouraging the use of contrast when it is not necessary.

In addition, we have concluded that radiology procedures that are integral to the performance of, and performed during, a nonradiology medical procedure are not within the scope of DHS. The list of codes that defines the scope of “radiology and certain other imaging services” will make this distinction clear. Examples of these integral services include, but are not limited to, imaging guidance procedures and radiology procedures used to determine, during surgery, whether surgery is being conducted successfully. In the CPT, these radiology procedures are identified as cross-references to the principle procedures with which they are associated. A radiology procedure, such as a CAT scan or a chest x-ray, performed before or after another

procedure, such as a lung cancer resection, is considered to be a diagnostic radiology procedure that is not integral to the principle procedure (that is, the lung cancer resection). While these radiology procedures are essential to the performance of the principle procedure, physicians have discretion in choosing which entity provides the radiology service independent of the entity providing the principle surgical service. These nonconcurrent services are DHS.

Regardless of our definition of "radiology and certain other imaging services," some services that are not within the scope of that definition may still be DHS if they are inpatient or outpatient hospital services, a separate category of DHS under section 1877(h)(6)(K) of the Act. These services would be subject to the physician referral rule if the referring physician has a financial relationship with the hospital. We anticipate most of these financial arrangements will meet an exception under section 1877 of the Act (for example, the exception for hospital ownership or either the employment or personal service arrangements exception).

We address comments related to the definition of services covered by section 1877(h)(6)(D) of the Act below. To the extent some commenters raised issues such as the general effects of section 1877 of the Act on physicians' practices or on medicine in general, those issues are addressed elsewhere in the preamble, where relevant.

Comment: Several commenters asserted that the proposed definition of "radiology services" that included all sound-based or imaging-based technologies is contrary to congressional intent. The commenters argued that the Congress intended to limit the definition by removing original language that included the phrase "other diagnostic services" along with radiology services.

Response: The phrase "radiology, or other diagnostic services" was added in section 1877(h)(6)(D) of the Act by OBRA 1993 as one of the categories of DHS the Congress chose to cover in addition to clinical laboratory services. This one set of services appeared to include the extremely broad category of "other diagnostic services," in addition to radiology services. The Congress narrowed this category in section 152 of the Social Security Act Amendments of 1994 (SSA 1994), Public Law 103-432, enacted on October 31, 1994, perhaps because it realized the huge scope of "diagnostic services." The amendments revised section 1877(h)(6)(D) of the Act, effective January 1, 1995, by replacing

the category with "radiology services, including magnetic resonance imaging, computerized axial tomography, and ultrasound services." While all of these services might not be subsumed in the category "radiology services," the Congress clearly intended to include them as DHS. We have renamed the category "radiology and certain other imaging services" to reflect the Congress's intent.

Comment: One commenter questioned why cardiac, vascular, and obstetric ultrasound procedures could not be referred. The commenter stated that in most institutions these procedures are not considered radiology procedures since radiologists may never supervise or interpret them. Another commenter argued that although echocardiography is a type of ultrasound procedure, it should not be considered a radiology service because echocardiography is a service developed and performed primarily by cardiologists, billed under cardiologic CPT codes, and furnished to cardiac patients. As a result, the commenter argued that it is inaccurate and inappropriate to include echocardiography within the definition of radiology services.

Response: Cardiac, vascular, and obstetric ultrasound procedures are subject to the physician self-referral provisions because section 1877(h)(6)(D) of the Act specifically includes ultrasound as a designated health service, not because they are ordinarily considered to be "radiology services." Simply stated, the term "radiology services" as applied to the services described by section 1877(h)(6)(D) of the Act is a misnomer. Section 1877(h)(6)(D) of the Act includes any services that are traditionally regarded as "radiology" services, as well as MRIs, CAT scans, and ultrasound services. Cardiac echography and vascular echography are clearly ultrasound services. Nothing in the regulation would prohibit a vascular surgeon, neurologist, or other specialist from ordering a particular service from an entity with which he or she has no prohibited financial relationship.

Comment: Several commenters were opposed to our proposal to exclude as "invasive" radiology only those invasive procedures used to guide a needle, probe, or catheter accurately. Two of the commenters were concerned that invasive radiology procedures, which use an imaging modality not only to guide a needle, probe or catheter, but also to record an accurate picture of the areas of the body being probed or catheterized, would be included in the definition of radiology. (An example of this would be an ultrasound device

placed at the end of a catheter or endoscope.)

Response: We agree and have not included x-ray, fluoroscopy, and ultrasound services that require the insertion of a needle, catheter, tube, or probe on the list of HCPCS/CPT codes that defines the full scope of radiology and other imaging services for purposes of section 1877 of the Act. Some of these services may still be DHS when they fall within the category of inpatient and outpatient hospital services.

Comment: Several commenters objected to our proposal to exclude radiology services that were "merely incidental or secondary" to another procedure that the physician has ordered. (See our January 1998 proposed rule, 63 FR 1676.) Some commenters noted that it is generally not possible to establish, based on the CPT code used, whether or not the primary purpose of the procedure was the interventional procedure itself (with the imaging being an adjunct procedure) or whether the primary purpose was to take a picture with an imaging modality. Because it is extremely difficult and impractical in the commenters' view to separate the radiology component from the underlying procedure, the commenters recommended that we exclude all invasive radiology services, encompassing those procedures that may include an adjunct radiology procedure performed at the same time as the interventional procedure. Other commenters thought that the definition of radiology services should also exclude imaging services when they are performed before and/or after a surgical procedure. For example, a commenter requested that we add language to the proposed definition of radiology to exclude any radiology procedure in which the imaging modality is used to plan the invasive procedure. The commenter noted that for many invasive procedures, an ultrasound before the actual procedure might be routinely necessary in order to plan the manner in which the needle, catheter, or probe would be guided during the actual invasive procedure. In these circumstances, the patient already has received the diagnosis that the invasive procedure is necessary. The commenter believes that we should maintain the view that a physician would not refer a patient for these procedures in order to profit from unnecessary radiology services. Another commenter stated that under our proposed interpretation of invasive procedures, an echocardiogram that showed a need for bypass surgery would be a designated health service, while one that ruled out surgery would not, since there would be no surgical

procedure to which the imaging service would be "incidental." Finally, a neurologist commented that there are a number of radiology procedures performed by neurologists that are incidental to other procedures, particularly certain surgical services. One of the examples given by the commenter was carotid duplex or transcranial Doppler ultrasound, which are tests performed after carotid endarterectomy to look for clots. The commenter believes these radiology services should be excluded.

Response: We agree with the commenter that the "incidental/secondary" test in the January 1998 proposed rule has led to some confusion and uncertainty and have abandoned it in Phase I of this rulemaking. We believe the list of codes set forth in Phase I of this rulemaking (and annually thereafter in the physician fee schedule rule) will create a "bright line" test that will ease compliance. In selecting the codes for radiology and ultrasound, we are not including any codes for radiology or ultrasound procedures that have an invasive component; that is, that include the insertion of a needle, catheter, tube, or probe through the skin or into a body orifice. ("Invasive" would encompass radiology services involving contrast that must be injected, but not contrast materials that are ingested by the patients themselves.) In addition, we are not including radiology and ultrasound procedures that are integral to and performed during the time a nonradiology procedure is being performed, such as ultrasound used to provide guidance for biopsies and major surgical procedures or used to determine, during surgery, whether surgery is being conducted successfully. Phase I of this rulemaking requires that to be considered integral to a nonradiology procedure (and therefore not a radiology or other imaging service for purposes of section 1877(h)(6)(D) of the Act), the imaging procedure must be performed during the nonradiology procedure. A radiology or ultrasound procedure performed before or after another procedure (for example, a scan or a chest x-ray before a lung cancer resection, an echocardiogram before a bypass, or a duplex carotid ultrasound before or after surgery) is a diagnostic radiology procedure that is not integral to another procedure and therefore is a radiology or other imaging service under section 1877(h)(6)(D) of the Act. In the case of services performed before or after a procedure, referring physicians have discretion in choosing the entity that provides the radiology service independent of the entity providing the

surgical service. Depending on the facts, referrals for these services to entities with which the referring physician has a financial relationship may be protected under the various exceptions to the statute.

In all cases, the definitional list of codes controls in determining whether a service falls within the scope of "radiology or certain other imaging services" for purposes of section 1877 of the Act.

Comment: Two commenters were opposed to our proposal to exclude "invasive" or "interventional" radiology procedures from the definition of radiology services. The commenters believe that these procedures should be included as DHS in order to safeguard against overutilization and ensure that appropriately trained physicians perform the services. One commenter argued that as a clinical matter, "invasive" or "interventional" radiology services rarely are performed in an office setting. Typically, interventional radiologists perform such procedures as angiography or angioplasty in a hospital because they involve significant and delicate work on a patient's cardiovascular system. Patients who undergo invasive procedures must then be monitored for a period of time in an appropriate medical setting. Consequently, that commenter, as well as another, objected to our statement in the preamble to the January 1998 proposed rule (63 FR 1676) that invasive procedures ordinarily are "merely incidental or secondary to another procedure that the physician has ordered." One of the commenters stated that the radiology services are neither incidental nor secondary, but a vital and integral part of the invasive procedure performed. The procedures are as much radiological as they are any other portion. One commenter stated that if invasive procedures occur in an office, they should be performed by a radiologist. The commenter believes that excluding invasive or interventional radiology procedures could result in certain referral arrangements by physicians that might pose some risk of patient or program abuse. One of the commenters noted that when interventional radiologists perform invasive radiology procedures, there is no risk of program or patient abuse. This is because interventional radiologists do not typically make referrals; they merely perform the invasive radiology procedures and return the patient to the care of the referring physician. The commenter believes, however, that physicians other than interventional radiologists may have an incentive to self-refer.

Response: We agree with the commenter that we were incorrect to characterize interventional radiology as "secondary" to many procedures, when it can in fact be a vital and integral part of the invasive procedure being performed. It is not the purpose of the physician self-referral law to discourage any physicians from furnishing their own services, such as interventional radiology, within their own practices, provided the physicians are functioning within the scope of their license to practice.

Comment: Many commenters asserted that all or particular invasive cardiology services should be excluded from the definition because they are not subject to program or patient abuse. Another commenter asked that we be consistent with regard to all forms of cardiac catheterizations and endoscopy procedures. The commenter stated that providers want to be able to perform all endoscopy services or cardiac catheterization services in the same setting and not have to limit their services.

Response: Cardiac catheterizations and endoscopy procedures are not included on the CPT code list that defines the scope of "radiology and certain other imaging services," because they do not involve imaging services that are covered under any of the categories in section 1877(h)(6)(D) of the Act. These services may still constitute DHS as inpatient or outpatient hospital services.

Comment: Two commenters noted that in the preamble to the January 1998 proposed rule (63 FR 1676), we stated that percutaneous transluminal angioplasty was an example of an invasive radiology procedure that we would exclude from the definition of radiology. The commenters stated that this procedure is not commonly considered to involve "invasive radiology."

Response: The commenters are correct in stating that percutaneous transluminal angioplasty is not fundamentally radiological in nature; it is predominantly a therapeutic intervention. Our wording in the examples for invasive radiology may have been confusing. We intended to convey that the imaging procedures associated with percutaneous transluminal angioplasty would be considered integral to the performance of the angioplasty. However, by using specific CPT codes to define the scope of services covered by section 1877(h)(6)(D) of the Act, we have now narrowed the definition of radiology services so that it does not include radiology that is integral to

interventional procedures, such as angioplasty.

Comment: One commenter supported our proposal to exclude screening mammography from the definition of DHS. The commenter believes that we should expand the exclusion to cover all DHS for which we have specified coverage or frequency limits. The commenter stated that screening tests by definition are not subject to overutilization.

Response: We agree with this commenter and have modified Phase I of this rulemaking to exclude from the reach of section 1877 of the Act certain legislatively mandated preventive screening and immunization services that are subject to HCFA-imposed frequency limits and are paid based on a fee schedule. The preventive services to which this exception applies are identified in Appendix A. We will add codes for new preventive screening tests and immunizations, as appropriate, through the annual updating of the attachment to this final rule.

Comment: One commenter recommended that all mammography be excluded from the definition of "radiology services." The commenter argued that generally diagnostic mammography procedures are performed only when a woman has clinical indications for a diagnostic mammogram. Thus, any risk of program or patient abuse is significantly reduced, if not eliminated. The commenter also mentioned that the quality-centered requirements of the Mammography Quality Standards Act of 1992 minimize the risk of potential overutilization of mammography services. Another commenter recommended the exclusion of "diagnostic" mammography services because he stated that it is necessary to perform the mammography on the same equipment for purposes of comparing the initial screening with the second diagnostic mammography. To prohibit patients from using the same facility adds an unnecessary element of potential error to the equation.

Response: Diagnostic mammography is clearly a radiological service under section 1877(h)(6)(D) of the Act, and it could be subject to abuse. It is our understanding that most women receive mammography from a radiologist who is requesting diagnostic radiology services. These physicians have not made a referral under section 1877(h)(5)(C) of the Act if they request diagnostic mammography as the result of a consultation requested by another physician. We are regarding this exception as applying to diagnostic mammography that results when a radiologist has first performed a

screening mammography as the result of a consultation, and then recommends follow-up diagnostic mammography, or begins his or her consultation with diagnostic mammography. (The physician who initiated the consultation with the radiologist has made a referral that could fall within the scope of the physician self-referral law if he or she has a financial relationship with the radiology facility.)

Comment: A commenter asked if stress tests are DHS. The commenter noted that some stress tests use nuclear medicine procedures.

Response: Stress tests are generally considered to be a physician service that does not involve radiology, and stress tests are not specifically listed in the law as DHS. Some stress tests use nuclear medicine procedures to create an image of the heart. Because these services are not included on the definitional CPT code list for radiology or other imaging services, they are not DHS.

Comment: One commenter stated that unless changed or clarified, the proposed regulations could inhibit the development and application of telemedicine technology to populations covered by the physician referral rules. Of specific concern was the area of ultrasound and a "unified" payment (that is, a combined payment for the technical and professional components of the service). The commenter asserted that Medicare and many State Medicaid programs provide a unified payment for ultrasound. The commenter described the problems of a unified payment with an example of a community physician performing the technical component of an ultrasound service and a distant tertiary hospital's physician performing the professional component. If the tertiary provider billed for the ultrasound service under a "unified" (that is, global) fee-for-service payment to cover the professional component of the ultrasound service, the tertiary facility logically should determine a payment for the technical component to pay the community physician who provides that service. However, since the community physician would be referring to the tertiary facility for the ultrasound study, such a payment could violate the physician referral regulations (that is, it would not fall within an exception).

At the time of the comment period for the January 1998 proposed rule, the commenter was aware that we were considering the publication of a separate proposed rule that would specify an appropriate "split" of global payments in the area of telemedicine; that is, it would specify separate payment

amounts for the technical and professional components of services. The commenter suggested that if we did issue those regulations, we should also recognize in the physician referral rules that payment by the tertiary provider to the referring community physician for providing the technical component of an ultrasound service performed via telemedicine should be exempted if it is under a HCFA-designated, or insurer-designated, allocation between the two aspects of an otherwise "global" payment.

Response: We believe that Phase I of this rulemaking addresses this issue satisfactorily. The basic principle of Phase I of this rulemaking is that any payment from an entity furnishing a designated health service to a referring physician must be at fair market value, not taking into account the volume or value of any referrals or other business generated by the referring physician (when this latter language is included in an exception). We are revising Phase I of this rulemaking to make clear that "per service" payments are allowed, even with respect to DHS ordered by the physician, provided the payment meets the fair market value standard. In the situation described by the commenter, the split is determined by the Medicare program based on its independent view of the value of the services provided. Of course, any split between a referring physician and another provider may also raise concerns under the Federal anti-kickback statute.

With respect to Medicare reimbursement for telehealth services, we published a proposed rule on June 22, 1998 (63 FR 33882) and final rule on November 2, 1998 (63 FR 58814) to implement section 4206 of the BBA 1997. Specifically, the November 1998 final rule permitted payment for professional consultations via interactive telecommunication systems in rural HPSAs and established separate payment amounts for the referring and consulting practitioners of a teleconsultation in a rural HPSA. As we noted in the preamble (63 FR 58883) to that November 1998 final rule, the rule specifies that the consulting practitioner must submit the claim for the consultation service and must share 25 percent of the total payment with the referring practitioner.

We clarified in the November 1998 telehealth final rule that these provisions only apply to teleconsultation services. Under Medicare, a teleconsultation is a consultation service delivered via telemedicine. These services are represented by CPT codes 99241 through 99275. Diagnostic ultrasound

(CPT code 76506) on the other hand, is a radiology service and would not fall within the purview of a teleconsultation under Medicare. Therefore, the payment methodology requiring the sharing of payment between the consulting and referring practitioners would not apply to diagnostic ultrasound services. In the case of diagnostic ultrasound, the physician providing the interpretation of the image typically would bill for the interpretation, while the technical component (that is, conducting the test) is billed by the practitioner or facility that captured the ultrasound image. Medicare has no national rule stating that the professional and technical components of a service, including ultrasound services, must be billed in a "global" manner. In fact, in the annual update to the physician fee schedule, separate codes for the professional component as well as the technical component of a service are listed, including the diagnostic ultrasound codes. Of course, in those cases in which there is no technical component, one code is used for Medicare payment and billing.

G. Radiation Therapy

Section 1877(h)(6)(E) of the Act includes radiation therapy services and supplies. In the January 1998 proposed rule, we combined radiation therapy with radiology in a single definition.

Because commenters found the combined definition to be confusing, we are amending the January 1998 proposed regulation so that radiology services and radiation therapy services are now separate categories (as in section 1877 of the Act itself). This change makes it clear that the two categories are actually very separate kinds of services. We are basing our definition of radiation therapy services and supplies on section 1861(s)(4) of the Act. This provision includes, as "medical and other health services" covered by Medicare, "x-ray, radium, and radioactive isotope therapy, including materials and services of technicians." However, we want to clarify that, for physician referral purposes, the list of codes that defines "radiation therapy services and supplies" in Phase I of this rulemaking does not include nuclear medicine services. While nuclear medicine involves the injection of radioactive isotopes directly into a patient's bloodstream, these services are not generally regarded as radiation therapy, they involve different equipment and procedures, and physicians who provide nuclear medicine have a separate certification. We have included in the attachment to this final rule a list

of codes that will define radiation therapy services and supplies. This list will be updated and reprinted in full annually as part of the physician fee schedule.

Comment: A commenter noted that because the January 1998 proposed regulations bundle radiology services and radiation therapy and supplies into a single category of DHS, the professional component of radiation therapy services has also been included within the definition of DHS. The commenter stated that some radiation oncologists would effectively be precluded from being paid on a productivity basis for their services, given that virtually all of the professional services that some physicians perform are radiation therapy services for Medicare patients. The commenter believes that the Congress did not intend this result.

Response: The law excludes from the definition of a "referral" any request by a radiation oncologist for radiation therapy if these services are furnished by (or under the supervision of) the radiation oncologist pursuant to a consultation requested by another physician. In addition, we are amending the definition of a "referral" to exclude any professional components personally performed by referring physicians themselves. Together, these provisions should largely address the commenter's concerns.

Comment: Several commenters recommended that we exclude prostate brachytherapy from the definition of radiation therapy. Prostate brachytherapy is the placement of radioactive sources into the prostate, through ultrasound guidance, for the purpose of treating prostate cancer. The commenters argued that this procedure should be excluded because it is performed once and is only performed on persons with a biopsy-proven diagnosis of prostate cancer. They advocated the use of physician ownership of brachytherapy facilities and equipment because it means that the urologists and radiation oncologists involved are actually performing the procedure themselves in a facility contracting with those physicians. The design of this model includes the supervision of every case by an experienced brachytherapist present in the operating room. According to the commenter, physician ownership of the equipment also ensures quality of physician education and of surgical technique.

The commenters asserted that we should allow multiple physicians to own brachytherapy equipment because centralized planning for radiation

physics results in all cases being planned in a controlled and uniform fashion. Uniformity eliminates many empirical physician decisions that in the past led to dosimetry errors. In addition, having two or more physicians owning the equipment encourages reporting of outcome data collection to a central agency, resulting in a continuous and rapid review of treatment results and complications. Commenters pointed out that experts have published restrictive dose guidelines for the various stages of prostate cancer treated with brachytherapy, so there is no risk of overutilization. Also, brachytherapy is less expensive and has a lower complication rate than the other forms of treatment (radical prostatectomy or external beam radiation therapy).

The commenters believe that because of all of these factors the procedure has little potential for program or patient abuse and should be exempt from the physician self-referral prohibition.

Response: We are aware of no logical or empirical evidence that physician ownership improves quality of services or physicians' skills. On the other hand, brachytherapy is one of several therapy options for certain prostate conditions. We believe that ownership of a brachytherapy center by urologists could well influence their recommended therapy and, therefore, affect utilization. In short, the relationship is exactly the type of financial relationship section 1877 of the Act is intended to address. The law excludes from the definition of a "referral" any request by a radiation oncologist for radiation therapy if these services are furnished by (or under the supervision of) the radiation oncologist pursuant to a consultation requested by another physician. In addition, we have amended the definition of a "referral" to exclude any professional components performed by referring physicians themselves.

H. Durable Medical Equipment (DME)

In § 411.351 of the January 1998 proposed rule, we defined DME as having the meaning given in section 1861(n) of the Act and § 414.202 (Definitions). In the preamble to the January 1998 proposed rule (63 FR 1677 through 1678), we offered explanations of the terms and a list of the general DME categories. However, we stated in the preamble (63 FR 1677) that because the number of items considered to be DME was so extensive, we could not in the proposed rule identify all of them. Commenters were concerned about our failure to articulate a "bright-line" definition of DME. The commenters

stated that if we could not do that, physicians would have to assume that the dispensing of all DME falls under the referral prohibition.

The most frequent complaint was the difficulty the commenters had in determining whether a given item was DME or a prosthetic, prosthetic device or orthotic. (The distinction is significant since under section 1877(b)(2) of the Act prosthetics, prosthetic devices, and orthotics may be provided to a patient by a physician under the in-office ancillary services exception, while DME (other than infusion pumps) cannot.) The easiest way to determine the proper classification of an item is to consult the Durable Medical Equipment, Prosthetics/Orthotics, and Supplies (DMEPOS) fee schedule, which is updated quarterly and available on the internet under HCFA's public use files (www.hcfa.gov/stats/pufiles.htm). Under the DMEPOS fee schedule, items are identified by their HCPCS code and also include a category designation that identifies whether the item is DME, prosthetics, orthotics, or prosthetic devices. DME items include the following categories:

CR, capped rental DME.

FS, DME requiring frequent and substantial servicing.

IN, inexpensive or routinely purchased DME.

OX, oxygen and oxygen equipment.

SU, DME supplies.

TE, transcutaneous electrical (or electronic) nerve stimulator.

Additionally, DME includes the HCPCS code E1399. This code covers a number of miscellaneous DME items, but does not appear on HCFA's national fee schedule. Each DMERC (regional DME carrier) is responsible for creating a fee schedule for individual items that are not included on HCFA's fee schedule.

We note that Phase I of this rulemaking does not change existing definitions for DME, prosthetics, prosthetic devices, or orthotics. Thus, the existing classification of an item (that is, its classification as either DME, prosthetic, prosthetic device, or orthotic) will remain the same.

In sum, if, after reviewing the definitions and accompanying explanations that we provided in the January 1998 proposed rule, as well as the DMEPOS fee schedule and the HCPCS codes covering miscellaneous items, physicians and their staffs still have questions about whether a specific item is considered to be DME, we would suggest that they contact their local carrier or DMERC for clarification.

Comment: One commenter asked for clarification on whether prosthetic and orthotic devices that seem to meet the criteria for DME are considered DME supplies and whether they could be provided under the in-office ancillary services exception. The commenter expressed some confusion regarding whether crutches are DME or a prosthetic or orthotic device.

Response: The categories of prosthetics, orthotics, prosthetic devices or DME are mutually exclusive; no item can fall into more than one of these categories. If individuals are concerned about a particular type of equipment or a supply, we would suggest that they review the HCPCS codes or DMEPOS fee schedule or contact their local carrier or DMERC for clarification. Again, we note that DMERCs process more than DME claims. They also are responsible for claims for other types of devices and supplies. Crutches are DME.

Comment: A commenter recommended that we exempt crutches from the definition of DME. The commenter suggested that crutches are provided as peripheral parts of a major service (that is, a diagnosis of a broken leg) and that it is unlikely a physician would over-prescribe crutches for a diagnosis of a broken leg just so that the physician can bill for the crutches. The commenter believes that having the physician provide the crutches and instruct the patient on how to use them helps to prevent further damage to the patient and is essential to good patient care.

Response: We believe that crutches are clearly DME and therefore DHS under section 1877(h)(6)(F) of the Act. As we stated in the January 1998 proposed rule, although we cannot justify excluding crutches as a designated health service, we recognize that including crutches could greatly inconvenience patients if physicians were barred from providing them to patients who need them to ambulate following treatment for an injury or an incapacitating procedure. For this reason, we proposed expanding the in-office ancillary services exception to cover crutches when furnished in a manner that meets the in-office ancillary services exception requirements and in which the physician realizes no direct or indirect profit from furnishing the crutches. We have adopted the proposal in an expanded and modified form—without the proposed profit restriction—as described in section VI.B.1 of this preamble.

Comment: Several commenters opposed the inclusion of DME as a designated health service and argued

that the inclusion of DME will result in additional delays in treatment and barriers to access for the nation's poor and elderly populations. Two of the commenters urged us to support a legislative change to remove DME from the DHS list, while others urged us to revise the January 1998 proposed rule to remove DME entirely as a designated health service. Those commenters argued that when DME is furnished as an in-office service, it has not been associated with program abuse and offers little or no opportunity for overutilization. One of the commenters contended that an unintended effect of the inclusion of DME on the DHS list would be underutilization, because physicians would be prohibited from furnishing DME in their offices.

Response: We believe that we cannot create a separate exception for DME because we cannot guarantee that such an exception would always be free from program or patient abuse. The Congress explicitly included DME as a designated health service in section 1877(h)(6)(F) of the Act; we have no authority to vitiate that judgment. We note that physicians would only be prohibited from furnishing DME services when they have an unexcepted financial relationship with the DME supplier. Moreover, although we are not removing DME from the list of DHS, we are substantially revising the manner in which the in-office ancillary services exception applies to DME. These changes will expand the provision of DME under the in-office ancillary services exception as detailed in section VI.B.1 of this preamble.

I. Parenteral and Enteral Nutrients, Equipment and Supplies

Section 1877(h)(6)(G) of the Act includes as DHS the category of parenteral and enteral nutrients, equipment, and supplies (PEN). Enteral and parenteral therapy as a Medicare Part B benefit is provided under the prosthetic device benefit provision in section 1861(s)(8) of the Act. The regulations cover prosthetic devices in § 410.36 (Medical suppliers, appliances, and devices: Scope), paragraph (a)(2). Details for enteral and parenteral therapy are set forth in section 65–10, “Enteral and Parenteral Nutritional Therapy Covered as Prosthetic Device,” of the Medicare Coverage Issues Manual (HCFA Pub. 6). When the coverage requirements for enteral or parenteral nutritional therapy are met, Medicare also covers related supplies, equipment, and nutrients.

We proposed in § 411.351 of the January 1998 rule to 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. (See section 65–10, “Enteral and Parenteral Nutritional Therapy Covered as Prosthetic Device,” of the Medicare Coverage Issues Manual (HCFA Pub. 6) for additional information.)

We proposed in § 411.351 to 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, “Enteral and Parenteral Nutritional Therapy Covered as Prosthetic Device,” of the Medicare Coverage Issues Manual (HCFA Pub. 6).

We are clarifying in Phase I of this rulemaking that this category includes all HCPCS level 2 codes for these services. We believe this list will address any uncertainties that physicians and providers might have about what constitutes PEN, and is consistent with our definition in the proposed rule.

We also pointed out in the preamble to the January 1998 proposed rule that, like DME, section 1877(b)(2) of the Act specifically excludes PEN as services that can qualify for the in-office ancillary services exception.

Comment: A physician representing himself and an infusion therapy association asserted that physicians should be allowed to prescribe, provide, and be reimbursed for parenteral nutrition for their own patients as an extension of their practices. The commenter asserted that there has been no evidence of abuse, while there have been major problems with fraud and abuse and excessive profits by nonphysician home infusion providers, which function essentially without physician control and minimal input from physicians. The commenter believes that because patients with increasingly complex medical problems are sent home earlier from the hospital, the role of the physician office-based model is increasingly important. The January 1998 proposed referral regulations, the payment schedule for medications, and the restriction on physician reimbursement for ambulatory infusion pumps all discourage a physician’s involvement in these services.

Response: Section 1877 of the Act does not prohibit physicians from prescribing enteral and parenteral nutrition for their own patients; nor does it prohibit infusion companies from contracting with expert or knowledgeable physicians for consulting services provided the remuneration is fair market value and does not take into account referrals or other business between the parties. Section 1877 of the Act does, however, prohibit a physician from furnishing enteral and parenteral nutrition in his or her own office and billing for it unless the physician’s arrangement qualifies for an exception, such as the rural provider exception in section 1877(d)(2) of the Act. The Congress specifically excluded the provision of enteral and parenteral nutrition and durable medical equipment (DME, other than infusion pumps) from the in-office ancillary services exception in section 1877(b)(2) of the Act.

We have the authority to create additional exceptions to the referral prohibition for financial relationships under section 1877(b)(4) of the Act, but only if we determine that there is no risk of program or patient abuse. However, we believe that physicians could potentially over-prescribe parenteral nutrition if they have the financial incentive to do so.

We only cover parenteral nutrition when there is a permanent need (except when covered under the home health benefit). (See the Medicare Coverage Issues Manual (HCFA Pub. 6), section 65–10, “Enteral and Parenteral Nutritional Therapy Covered as Prosthetic Device,” for additional information. Because coverage of nutritional therapy as a Part B benefit is provided under the prosthetic device benefit provision, the patient must have a permanently inoperative internal body organ or function.) We see no reason why a patient should have to go to a physician’s office regularly to receive parenteral nutrition. Medicare already covers parenteral nutrition delivered in the home through the home health benefit or the prosthetic device benefit. Because enteral nutrition is widely available through grocery stores, drug stores, and other retail outlets, we see no reason why a patient must purchase enteral nutrition from a physician. A patient can purchase certain more specialized types of enteral nutrition that are not widely available from a DME supplier.

If a patient is to receive nutrition via an infusion pump, the in-office ancillary services exception cannot be used for the furnishing of the pump, since this exception only allows physicians’

offices to furnish infusion pumps that are DME. See section VI.B.1 of this preamble for more details about infusion pumps. (To furnish an infusion pump that is DME for use in the home, a physician would have to meet all of the supplier requirements in § 424.57.)

As for the commenter’s concerns about the payment schedule for medications, that issue is not addressed by the physician referral regulation.

J. Prosthetics, Orthotics, and Prosthetic Devices and Supplies

Prosthetics, orthotics, and prosthetic devices and supplies are included as DHS under section 1877(h)(6)(H) of the Act. We proposed in the January 1998 rule to define “prosthetics” at § 411.351 as artificial legs, arms, and eyes, as described in section 1861(s)(9) of the Act. We defined “orthotics” as leg, arm, back, and neck braces, as listed in section 1861(s)(9) of the Act. We proposed to define a “prosthetic device” as a device (other than a dental device) listed in section 1861(s)(8) of the Act 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, as well as services necessary to design the device, select materials and components, measure, fit, and align the device, and instruct patients in its proper usage. We proposed defining “prosthetic supplies” as “supplies that are necessary for the effective use of a prosthetic device (including supplies directly related to colostomy care).”

We are clarifying in Phase I of this rulemaking that this category includes all HCPCS level 2 codes for these services that are covered under Medicare. Physicians and other persons can readily determine the classification of an item by consulting the DMEPOS fee schedule. However, as with DME, there are several specific HCPCS codes representing miscellaneous items classified as prosthetics, orthotics, or prosthetic devices that do not appear in the fee schedule.

We explained in the preamble of the January 1998 proposed rule (63 FR 1678) that Medicare regards intraocular lenses (IOLs) used as part of cataract surgery as prosthetic devices. We also stated in the preamble that if these lenses are implanted in an ASC, they would be covered under the ASC payment rate and would have been excluded under the exception we proposed to create in § 411.355(d). As explained above, we are no longer considering DHS that are included in a bundled ASC payment to be DHS.

Accordingly, when an IOL is included in an ASC bundled payment rate, it will not be considered to be a designated health service.

We are also addressing a number of commenters' requests by creating exceptions (through our authority under section 1877(b)(4) of the Act) for prosthetic devices that are implanted in a Medicare-certified ASC and for eyeglasses or contact lenses that are prescribed after cataract surgery. We explain our reasons for these exceptions in our responses to specific comments.

Comment: One commenter asserted that the final rule should allow physicians to provide durable medical equipment, orthotics, and prosthetics directly to patients when they are medically necessary. Physicians currently supply splints, braces, or other devices directly to patients who have injuries, thereby ensuring that the patient gets the appropriate device, that the item is properly fitted, and that the patient is properly instructed in its use. To require a patient with an injury to leave the office, go to a DME supplier, purchase the necessary equipment, and return to the physician's office for fitting or placement and instructions on use, would be unwise, inconvenient, and could frequently cause unnecessary pain or further injury.

Response: The splints, casts, and other devices used to treat fractures and dislocations the commenter mentions are covered under section 1861(s)(5) of the Act, a benefit category that is different from the benefit categories that include DME, prosthetics, orthotics, and prosthetic devices. They are therefore not DHS under section 1877(h)(6) of the Act. Leg, arm, back, and neck braces are considered to be "orthotics" and are thus included as DHS. These can be provided by a physician within his or her own practice under the in-office ancillary services exception in section 1877(b)(2) of the Act, which excepts a physician's referral if the services meet certain supervision, location, and billing requirements. This exception could apply to referrals for any prosthetics, orthotics, or prosthetic devices. As modified by these regulations, the in-office ancillary exception could also apply to referrals for certain DME services. (See section VI.B.1 of this preamble.)

Comment: A number of commenters favored our proposal to exclude IOLs implanted during cataract surgery performed in an ASC because the IOLs are included in the ASC payment rate. The commenters asserted that a substantial number of ASCs are owned by the physicians who perform surgical procedures in them and that these

physicians are not members of one group practice. The commenters see the ASCs as an extension of the physician's own office and believe they provide a high quality, low cost setting for outpatient surgery.

Commenters requested that we exempt from the physician self-referral prohibition other prosthetic devices implanted in conjunction with surgical procedures because the provision of the prosthetic devices is incidental to the provision of ASC facility services, which are exempt from the physician self-referral prohibition. The commenter asserted that, as we noted in the January 1998 proposed rule, a physician would not unnecessarily subject patients to a surgical procedure to profit from the implant. In addition, there is no risk of program abuse because the Medicare payment for prosthetic devices implanted in conjunction with ASC facility services is limited to the lower of the actual charge for the device or a fee schedule amount. Commenters emphasized that the use of implanted prosthetic devices in reconstructive surgery is immensely beneficial to patients.

Response: We agree with the commenters that all prosthetic devices implanted in a Medicare-certified ASC by the referring physician or a member of the referring physician's group practice should be excluded. We have chosen this position because, if surgeons refer to an ASC in which they have an ownership interest, there will, in many cases, be no exception that would apply to their financial relationship with the ASC. Implanted prosthetic devices, implanted prosthetics, and implanted DME are not included in the bundled ASC payment rate and thus would retain their character as DHS even when implanted in an ASC. As a practical matter, the absence of an exception for all of these items implanted in ASCs is likely to result in these procedures moving to more costly hospital outpatient settings. We believe that the exclusion of these implants from the reach of section 1877 of the Act (using our authority under section 1877(b)(4)) will not increase the risk of overutilization beyond what is already presented by the surgeon's Part B physician fee and is consistent with the Congress's decision not to include ambulatory surgical services as a specific designated health service. We are specifically providing that the exception does not protect items implanted in other settings. Nor does it protect arrangements between physicians and manufacturers or distributors of implants where the manufacturers or distributors furnish

DHS, for example, through subsidiaries or affiliates. We are providing that the arrangement for the provision of the implant in the ASC may not violate the anti-kickback statute and all billing and claims submission must be proper.

Comment: Some commenters recommended that we exclude some or all implants to assure that there is no chilling of the ability and opportunity of Medicare patients to obtain the most appropriate and up to date technology that will be both effective and cost efficient. In addition, commenters pointed out that invasive surgery always entails a risk to the patient and is not undertaken without a physician seriously evaluating that risk in relation to the therapeutic or diagnostic benefit likely to be brought by the device to be implanted and determining what specialized model and brand of device will be most effective. Commenters believe that including implants in the definition of prosthetic devices will have the counterproductive effect of preventing surgeons from participating in research and development of these products, thereby curtailing research activity and blunting future development. This chilling effect would dramatically affect the quality of patient life and severely limit progress in reducing the cost to patients.

Response: Surgeons should be able to provide implants to their patients in any appropriate setting by meeting exceptions to the physician self-referral law. As we described in responses to earlier comments, we are creating an exception for implants that are performed in Medicare-certified ASCs. As to implants in other settings or those in ASCs that do not meet the new exception, other exceptions may still apply. Physicians who perform implants within their own practices may be able to use the in-office ancillary services exception in section 1877(b)(2) of the Act, which is discussed in section VI.B.1 of this preamble. If a physician performs the surgery in a hospital, and the hospital bills for the implant, the service would be a designated hospital service, regardless of whether the implant is a prosthetic or prosthetic device. In these cases, any financial relationship between the physician and the hospital would have to fit in an exception or the physician could not perform the surgery, much less the implant, since all hospital services are DHS. There are several exceptions that apply to referrals for hospital services.

The commenters seem to be under the misapprehension that section 1877 of the Act would prevent financial relationships between the manufacturer of an implant and a physician. These

financial relationships would not be subject to section 1877 of the Act unless the manufacturer were an entity that bills Medicare directly. However, arrangements between physicians and manufacturers may be problematic under other legal authorities, including, for example, the Federal anti-kickback statute.

Comment: One commenter believes that we should not interpret the definition of prosthetics, orthotics, and prosthetic devices and supplies for physician referral purposes to include hip and knee implants. The commenter believes that hip and knee implants do not fall within the definitions of prosthetics, orthotics, and prosthetic devices and supplies that we included in the January 1998 proposed rule. The commenter pointed out that "prosthetics" is defined as artificial legs, arms, and eyes, that "orthotics" is defined as leg, arm, back and neck braces, and "prosthetic devices" is defined as devices that replace all or part of an internal body organ. The commenter believes that hip and knee replacements do not fall under any of these categories.

The commenter further stated that, if hip and knee implants are somehow considered as prosthetic devices under Medicare, they should be excluded from the referral prohibition on the basis that they are only a component of a primary surgical procedure meant to repair damaged or painful joints. The commenter believes physicians will not ask patients to undergo painful and debilitating surgery for the sake of implanting an unnecessary artificial knee or hip implant. Also, if these items are billed as part of the hospital diagnosis-related group (DRG) payment for a surgical procedure, there is no financial incentive to use more costly or unnecessary implants and there is no increased cost to the program if one implant is chosen over another.

Response: Knee implants are considered to be "prosthetics." They are components of the artificial legs that are identified as prosthetics under section 1861(s)(9) of the Act. Artificial hips are only furnished to hospital inpatients under Medicare Part A, so we consider them to be a component of an inpatient hospital service. If a physician sends a patient to a hospital for a hip or knee implant or the insertion of a prosthetic device, all the services billed by the hospital would qualify as DHS under section 1877(h)(6)(K) of the Act because they are "inpatient or outpatient hospital services." The implants would therefore be subject to the physician self-referral law, even if we excluded them from the separate category of

"prosthetics, orthotics, or prosthetic devices and supplies."

Comment: A commenter asserted that we should exclude cochlear implants from the definition of prosthetic devices. In the January 1998 proposed rule, we had indicated our concern that a physician would choose a particular device because he or she had supplied it to the ASC where the patient's implant surgery was performed or because the physician receives money from a supplier for ordering the particular device. The commenter stated that the professional association he represents is unaware of any abuses in this area and, if there were abuses, they would be subject to the anti-kickback law.

Another commenter from an association of audiologists agreed with us that cochlear implants are a type of prosthetic device that is properly within the scope of the proposed rule. The commenter regards a cochlear implant as clearly being a prosthetic device because it replaces all or part of an internal body organ. A cochlear implant is an electronic device specifically designed to replace the function of a damaged cochlea.

Response: We agree with the second commenter that cochlear implants are covered as prosthetic devices under Medicare and are categorized as such in the CPT codes in the attachment to this final rule. As noted above, we are excepting all implants performed in a Medicare-certified ASC by the referring physician or a member of the referring physician's group practice, subject to certain conditions set forth in the exception.

Comment: A commenter noted that in the January 1998 proposed rule we stated that a prosthetic device includes services necessary to design the device, select materials and components, measure, fit, and align the device, and instruct patients in its proper usage. The commenter requested that we expressly clarify that certain services provided to patients after a cochlear implant are subject to the physician self-referral provisions. These services include device mapping, aural rehabilitation programs for adults to enable them to learn to use the device, and aural habilitation programs for children to maximize speech and language development.

The commenter asserted that these postsurgical services are provided by audiologists without physician involvement or supervision of any kind. In addition, the commenter stated that cochlear rehabilitation services are not included in the global fee for cochlear implantation surgery. Instead, these

services are billed under a unique CPT code, 92510.

Response: The Medicare definition of a prosthetic device ordinarily includes the services necessary to design the device, select materials and components, measure, fit, and align the device, and instruct patients in its proper usage. In fact, the costs of delivery, fitting, measuring and instructing the patient are bundled into the fee schedule payment amount for not only prosthetic devices, but for DME, orthotics, and prosthetics as well. However, cochlear implants are somewhat unique. Because it can be particularly difficult for a patient to learn to use the implant, cochlear rehabilitation services are categorized separately as speech-language pathology services. These services are billed under CPT code 92510 (which is included as a PT service because it is a speech-language pathology service). Therefore, all of these services qualify as "designated health services," but under different categories.

Comment: A commenter pointed out that items such as rib belts, slings, and basic braces (those not custom-fitted) are in the prosthetic/orthotic section of the HCPCS. The commenter asked whether these items would be considered orthotics or DME, since the patient would be wearing the item home. The commenter believes that, in either case, it would be inappropriate to prevent a physician from supplying and billing for these items when the patient has come to the office with an injury. The commenter asserted that requiring a patient to leave the physician's office to purchase necessary equipment is inconvenient and unwise because it may result in unnecessary pain or injury to the patient.

Response: The items described as "rib belts" and "slings" are not included in any DHS category. The items described as "basic braces" are orthotics. Nothing in Phase I of this rulemaking moves any item or device from one coverage category to another coverage category. If the items qualify as in-office ancillary services under section 1877(b)(2) of the Act, a physician who supplies them in his or her office in the course of seeing a patient should be able to use the in-office ancillary services exception in order to provide them to the patient, even if the patient takes the items home. We regard the physician as "furnishing" an item in his or her office if the physician dispenses the item to the patient there.

Comment: Several commenters urged us to exclude eyeglasses and contact lenses from the definition of prosthetic devices. Commenters noted that there is

no incentive to overutilize or abuse this benefit because we acknowledge that one pair of conventional eyeglasses or contact lenses is medically necessary after cataract surgery; Medicare coverage is limited to one pair of conventional eyeglasses or contact lenses; and Medicare payment is on a reasonable charge basis.

Response: We agree with the commenters that eyeglasses and contact lenses should be excluded from the reach of section 1877 of the Act for purposes of Medicare referrals. The Medicare coverage of these items is unique in that it is limited to one pair of either item after each cataract surgery and is available to any patient who has had this surgery. In that respect, the coverage is similar to the coverage of preventive screening services that are subject to frequency limits, as discussed earlier in this section. In addition, the Medicare-approved amount of payment does not vary based on the expense of a particular pair of glasses or contact lenses. Medicare pays fixed amounts for eyeglasses and contact lenses that are single focal, and fixed amounts for eyeglasses and contact lenses that are bifocal. In sum, we see little opportunity or incentive for a physician to either under or overutilize these items in the Medicare program. Accordingly, we are creating a new exception under the authority in section 1877(b)(4) of the Act for eyeglasses and contact lenses after cataract surgery. Like other section 1877(b)(4) exceptions, the new exception is subject to there being no violation of the anti-kickback statute or any billing or claims submission law or regulation.

K. Home Health Services

In the January 1998 proposed rule, we proposed to define home health services as the services described in section 1861(m) of the Act and part 409, subpart E. We included in the preamble to that rule (63 FR 1679), a discussion of how we proposed to reconcile section 1877 of the Act and the physician certification requirements for home health services in § 424.22 (Requirements for home health services), paragraph (d) (Limitations on the performance of certification and plan of treatment functions). In that discussion, we explained that the home health agency (HHA) rule and its exceptions have been superseded by section 1877 of the Act. Phase I of this rulemaking reflects this change. Our responses to comments mostly serve to clarify how the modified home health rule will work.

Comment: Four commenters supported our proposal to reconcile the

physician self-referral law with the physician certification requirements for home health services contained in § 424.22(d). One commenter specifically expressed agreement with our proposed position that the exceptions to the physician self-referral law would also apply to physician certification requirements for home health services. Another commenter specifically supported the proposed changes that would eliminate the 5 percent ownership and \$25,000 financial or contractual relationship limits and replace them with the prohibition on self-referral contained in section 1877 of the Act. The commenter stated that this change would allow HHAs to provide for medical oversight by a salaried physician as permitted under the Medicare hospice benefit. (We believe that commenter meant that the proposed elimination of the \$25,000 financial or contractual relationship provision would allow an HHA to pay a physician medical director more than \$25,000 as long as the HHA meets relevant ownership and compensation exceptions described in the proposed rule.) Another commenter asked that we clarify whether the current \$25,000 limit on financial or contractual relationships as it relates to medical directors of home care agencies will be removed.

Response: We are removing the current 5 percent ownership limit and the \$25,000 limit on financial or contractual relationships from § 424.22(d). The new § 424.22(d) appears exactly as we proposed it: "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, 'Definitions,' with that HHA, unless the physician's relationship meets one of the exceptions in §§ 411.355 through 411.357 of this chapter * * *." The elimination of the \$25,000 financial or contractual relationship provision will allow an HHA to pay a physician medical director more than \$25,000 as long as the financial relationship meets a relevant ownership or compensation exception under section 1877 of the Act.

Although we are delaying the effective date for most of Phase I of this rulemaking for 1 year, we are making the change in § 424.22(d) effective February 5, 2001. Having weighed the alternatives, we believe an effective date of February 5, 2001 for the revision of § 424.22(d) is desirable, even though the revisions to §§ 411.355 and 411.357 will not be effective until later. In the

interim, the references to §§ 411.355 and 411.357 will cross-refer to the statutory exceptions set forth in section 1877 of the Act. It is our view that during the interim period, the exceptions set forth in those sections would apply under § 424.22(d) for services other than laboratory services.

Comment: One commenter requested that we retain the provisions in § 424.22(e) (Exceptions to limitations), (f) (Procedures for classification as a sole community HHA) and (g) (Basis for classification as a sole community HHA) that except governmental entities and sole community HHAs from the prohibition on certification of need for home health services by related physicians. The commenter noted that keeping this language would remove the threat of unfair competition for agencies that have historically been the sole providers in their communities. The commenter explained that the "rural provider" exception to the physician self-referral law would permit an urban physician to establish a new HHA in a rural area, as long as the agency's service population is at least 75 percent rural. This would create new and unfair competition for many rural agencies that are small, nonprofit organizations.

Response: We realize that eliminating the exceptions for governmental entities and sole community HHAs in combination with the ownership exception for rural providers under the physician self-referral law may create new competition for small, nonprofit HHAs. Nonetheless, we believe that we do not have the legal authority to retain these exceptions in any meaningful way. As we pointed out in the preamble to the January 1998 proposed rule (63 FR 1680), even if a physician and an HHA are involved in an arrangement that meets one of the home health exceptions at issue, the arrangement simultaneously remains subject to the requirements in section 1877 of the Act. That is, if an exception under the HHA certification regulations is subsumed within the exceptions in section 1877 of the Act, 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, the HHA exceptions have been superseded by section 1877 of the Act.

The Secretary does have the authority to create additional exceptions to the referral prohibition under section 1877(b)(4) of the Act, but only in situations in which she determines that there is no risk of program or patient abuse. We believe that the fact that an entity is run by the government or is a sole community HHA does not guarantee that there will be no

unnecessary referrals. In addition, it is our view that we should treat all providers equally and allow them an equal opportunity to compete, particularly in areas where there have historically been too few providers. In fact, the purpose of the "rural provider" exception in section 1877(d)(2) of the Act is to encourage physicians to invest in or remain invested in under-served areas. (Note that hospitals do not have similar exceptions for governmental entities or sole community hospitals.) Therefore, we do not intend to include the exceptions for governmental entities and sole community providers in the revised HHA certification regulations because we believe that our proposed approach provides the best protection against possible program abuse and fulfills the intent of the law.

Comment: A commenter representing home care physicians asked that we clarify whether physicians making home visits are providing services that qualify as DHS under the January 1998 proposed regulations.

Response: Under the Medicare program, when a physician performs a physician service, including a visit to a home health patient, the physician service is billed as a physician service and is not considered a home health service. This is the case even when the physician has an employment contract with the HHA, such as when a physician is employed as a medical director. Thus, the commenter is correct in noting that physician home visits are not themselves on the list of DHS in section 1877(h)(6) of the Act, and would only qualify as such if the physician was actually performing a specific designated health service (for example, performing physical therapy). In these cases, the service would still be protected if it is personally performed by the referring physician, since it would not be considered a referral under the final rule. (See section III.B of this preamble.) In addition, some in-home services provided by a home care physician may qualify under the in-office ancillary services exception. (See section VI.B of this preamble.)

L. Outpatient Prescription Drugs

Section 1877(h)(6)(j) of the Act provides that "designated health services" includes the category of "outpatient prescription drugs," but does not define this term. Because Medicare does not cover a category of services called "outpatient prescription drugs," we proposed to define this term in the regulation. We proposed to include only drugs (including biologicals) defined or listed under section 1861 (s) and (t) of the Act, and

in part 410, furnished under the Medicare Part B benefit that patients can obtain from a pharmacy with a prescription, even if patients can only receive the drug under medical supervision. In the preamble to the January 1998 proposed regulation (63 FR 1680), we included as an example 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.

We proposed specifically to exclude from the definition of "outpatient prescription drugs" erythropoietin (EPO) and other drugs furnished as part of a dialysis treatment for an individual who dialyzes at home or in a facility.

Upon further review of the law, existing regulations, and the public comments, we have concluded that our proposed definition of "outpatient prescription drugs" was not clear enough. In Phase I of this rulemaking, we are revising the definition of outpatient prescription drugs to make clear that it includes all prescription drugs covered by Medicare Part B. We are not excluding any outpatient prescription drugs from the DHS category of "outpatient prescription drugs." Including all outpatient prescription drugs is consistent with our policy throughout these final regulations of avoiding carving services out of DHS definitions through service-by-service analyses of the potential for fraud and abuse. Our definition of outpatient prescription drugs provides physicians and DHS entities with a "bright line," common sense rule. Moreover, the breadth of the definition is ameliorated to a very large extent by our expansion of the exception for in-office ancillary services, which includes much greater flexibility with respect to the direct supervision requirement, and our promulgation of a new limited exception under section 1877(b)(4) of the Act for the provision of EPO and certain other dialysis-related drugs by or in ESRD facilities (described in greater detail below). Those changes, together with the changes in the definition of "group practice" and "referral," should permit a physician to furnish patients with covered drugs, either by administering or dispensing the drugs to patients in his or her office or, in the case of EPO and other specific dialysis drugs, by furnishing the drugs in or through a physician-owned ESRD facility. We wish to make clear that nothing in this regulation affects, or is intended to affect, current or future coverage of any particular prescription drug.

We are creating an exception for EPO and certain other specific drugs that are required for the efficacy of dialysis when they are furnished by an ESRD facility with which the referring physician has a financial arrangement. We are similarly excepting certain vaccinations, immunizations, and preventive screening tests that are subject to HCFA-imposed frequency limits. We are also clarifying that physicians who provide drugs in their own offices are not required to pass on to Medicare discounts they receive in purchasing these drugs, unless otherwise required to do so by the Medicare program. These issues are discussed in detail below.

Comment: A number of commenters raised the issue of whether drugs and biologicals provided incident to physician services are included in the definition of outpatient prescription drugs. The commenters pointed out that most drugs and biologicals are covered under Medicare Part B only if they require administration by a physician, and thus typically are covered in the physician office setting only if furnished as "incident to" physician services. Thus, the resulting "self referral" is effectively a requirement for Medicare coverage. In the commenters' view, excluding drugs furnished incident to physician services from the definition of "outpatient prescription drugs" would ensure that the physician self-referral law does not discourage the types of "referrals" that are prerequisites to Medicare coverage.

One commenter asserted that drugs that are covered under Medicare only as a component of a physician service should be excluded because physician services were never intended to be included within the referral prohibition. Another commenter recommended that we make all injectable drugs exempt from the referral prohibition under the in-office ancillary services exception.

Several commenters were particularly concerned about antigens and serums that a patient receives in a physician's office, stating that they should be excluded from the category of outpatient prescription drugs, along with chemotherapy. Another commenter pointed out that if our definition of outpatient prescription drugs includes drugs administered during a patient's office visit, patients could have serious access problems to such drugs as antibiotics, renal therapy, and vaccines. Another commenter recommended that we limit outpatient prescription drugs to those that are self-administered, such as oral cancer drugs, oral antiemetics, and immunosuppressives, for which there is Medicare coverage that does not

depend on administration in a physician's office.

Response: We believe the commenters are conflating two issues: (1) What drugs fit in the term "outpatient prescription drugs" in section 1877(h)(6)(J) of the Act and (2) the scope of the in-office ancillary services exception in section 1877(b)(2) of the Act. Upon review, for purposes of defining "outpatient prescription drugs" under section 1877(h)(6)(J) of the Act, we can ascertain no meaningful distinction between prescription drugs dispensed by pharmacies or those mixed and administered in a physician's office. To the extent the latter is permitted, it is through the vehicle of the in-office ancillary services exception. The scope of that exception is discussed in section VI.B.1 of this preamble.

Comment: Many commenters stated that oncology drugs administered to patients by injection or infusion in a physician's office should be excluded from the definition of outpatient drugs because a patient essentially cannot obtain these drugs from a pharmacy before visiting his or her physician. When a patient comes to a physician's office for chemotherapy, the patient receives a series of blood tests to determine the patient's physiological state. Based on these tests, the chemotherapy agents are mixed and tailored by the oncologist's staff to address the patient's current health status. Therefore, a patient cannot pick up from a pharmacy the medication he or she needs before visiting the physician. We may have misunderstood how chemotherapy drugs are actually administered.

In addition, the commenters pointed out that a great majority of retail pharmacies are not currently prepared to provide chemotherapeutic mixing and dispensing services for infusion drugs. That is because Federal regulations and accepted standards of practice for physicians, oncology nurses, technicians, and pharmacists require that the preparation, storage, transportation, and disposal of chemotherapy drugs and applicable supportive agents be conducted under the most rigorously controlled circumstances.

Response: We agree that chemotherapy agents are not commonly available from retail pharmacies, but are prepared for individual patients. However, these drugs are outpatient prescription drugs; they are available only upon a physician's order and are provided in an outpatient setting. (When provided in an inpatient setting, they would be inpatient hospital services under section 1877(h)(6)(K) of

the Act.) We believe these drugs are usually administered in oncologists' offices and typically should qualify for the in-office ancillary services exception. (See discussion in section VI.B.1 of this preamble.)

Comment: Several commenters have stated that in-office x-rays and laboratory tests that are performed in conjunction with the provision of chemotherapy should be excluded from the definition of DHS. The commenters seemed particularly concerned that if these services are regarded as DHS, a physician would have to directly supervise them. The commenters expressed concern that requiring a physician to be present during the times these services are provided would run directly counter to common practice in oncology offices and would greatly inconvenience patients.

These commenters asserted that it is extremely unlikely that a physician would refer a patient for chemotherapy simply to obtain the revenue from the x-ray and laboratory tests that are performed in conjunction with the provision of chemotherapy. They regard as a precedent for this exception our proposals to exclude from the definition of radiology certain invasive radiology services in which an imaging modality is used to guide a needle, probe, or catheter properly and to exclude EPO from the definition of outpatient prescription drugs when EPO is provided incidental to dialysis treatment. We had proposed to exclude these invasive radiology procedures and EPO because they are merely furnished incidental to, or secondary to, another procedure that the physician has ordered.

Response: The Congress has imposed certain constraints on physicians' financial arrangements with entities to which they refer patients for DHS. The provision of chemotherapy is a designated health service, as is the provision of radiology and clinical laboratory services. In order for a physician to refer patients to an entity with which the referring physician has a financial arrangement, the physician's financial relationship with the entity must come within an exception to section 1877 of the Act.

As discussed elsewhere, we are not prepared to limit the scope of DHS under section 1877(h)(6) of the Act except in rare situations. We believe that most arrangements for the provision of chemotherapy and related ancillary services by physicians to their patients can be restructured to come within the in-office ancillary services exception as modified by this final rule. (See section VI.B of this preamble.) As discussed

above, we are abandoning the "peripheral/incidental" test that was proposed in the January 1998 proposed rule; we point out that even under that test, the primary procedure could not itself be a designated health service.

Finally, we wish to clarify that we are excepting EPO under certain circumstances because we believe that the Congress did not intend to preclude physician ownership of ESRD facilities. Commenters have noted that when the Congress intended to cover specific Medicare services, including composite rate services, it did so expressly. We agree. The Congress did not list ESRD facility services under section 1877(h)(6) of the Act, while it did list home health services and hospital services. Therefore, we do not regard services furnished under a composite rate by an ESRD facility as DHS. Given the high correlation between EPO and ESRD services, the inclusion of EPO as a DHS would vitiate the Congress' apparent intent. Accordingly, we are excepting from the reach of the statute under our section 1877(b)(4) of the Act authority EPO or other drugs required for dialysis when furnished in or by an ESRD facility owned by physicians. The list of these drugs is set forth in the attachment to this final rule. Given the strict utilization and coverage criteria for EPO in particular and ESRD in general, we conclude this narrow exception presents no quantifiable risk of fraud or abuse. We are not protecting any physician investment in a home dialysis supply company or other entity that supplies EPO to ESRD facilities or that supplies EPO to patients pursuant to a contract with an ESRD facility; in such situations, the physician's investment in the dialysis supply company is no different from any other investment in a DHS entity and there is no indication in the legislative history that home dialysis supply companies were not meant to be covered by the statute.

Comment: A substantial number of commenters requested that we not require physicians to pass on to Medicare discounts they receive in purchasing oncology drugs. Commenters pointed out that the proposed regulations appear to require this result. Some commenters believe that this proposed requirement conflicts with section 1877(e)(8)(B) of the Act, which excepts any payment made by a physician for items and services if the price is consistent with fair market value.

Response: Nothing in this section 1877 of the Act or these regulations is intended to impose on physicians a requirement to pass discounts on drugs

on to the Medicare and Medicaid programs; whether a discount must be passed on to a Federal health care program by physicians or others, however, remains the subject of other statutory and regulatory provisions.

Comment: One commenter asked that we confirm that the definition of "outpatient prescription drugs" would apply only to those drugs that are furnished to "outpatients" of any facility, including a SNF or nursing facility. The commenter believes that if the Congress had intended that the statute cover drugs provided to "inpatients" of facilities, it could have easily written the statute to do so. The commenter pointed out that drugs provided to "inpatients" are generally covered under Medicare Part A and are peripheral components of the services being provided and billed for, particularly under the prospective payment system for SNFs under which SNFs receive a per diem rate for virtually all items and services furnished to a Medicare Part A patient.

Response: In the January 1998 proposed rule, we proposed to include only drugs furnished to an individual under the Medicare Part B benefit and to exclude drugs furnished by providers under Medicare Part A. We have reflected this in Phase I of this rulemaking. A patient may reside in a SNF under a Part A stay or a patient may reside in a SNF without being covered under Part A. If the stay is not covered under Part A, it is possible that the patient may receive some drugs under the Part B benefit that are considered "outpatient prescription drugs" under these physician self-referral provisions. In addition, under section 1835(a) of the Act, a SNF may furnish services to an individual who is not a SNF inpatient. That is, it is possible for a SNF to provide services to an individual who does not reside in the SNF. For example, a SNF with an x-ray machine may furnish x-ray services to a nonresident if the individual has a referral for an x-ray and he or she wishes to receive the x-ray at this location. We assume the individuals who receive these services are the "outpatients" to whom the commenter is referring. (We note that drugs provided to patients in a hospital setting would be inpatient or outpatient hospital services under section 1877(h)(6)(K) of the Act.)

Patients in nursing facilities are typically covered under the Medicaid program. We intend to address all Medicaid-related physician referral issues in a separate rulemaking.

Comment: A commenter requested that we amend the January 1998

proposed rule to clarify that immunizations are not DHS under the definition of "outpatient prescription drugs." The commenter pointed out that immunizations, particularly in pediatric and family care practices, are often personally administered by a physician to his or her own patients or are furnished on an "incident to" basis under the physician's direct supervision. In the adult population, there is also an increasing public awareness of the need for preventive immunizations, such as pneumococcal vaccine and influenza vaccine. These immunizations are widely and actively promoted in this country as constituting good preventive medicine. The commenter believes that the January 1998 proposed regulation could discourage immunizations because under the proposed interpretation of productivity bonuses in the group practice definition, a physician would be unable to share in a productivity bonus based on his or her own administration of, or direct supervision of, these immunizations.

Response: The commenter raised issues relating to immunizations that are covered by Medicare under section 1861(s)(10) of the Act, which covers pneumococcal vaccine and influenza vaccine and their administration, as well as hepatitis B vaccine and its administration if furnished to an individual who is at high or intermediate risk of contracting hepatitis B. Under our authority to create additional exceptions in section 1877(b)(4), we are excluding from the reach of section 1877 of the Act certain immunizations and vaccines covered under section 1861(s)(10) of the Act that are subject to HCFA-imposed frequency limits and that are paid by Medicare on the basis of a fee schedule. We believe that under the terms of the exception the risk of abuse for these services is extremely low and that this exclusion is consistent with the statutory language and structure and the expressed Congressional intent to provide preventive care to Medicare beneficiaries.

In referring to drugs furnished in pediatric and family practices, we assume that the commenter was interested in the definition of outpatient prescription drugs under the Medicaid program. We intend to address the effects of the physician self-referral prohibition on the Medicaid program in Phase II of this rulemaking.

Comment: A commenter raised questions about our decision to exclude EPO and other drugs furnished as part of a dialysis treatment from the definition of "outpatient prescription

drugs." The commenter considered this exclusion ambiguous and requested clarification about whether a particular drug provided by a facility is "part of a dialysis treatment." The commenter pointed out that EPO and other pharmaceuticals are typically administered during the course of treatment to avoid the painful process of injecting the patient multiple times, but that it could be argued that these pharmaceuticals are not "part of" the treatment itself. Therefore, the commenter requested that we revise the exclusion of "other drugs furnished as part of the dialysis treatment" to instead apply to "other drugs furnished to an individual who dialyzes at home or in a facility, as part of an ESRD patient's plan of care."

Response: When we carved out of the definition of "outpatient prescription drugs, EPO and other drugs furnished as part of the dialysis treatment," we did not aim to carve out the far broader category of all "other drugs furnished * * * as part of an ESRD patient's plan of care." We regard "other drugs furnished as part of the dialysis treatment" to be those furnished so that the dialysis treatment can be effective and to counteract the problems that can be caused directly by dialysis. For example, dialysis makes some patients anemic, so EPO is provided to deal with this dialysis-related problem. In addition, iron therapy is covered to make EPO therapy effective and Vitamin D hormone therapy is covered to correct for bone density loss caused by dialysis. Other drugs furnished to an individual who dialyzes at home or in a facility may include drugs that a patient uses for reasons other than to make the dialysis treatment effective. In fact, these other drugs may have nothing whatsoever to do with a patient's renal problems.

Comment: Another commenter agreed with our proposal to exclude EPO in the January 1998 proposed rule because it would allow physicians who own a dialysis facility to prescribe Medicare-covered medications to patients of the dialysis facility on the basis that the drugs are an integral part of the dialysis procedure. The commenter asked that we clarify that self-administered medications for home dialysis such as EPO can only be furnished by the dialysis provider or a supplier that has an agreement with the dialysis provider (a Method II supplier) and cannot be provided through the referring physician's office. The commenter contended that teaching the home dialysis patients to self-administer medications and monitoring the effects

of self-administered medications is the responsibility of the dialysis facility.

Response: We agree with the commenter. As provided in § 414.335 (Payment for EPO furnished to a home dialysis patient for use in the home), medications for home dialysis can only be furnished by the dialysis provider or a Method II supplier that has an agreement with a provider. If a referring physician has a financial agreement with a Method II supplier, the arrangement must meet an exception.

Comment: A commenter asked that immunosuppressant drugs prescribed for patients following organ transplants and covered by Medicare be excluded from the definition of "outpatient prescription drugs." The commenter believes that the rationale for excluding these drugs is similar to the rationale for excluding EPO, since the use of these drugs is peripheral to the transplant surgery, but medically integral to the success of the surgery.

The commenter contended that excluding immunosuppressants from the definition will not provide an opportunity for program or patient abuse because their cost is an economically minor, though medically critical, part of a large and immensely complicated treatment. In addition, the commenter believes that physicians have no motivation to overprescribe these drugs, because the drugs are only used for transplant patients according to clinically accepted protocols that are designed to prevent organ rejection while avoiding unnecessarily high levels of toxicity. The commenter believes that the transplant community adheres to the prevailing standards of medical care with only minor deviations. In addition, each transplant center is required to report its transplant survival rates to an HHS contractor. Centers with survival rates below established thresholds can lose their certification.

Response: Immunosuppressant drugs furnished in an outpatient setting are "outpatient prescription drugs" under Phase I of this rulemaking. (They are inpatient or outpatient hospital services when furnished in a hospital setting.) We are not persuaded that an exception is appropriate or necessary. We believe that to the extent physicians provide transplant drugs to patients in their offices, they will generally be able to do so under the in-office ancillary services exception. If a referring physician has an ownership or investment interest in a free-standing transplant pharmacy or other pharmacy that provides transplant drugs to his or her patients pursuant to a referral, the financial relationship

would have to fit in an applicable exception.

M. Inpatient and Outpatient Hospital Services

In § 411.351 of the January 1998 proposed rule, we defined inpatient hospital services as services that a hospital provides for its patients that are furnished either by the hospital or by others "under arrangements" with the hospital. For outpatient services, we explained in the preamble of the January 1998 proposed rule (63 FR 1683) that 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. We have revised the definition of outpatient hospital services in the regulations text to clarify that it includes services furnished "under arrangements." Inpatient services are not coded by HCPCS codes. Any outpatient hospital service, regardless of the HCPCS code, is a designated health service.

In the January 1998 proposed rule, we requested comment on whether we should exclude lithotripsy from the definition of inpatient or outpatient hospital services on the theory that it could not be overutilized, since the procedure itself apparently documents the medical necessity to prescribe it. Commenters were also concerned about physician services that are "bundled" into hospital payments and about services furnished by a hospital "under arrangements" with an outside facility. We discuss each of these topics below.

Comment: We received hundreds of comments on the subject of lithotripsy, mostly from urologists who have ownership interests in a lithotripter that a hospital rents. These commenters requested that lithotripsy be excluded from the definition of inpatient and outpatient hospital services so that they could continue to refer to the hospitals without being concerned about how the hospital compensates them. According to these commenters, urologist-owned lithotriptors increased quality of care and patient access without any risk of overutilization of lithotripsy. We also received comments on this topic from individual hospitals, a State and national hospital trade association, and nonphysicians who rented lithotriptors to hospitals in competition with physician owners. These commenters asserted that hospitals pay more for the use of physician-owned lithotriptors than hospitals pay for the use of their own lithotriptors or lithotriptors owned by nonphysicians and urged us to

include lithotripsy in the definition of inpatient and outpatient hospital services.

Response: We have determined that there is no reason to treat lithotripsy any differently than other inpatient or outpatient hospital services. As we have said elsewhere in the preamble, we believe the Congress did not intend that we make service-by-service decisions on whether a service is a designated health service based on the service's potential for overutilization. Even were we able to determine that there is no potential for overutilization of lithotripsy (including comparisons to alternative treatments), there is a substantial potential for urologists who own lithotriptors to extract higher than market rate rents for their equipment or for the financial arrangement between the lessor urologists and the lessee hospital to encourage overutilization of other hospital services. Commenters provided no evidence to support their claims that physician ownership of lithotriptors increased quality of care or access to treatment.

In any event, the exclusion of lithotripsy from the definition of inpatient and outpatient services would not obviate the need for the physician-owners to structure their rental arrangements to comply with section 1877 of the Act. Whether lithotripsy is a designated health service or not, the rental arrangement itself would create a financial relationship between the physician-owners and the hospital. Unless the financial relationship (that is, the lithotripter lease) fit into a compensation exception (such as the equipment rental exception), the physicians could not refer any Medicare patients to the hospital for any inpatient or outpatient services. In short, the relief sought by these commenters would be illusory.

We believe that the changes we have made in § 411.354(d) of these regulations to the volume or value standard (discussed in section V of this preamble) will enable hospitals and urologists to protect *bona fide* arrangements either under an equipment lease or a personal service arrangements exception or under the fair market value exception. Most importantly, Phase I of this rulemaking clarifies that "per service" or "per use" rental or services payments are permitted, even for services performed on patients referred by the urologist-owner, provided the rental or services payment is fair market value and does not take into account any Federal or private pay business generated between the urologist and the hospital (and provided all other conditions of an

exception are met). Because the prevalence of physician ownership of lithotriptors may distort pricing in the marketplace, we believe valuation methods that look to the prices charged by persons not in a position to refer to the hospital or that consider acquisition cost and rate of return are especially appropriate. We also are aware that some manufacturers of lithotriptors lease the machines to urologists on a "per use" basis with the urologists, in turn, leasing the lithotriptors to hospitals on a "per use" basis. In these circumstances, any disparity in the "per use" fee charged by the manufacturer to the urologists and the "per use" fee charged in turn by urologists to the hospital would call into question whether both sets of fees could be fair market value.

Comment: Several commenters suggested that section 1877 of the Act was only intended to address diagnostic procedures. Accordingly, they asked that we exclude therapeutic treatments such as lithotripsy from the definition of inpatient or outpatient hospital services in cases in which the referring urologist or a member of his practice actually treats the referred patient.

Response: The list of DHS in section 1877(h)(6) of the Act contains both therapeutic and diagnostic types of service (for example, physical therapy services are therapeutic and clinical laboratory services are diagnostic). This indicates that the Congress believed that both types of services could be subject to abuse. We have concluded that when a physician initiates a designated health service and personally performs it him or herself, that action would not constitute a referral of the service to an entity under section 1877 of the Act. However, in the context of inpatient and outpatient hospital services, there would still be a referral of any hospital service, technical component, or facility fee billed by the hospital in connection with the personally performed service. Thus, for example, in the case of an inpatient surgery, there would be a referral of the technical component of the surgical service, even though the referring physician personally performs the service. If the referring physician has a financial relationship with the hospital, that relationship must fit in an exception. Potentially available exceptions, depending on the circumstances, include, for example, the personal service arrangements exception, the employee exception, the space or equipment rental exception, the whole hospital exception, and the fair market value exception.

Comment: Several commenters stated that the only reason extracorporeal

shock wave lithotripsy (ESWL) is even subject to the physician self-referral provisions is because Medicare only pays for lithotripsy if it is billed through a hospital, thus forcing the procedure into the realm of inpatient or outpatient hospital services. Many commenters have cited debate language pertaining to adopting the Conference Report for OBRA '93, which language suggests that the sponsor of section 1877 of the Act, Representative Stark, did not intend for ESWL to come under the law.

Response: We believe that lithotripsy was meant to be a "designated health service" under the law, since the law does not exclude any particular hospital services, nor does the legislative history indicate that the Congress meant to exclude them. The House Report for the first version of the physician self-referral law mentioned a specific exception for a facility providing lithotripsy services performed personally by the referring physician. (See H. Rep. No. 101-247, 101st Cong. 1041 (1989).) This exception did not apply to the hospital services at issue, nor was it enacted. In adding hospital services to the list of DHS, the legislative history reveals that the Congress was concerned about increased admissions to hospitals, regardless of the reason for the admission. (We discuss this issue further below, where we address hospital services provided "under arrangements.")

Comment: Another commenter pointed out that we proposed excluding from the definition of inpatient hospital services those services performed by physicians and other providers who bill independently. The commenter asked us to clarify whether physician and individual professional services are excluded from the definition of inpatient hospital services when they are billed by a hospital. Hospitals bill for these services when they are part of a global fee that covers both the technical and professional components of a service or when they bill on an assignment (or reassignment) basis. This commenter argued that if these services are not excluded under section 1877 of the Act, a hospital may not be able to compensate a physician for services performed in, and billed by, the hospital, or to compensate a doctor who supervises a nurse practitioner in a hospital. The commenter also suggested that we clarify that we will treat both inpatient hospital services and outpatient hospital services the same way.

Response: Professional services that Medicare pays independently of an inpatient or outpatient hospital service

do not become DHS if they are billed by a hospital under assignment or reassignment; they remain physician services and are not considered hospital services. Any other service for which a hospital bills is a hospital inpatient or outpatient service, even though it may consist of both a technical and professional component. Therefore, these services constitute DHS under section 1877 of the Act. However, if a hospital is paying the physician for his or her professional services under either a personal services contract or an employment agreement, the physician can still refer to the hospital as long as the compensation arrangement meets an exception, such as the exception that applies to personal service arrangements or the exception for employment agreements. These exceptions require, among other things, that the hospital pay the physician an amount that is based on a fair market value standard.

Comment: Several commenters expressed concern with the effect the definitions of inpatient and outpatient hospital services may have when a hospital purchases services "under arrangements" from an entity owned in whole or in part by a referring physician. Commenters fear that if services are deemed to be inpatient or outpatient hospital services for the purposes of 1877 of the Act when furnished by a hospital "under arrangements" with an entity owned by a physician, physicians may be unwilling to invest in equipment using new technologies. One commenter specifically proposed an exception that would apply to any service that would be exempt from the physician self-referral prohibition if the physician referred directly to the entity, outside of the hospital context. According to several commenters, it is the nature of the service itself that should determine whether or not a referral may be made, not the inpatient or outpatient status of the patient. Commenters were concerned that a physician will not be able to refer a patient to a hospital if the hospital has an arrangement with an entity that the physician owns. The commenters believe that, as long as the actual services are compensated at fair market value, there should be no risk of program or patient abuse.

Response: The Congress specifically chose to include inpatient and outpatient services as DHS under section 1877(h)(6)(K) of the Act. Inpatient and outpatient hospital services include any services that a hospital provides to a hospital patient, whether it provides them itself or provides them by purchasing them from another entity under arrangements; any

other policy would encourage hospitals to purchase as many services as possible under arrangements in order to avoid the effects of the physician self-referral provision. In light of the description of “volume or value” in Phase I of this rulemaking, we believe that *bona fide* “under arrangements” relationships can easily be structured to comply with the personal service arrangements exception, or, in some cases, the fair market value exception. We believe this approach is consistent with section 1877(e)(7) of the Act, which provides a limited exception for certain “under arrangements” relationships that were established before 1989 and met several other requirements.

We are concerned that the provision of services “under arrangements” could be used to circumvent the prohibition in section 1877(c)(3) of the Act of physician ownership of parts of hospitals. We understand that some hospitals are leasing hospital space to physician groups, which the groups then use to provide services “under arrangements” that the hospital had previously provided directly. These arrangements, especially when they involve particularly lucrative lines of business, raise significant issues under section 1877 of the Act, as well as the anti-kickback statute.

However, we also recognize that “under arrangements” relationships are pervasive in the hospital industry and that many of the services being provided by physician groups “under arrangements” are services that the physicians provide in physician-owned facilities primarily to their own patients who are hospital inpatients. In these situations, an “under arrangements” relationship can avoid unnecessary duplication of costs and underutilization of expensive equipment.

While we believe section 1877 of the Act could reasonably be interpreted to prohibit “under arrangements” relationships as constituting prohibited ownership interests in a part of a hospital, we decline to do so at this time for several reasons. First, given the sheer number of these arrangements, we think prohibiting these arrangements would seriously disrupt patient care. Second, almost all these arrangements could be restructured to fit into a combination of the personal service arrangements and equipment lease exceptions (or fair market value exception), although this restructuring will in some cases be administratively burdensome. Third, we believe there is precedent in the statute for treating this situation solely as a compensation arrangement. In section 1877(e)(7) of the Act, the Congress

created a specific compensation exception for certain hospital services provided by physician groups “under arrangements.” Since, by definition, all services protected under section 1877(e)(7) of the Act—and the resources used to produce them—were “owned” by the physician groups, the Congress would not have created a protected compensation relationship unless it had first determined that these arrangements did not create a prohibited ownership or investment interest in the hospitals. Simply stated, the Congress would not have excepted these relationships from the compensation arrangement restriction, if they were prohibited as an ownership or investment interest.

In sum, for purposes of section 1877 of the Act, we will treat “under arrangements” financial arrangements between hospitals and physician-owned entities as compensation and not ownership relationships. These arrangements can be protected provided they meet an appropriate compensation exception. We will, however, monitor these arrangements and may reconsider our decision if it appears that the arrangements are abused. We also caution physician groups and hospitals that these arrangements remain subject to the Federal anti-kickback statute.

Comment: One commenter requested that we clarify how the physician self-referral law applies in cases in which a financial relationship arises solely because of Medicare requirements. The commenter discussed a situation in which a radiation therapy group and a radiation therapy facility (owned by some or all of the group members) are located in a medical office building across the street from a hospital in a nonrural area. The closest comparable facility is over 35 miles away. Occasionally, the hospital sends an inpatient for radiation therapy to the radiation facility, which provides the services as “arranged for” inpatient hospital services. The hospital pays the facility for use of the radiation equipment from money it receives from Medicare for the inpatient hospital stay. (The group practice bills Medicare for the professional services of the radiation oncologists.) The commenter erroneously asserted that Medicare requires the hospital to pay the radiation facility for the amount that it would have received under Medicare Part B if the radiation therapy had been provided as an outpatient service. The commenter believes that the payment by the hospital to the radiation therapy facility creates a compensation arrangement with the facility and, in turn, the physicians.

Often, a radiation oncologist will refer a patient of the radiation facility to the hospital for certain tests and other services. The radiation oncologist receives no economic benefit for referring patients to the hospital and refers there for the patient’s convenience, not because there is any requirement to do so. The commenter believes that, under our proposed rule, the “under arrangements” compensation arrangement would trigger the physician self-referral law, preventing the radiation oncologists from referring Medicare patients to the hospital for services, even though this financial relationship is not voluntary and not subject to abuse.

The commenter requested clarification whether the proposed § 411.355(d)(2), covering services furnished under composite types of payment rates that the Secretary determines provide no financial incentive for underutilization or overutilization, or any other risk of program or patient abuse, would apply. The commenter also wished to know whether we could include an additional described compensation arrangement exception under § 411.357(d) (the personal service arrangements exception) or clarify § 411.357(g) (the exception for remuneration from a hospital to a physician if the remuneration does not relate to the furnishing of DHS) to include the arrangements the commenter mentioned, or create some variation in the fair market value exception in § 411.357(l)(3) that would allow compensation determined on the basis of the volume of services (that is, fee-for-service payments as covered under Medicare Part B) in the type of situation the commenter described.

Response: As discussed above in section VIII.A of this preamble, we have determined not to include the proposed § 411.355(d)(2) in Phase I of this rulemaking for DHS other than clinical laboratory services. However, as discussed in the preceding response, the arrangement described by the commenter would be a compensation arrangement that could be structured to fit in one of the compensation exceptions, such as the equipment rental, personal service arrangements, or the new fair market value exceptions.

N. Other Definitions

1. Consultation

The definition of “consultation” is addressed in section III.B.2 of this preamble and in the regulations in § 411.351.

2. Entity

In § 411.351 of the August 1995 final rule covering referrals for clinical laboratory services, we defined the term "entity" broadly to cover a sole proprietorship, trust, corporation, partnership, foundation, not-for-profit corporation, or unincorporated association. We revised this definition in the January 1998 proposed rule to make it clear that the definition covers a physician's sole practice or a practice of multiple physicians that provides for the furnishing of DHS, or any other sole proprietorship, trust, corporation, partnership, foundation, not-for-profit corporation, or unincorporated association. We explained in the preamble to the January 1998 proposed rule at 63 FR 1706 that we regard an "entity" for purposes of the referral prohibition as 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). We explained that we meant that the referral prohibition applies to a physician's referrals to any entity that directly furnishes services to program patients, or to any entity that arranges for the furnishing of these services under arrangements. We are clarifying in Phase I of this rulemaking that, for purposes of section 1877 of the Act, a person or entity is considered to be furnishing DHS if it is the person or entity to which we make payment for the DHS, directly or upon assignment on the patient's behalf, except that if the person or entity has reassigned its right to payment to (i) an employer pursuant to § 424.80(b)(1); (ii) a facility pursuant to § 424.80(b)(2); or (iii) a health care delivery system, including clinics, pursuant to § 424.80(b)(3) (other than a health care delivery system that is a health plan (as defined in § 1000.952(l)), and other than any MCO, PSO, or IPA with which a health plan contracts for services provided to plan enrollees), the person or entity furnishing DHS is the person or entity to which payment has been reassigned. Provided further, that a health plan, MCO, PSO, or IPA that employs a supplier or operates a facility that could accept reassignment from a supplier pursuant to §§ 424.80(b)(1) and (b)(2) is the entity furnishing DHS for any services provided by such supplier.

A number of commenters pointed out, in various contexts, that they did not believe a physician could make a "referral" to himself or herself. We agree and discuss this issue in section III.B of

this preamble, which covers the definition of a referral. In our analysis of this issue, we also concluded that when a physician is referring to himself or herself, that act is not a referral to an "entity," as we have defined it in § 411.351. However, when the physician requests a service from another member of his or her group practice or from the practice's staff, that would be a referral to the practice for purposes of the physician self-referral law. These concepts are discussed in more detail in our responses to specific comments on the definition of a "referral" and on some of the DHS.

In the preamble to the January 1998 proposed regulation (63 FR 1710), we addressed the question of when the owner of a DHS provider is considered to be equivalent to the entity providing DHS. We had proposed to equate a referring physician with the entity when the physician (or a family member) has a significant ownership or controlling interest that allows the physician to determine how the entity conducts its business and with whom. We used two examples to illustrate this concept. Commenters found both our analysis and those examples to be confusing. As a result, we have abandoned this analysis and will simply apply the rules related to indirect financial relationships and indirect referrals as described in detail in section III of this preamble, which covers the general referral prohibition under section 1877(a) of the Act. Section III.A of this preamble includes a discussion about when there is a financial relationship between a physician and an entity.

Comment: A commenter suggested that we clarify in both the preamble and regulations text that a medical device manufacturing company is not an "entity" for the purposes of section 1877 of the Act, and that the manufacturer does not receive payments from billings "under arrangements." Another commenter requested that we clarify that drug manufacturers are not "entities" for purposes of section 1877 of the Act, and that a referral for outpatient prescription drugs only occurs when a physician sends a patient to a particular entity that actively furnishes drugs, such as a pharmacy.

Response: We generally do not regard manufacturers as entities that furnish items or services directly to patients, or as entities that furnish services "under arrangements." Thus, the commenters are correct in stating that a medical device manufacturer or a drug manufacturer is unlikely to be an entity furnishing DHS for purposes of section 1877 of the Act, while a pharmacy, which delivers outpatient prescription

drugs directly to patients, would be one. (We discuss this issue in more detail in section VIII.B of this preamble.) A person or entity is considered to be furnishing DHS if it is the person or entity to which we make payment for the DHS, directly or upon assignment on the patient's behalf, except that if the person or entity has reassigned its right to payment to (i) an employer pursuant to § 424.80(b)(1); (ii) a facility pursuant to § 424.80(b)(2); or (iii) a health care delivery system, including clinics, pursuant to § 424.80(b)(3) (other than a health care delivery system that is a health plan (as defined in § 1000.952(l)), and other than any MCO, PSO, or IPA with which a health plan contracts for services provided to plan enrollees), the person or entity furnishing DHS is the person or entity to which payment has been reassigned. Provided further, that a health plan, MCO, PSO, or IPA that employs a supplier or operates a facility that could accept reassignment from a supplier pursuant to §§ 424.80(b)(1) and (b)(2) is the entity furnishing DHS for any services provided by such supplier.

Comment: A commenter asked us to clarify that State governments and their instrumentalities are not "entities" for purposes of section 1877 of the Act. The commenter noted that many State and local governments create integrated delivery systems and payment arrangements in order to increase access to and decrease the cost of publicly provided care. If the governments or their instrumentalities were to be considered "entities," the commenter argued that State-sponsored clinics and programs may cease to exist, thus restricting access to, and raising the costs of, public programs.

Response: The referral prohibition applies whenever a physician has an unexcepted financial relationship with "an entity" that furnishes DHS. The statute makes no distinction between private and governmental entities, nor do we believe that we have the authority to make such a distinction. We have no basis for concluding that referrals to governmental entities are always free from potential patient or program abuse, so we see no grounds for creating an additional exception under section 1877(b)(4) of the Act. However, we would assume that many governmental entities have compensation arrangements with physicians, rather than being owned in any way by physicians. If this is the case, there are a number of compensation related exceptions in the statute and regulations that are designed to allow physicians who receive fair compensation to continue making referrals.

3. 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 covering referrals for clinical laboratory services by using the definition that appears in section 1877(h)(3) of the Act. 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.

In the January 1998 proposed rule, we discussed what constitutes a value that is "consistent with the general market value." We drafted the definition as follows so that it applies to any arrangements involving items or services, including, but not limited to, employment relationships, personal service 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" in the proposed rule continued to include the additional requirements in section 1877(h)(3) of the Act 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. Most of the comments we received addressed the question of how to establish the fair market value of an asset or agreement and how to value rental property "for general commercial purposes." We have tried to clarify these concepts in our responses.

Comment: Several commenters asked that we clarify the documentation that will sufficiently establish a transaction as consistent with fair market value (and general market value) for the exceptions that apply to compensation arrangements. The proposed definition of fair market value states that "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." One commenter stated that using the word "usually" may create ambiguities and suggested making clear in the definition of fair market value that the standard of comparable transactions is only one potential means of establishing fair market value.

Another commenter stated that the January 1998 proposed rule is unclear about the steps that must be taken to confirm fair market value. The commenter asked that we adopt the position that a valuation from an independent person experienced in the valuation of health care operations is sufficient as one approach (but not the only approach) to establishing fair market value. However, the commenter further stated that, because sales of medical practices are private and not reported to any central data base, and because there is often a lack of a representative pool upon which to draw comparisons, we should adopt the position that confirmation of fair market value does not necessarily require the finding of comparable entities for comparison. Another commenter stated that the Internal Revenue Service (IRS) guidelines for determining fair market value with respect to tax exempt organizations are too restrictive and are inappropriate for application to for-profit entities.

Response: To establish the fair market value (and general market value) of a transaction that involves compensation paid for assets or services, we intend to accept any method that is commercially reasonable and provides us with evidence that the compensation is comparable to what is ordinarily paid for an item or service in the location at issue, by parties in arm's-length transactions who are not in a position to refer to one another. (As discussed in section V of this preamble, in most instances the fair market value standard is further modified by language that precludes taking into account the "volume or value" of referrals, and, in some cases, other business generated by the referring physician. Depending on the circumstances, the "volume or value" restriction will preclude reliance on comparables that involve entities and physicians in a position to refer or generate business.) The amount of documentation that will be sufficient to confirm fair market value (and general market value) will vary depending on the circumstances in any given case;

that is, there is no rule of thumb that will suffice for all situations. The burden of establishing the "fairness" of an agreement rests with the parties involved in the agreement. Depending on the circumstances, parties may want to consider obtaining good faith, written assurances as to fair market value from the party paying or receiving the compensation, although such written assurances are not determinative.

For example, a commercially reasonable method of establishing fair market value (and general market value) for the rental of office space can include providing us with a list of comparables. We would also find acceptable an appraisal that the parties have received from a qualified independent expert. Although some transactions are not subject to public scrutiny, we believe generally that there should be sufficient documentation of similar public transactions that the parties can use as a basis of comparison. In regions with inadequate direct comparables, such as rural areas, a reasonable alternative may involve comparing institutions or entities located in different, but similar, areas where property is zoned for similar use. For example, a hospital affiliated with a university in one part of the country could be comparable to other hospitals affiliated with universities that are located in similar types of communities. In other cases, all the comparables or market values may involve transactions between entities that are in a position to refer or generate other business. For example, in some markets, physician-owned equipment lessors have driven out competitive third-party lessors of similar equipment. In such situations, we would look to alternative valuation methodologies, including, but not limited to, cost plus reasonable rate of return on investment on leases of comparable medical equipment from disinterested lessors.

In contrast, there may be cases in which finding a commercially reasonable representation of fair market value (or general market value) could be as simple as consulting a price list. As for using the IRS guidelines for determining fair market value that applies to tax exempt organizations, we recognize that in some cases they may not be appropriate for for-profit entities. Nonetheless, it is our view that some elements of the IRS guidelines could be applied under certain circumstances, depending upon the specifics of any particular agreement. We do not wish to either mandate their use or rule them out if they can be appropriately used to demonstrate fair market value.

Comment: One commenter noted that, as part of our definition of "fair market

value,” we include the term “general market value,” which applies to any arrangement involving items and services, including employment relationships, personal service arrangements, and rental agreements. The commenter pointed out that in the January 1998 proposed rule we do not address the specific documentation requirements necessary to verify and document that the price of an asset or the compensation for certain services actually reflects the market rate. The commenter requested that we confirm that internally generated surveys are sufficient for establishing the market rate, and that there is no requirement to use an independent valuation consultant.

Response: We agree that there is no requirement that parties use an independent valuation consultant for any given arrangement when other appropriate valuation methods are available. However, while internally generated surveys can be appropriate as a method of establishing fair market value in some circumstances, due to their susceptibility to manipulation and absent independent verification, such surveys do not have strong evidentiary value and, therefore, may be subject to more intensive scrutiny than an independent survey.

Special Rule for Rental Property. Under section 1877(h)(3) of the Act, 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 where the lessor is a potential source of patient referrals to the lessee. We incorporated this provision into the August 1995 final rule covering referrals for clinical laboratory services and into the January 1998 proposed rule at § 411.351. Commenters raised questions about the meaning of the statutory provision.

Comment: With respect to the rental of property, commenters questioned our definition of fair market value as “the value of rental property for general commercial purposes (not taking into account its intended use).” The commenters believe this language is problematic for appraising a medical office building because it requires the appraiser to compare the property to the broad category of properties that are “used for general commercial purposes.” This latter category can include properties that are highly dissimilar in character and value. For example, the appraisal for medical

office property could include retail or industrial rates. Such an approach conflicts with the fundamental principle that appraisals should be based on comparing properties with similar attributes.

Response: We believe that a rental property meets the requirement that a payment reflect the “value of property for general commercial purposes, not taking into account its intended use” when the payment takes into account any costs that were incurred by the lessor in developing or upgrading the property, or maintaining the property or its improvements, regardless of why the improvements were added. That is, the rental payment can reflect the value of any similar commercial property with improvements or amenities of a similar value, regardless of why the property was improved. On the other hand, we also believe that rental payments would specifically take into account the intended use of the property if the lessee paid inflated amounts solely to enhance his or her medical practice. For example, rental payments by a physical therapist would not be fair market value for purposes of section 1877 of the Act if the physical therapist agreed to pay an inflated rate that was not justified by improvements or other amenities and was higher than the rate paid by other, similarly situated medical practitioners in the same building just because the building was occupied by several orthopedic practices.

A rental payment cannot be adjusted to reflect the *additional* value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor where the lessor is a physician and a potential source of patient referrals to the lessee. We interpret this requirement to allow rental payments that reflect the fair market value of the area in which the property is located, even if a lease is for medical property in a “medical community.” To qualify, the payments should not reflect any *additional* value, such as an amount that is above that paid by other medical practitioners in the same building or in the same or in a similar location, just because the lessor is a potential source of referrals to the lessee. That is, the rental payments should be roughly equivalent to those charged to similarly situated parties in arrangements in which referrals are not an issue.

Also, the statute requires that the rental payments not reflect the additional value either party attributes to the proximity or convenience to the lessor where the *lessor* is a potential *source of patient referrals* to the lessee. The definition of a “referral” by a

“referring physician” in section 1877(h)(5) of the Act focuses only on actions and requests for services that are initiated by physicians; it does not include any requests for services initiated by entities or other providers or suppliers, nor does the referral prohibition itself apply to anything but physician referrals. Thus, we believe that it is fair to interpret the limitation in the fair market value definition as confined to situations in which a physician is the lessor and a potential source of referrals to an entity lessee. That limitation does not appear to us to apply when an entity, such as a hospital, is the lessor that rents space to physicians, even if the hospital is in a position to refer to the physicians. As a result, we believe a hospital should factor in the value of proximity when charging rent to lessee physicians.

4. Group Practice

The definition of a group practice under section 1877(h)(4) of the Act is addressed in this preamble at section VI.C and in the regulations at § 411.352.

5. Health Professional Shortage Areas

The existing regulations covering referrals for clinical laboratory services define a health professional shortage area (HPSA) for purposes of section 1877 of the Act as “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)” and, in addition, “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. We proposed no changes to the existing rule.

The definition of a HPSA for purposes of Phase I of this rulemaking is intended to track the definition of a HPSA as promulgated by the Health Resources Services Administration (HRSA), which administers the HPSA designation process. HRSA has proposed revising the existing HPSA regulations. (See 63 FR 46538; 64 FR 29831.) We have modified the definition of a HPSA in these regulations to track current HRSA interpretations of the HPSA regulations and to make clear that the definition incorporates any future changes or amendments to HRSA’s definition of a HPSA, which is codified in 42 CFR part 5.

6. Employee

We defined an "employee" in the existing regulation and in the January 1998 proposed regulation in § 411.351 by reiterating the statute. Section 1877(h)(2) of the Act specifically defines an "employee" of an entity as an individual who would be considered to be an employee 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.

Comment: Two commenters recommended an expansion of the proposed definition of "employee" to include "leased employees" to better reflect the realities of the market place. The current definition, which references income tax law, limits an employee to an individual who meets the definition of a "common law" employee. But the definition of a common law employee does not include leased employees, who are defined by State law and have a quasi-common law status.

Response: We do not believe we have the authority to expand the definition of employee that appears in the law. It is our understanding that leased employees are essentially regarded by the courts, the IRS, and Federal legislators as "contingent employees." Contingent workers are generally described as workers who are not part of the employer's regular work force, but are hired to meet certain needs. These workers are technically employed by an entity other than the one for whom the services are performed. Other types of contingent workers include independent contractors and consultants.

A leased employee is defined in section 414(n) of the Internal Revenue Service Code as an individual who performs services under an agreement between the service recipient and a leasing/staffing organization; performs services under the primary direction or control of the service recipient; and performs services for the service recipient on a substantially full-time basis for a 12-month period. The labeling of a worker as a leased employee under a leasing/staffing arrangement does not mean that the worker will be defined as a "leased employee" under section 414(n) of the Internal Revenue Code for employee benefit plan purposes. The IRS determines the common law employment relationship between a worker and an organization by analyzing the facts and circumstances of each particular situation. The IRS uses guidelines, in the form of a list of

factors, for classifying workers as either employees or independent contractors, in order to determine whether there is actually an employer/employee relationship. We would regard any leased employee that qualifies as an "employee" under the IRS test as an employee for purposes of section 1877 of the Act.

7. Immediate Family Members

The referral prohibition in section 1877(a) of the Act 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 DHS, unless an exception applies. In the August 1995 final rule, we listed in § 411.351 the individuals who qualify as a physician's "immediate" family members. These individuals include a 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. We adopted this definition without any changes in the January 1998 proposed rule.

We did not receive any comments on this definition. We did receive comments that relate to whether physicians should be precluded from referring to people who qualify as members of their immediate family. We have addressed these comments in section VI.B of this preamble. To conform to common usage, we have amended the definition to substitute the term "birth" for "natural" parent.

8. Referral

The definition of "referral" is addressed in this preamble in section III and in § 411.351 of the regulations.

9. Remuneration and the Exceptions in Section 1877(h)(1)(C) of the Act

The definition of "remuneration" in section 1877(h)(1)(B) of the Act is drafted broadly to include "any remuneration, directly or indirectly, in cash or in kind." However, a "compensation arrangement" is defined in paragraph (h)(1)(A) of section 1877 of the Act to specifically exclude various kinds of remuneration that are listed in paragraph (h)(1)(C) of section 1877 of the Act. These are arrangements involving only the following remuneration:

(i) the forgiveness of amounts owed for inaccurate tests or procedures, mistakenly performed tests or procedures, or the correction of minor billing errors;

(ii) the provision of items, devices, or supplies that are used solely to—

(I) collect, transport, process, or store specimens for the entity furnishing the item, device, or supply, or

(II) to order or communicate the results of tests or procedures for such entity.

(iii) 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,

(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, and

(IV) the payment meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.

We incorporated these exclusions from the definition of "remuneration" into the August 1995 final rule and into the January 1998 proposed rule in § 411.351. We interpreted the exclusions in the January 1998 proposed rule at 63 FR 1693 through 1694 to mean that the portion of any business arrangement that consists of the remuneration listed in paragraph (h)(1)(C) of section 1877 of the Act alone does not constitute a compensation arrangement. The final regulation adopts our proposed regulations text and incorporates expressly the interpretation applicable to arrangements that include portions of remuneration that meet the exclusions in section 1877 (h)(1)(C) of the Act.

a. Minor Billing Errors.

Comment: One commenter, in referring to the exclusion from remuneration of forgiveness for amounts due to corrections of minor billing errors, stated that even a "minor" billing error might have large dollar consequences, particularly if the same minor mistake were repeated on numerous bills. This could easily happen because virtually all bills are now computer-generated. The commenter stated that the term "minor" should refer to the type of error, rather than the sum of money that may be involved.

Response: We agree with the commenter's suggestion that a "minor" billing error could have large dollar consequences, particularly in situations in which bills are computer generated. We also agree that the term "minor"

should refer to the kind of billing error rather than the sum of money involved. Therefore, we are interpreting “minor billing errors” to cover isolated or infrequent instances in which an administrative error, such as a typographic, keying, or other transcribing error, results in an incorrect charge or bill. On the other hand, a pattern of similar or consistent billing error “corrections” may suggest improper remuneration and subject the business arrangement to scrutiny.

b. Medicare as an Insurer.

Section 1877(h)(1)(C)(iii) of the Act “excepts” from the definition of a compensation arrangement situations involving payments made by an insurer or self-insured plan to a physician. The payments must satisfy a physician’s fee-for-service claim for furnishing health services to an individual who is covered by a policy with the insurer or the self-insured plan.

Comment: One commenter asked whether the term “insurer” includes the Medicare program. The commenter believes that Medicare is included within the meaning of the term “insurer,” and cited for support references in the preamble, as well as the designation of Medicare in the Act as “Health Insurance for the Aged and Disabled.”

Response: In the preamble to the January 1998 proposed rule at 63 FR 1694, we pointed out that we believed this provision was designed for situations in which an insurer is also 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 the physician’s claims.

The Medicare program is not directly involved in the delivery of services, but is simply a payer of services; that is, Medicare never actually furnishes services to program patients but pays for claims from providers and suppliers or makes payments to managed care organizations. The physician self-referral law is only implicated if a physician refers a patient to an entity for DHS and the physician has an ownership or investment interest in the entity or receives direct or indirect remuneration from the entity. Since a physician would never refer a patient to the Medicare program to receive a designated health service, these payments from Medicare to a physician are totally irrelevant under this law.

c. Items, Devices, or Supplies Used Solely To Collect Specimens.

Comment: One commenter thought there was a possible inconsistency in the preamble to the January 1998 proposed rule in the section discussing whether biopsy needles are excluded from the definition of remuneration under section 1877(h)(1)(C)(ii) of the Act. Section 1877(h)(1)(C)(ii) of the Act covers items, devices, or supplies that are used solely to collect, transport, process, or store specimens for the entity providing the items, devices, or supplies. First, the commenter noted our conclusion at 63 FR 1693 through 1694 that biopsy needles do not function solely as specimen collection devices and therefore are categorically excluded from “items, devices, or supplies that are used solely” for specimen collection purposes. In other words, biopsy needles may constitute remuneration under section 1877 of the Act. This discussion is followed in the preamble by a statement that any items, supplies, or devices provided to a physician must be used solely in connection with specimens sent by the physician to the entity that supplied the items, devices, or supplies. Accordingly, the preamble indicates that the number of items, supplies, or devices furnished should not exceed the number of specimens sent to the laboratory for processing. The commenter suggested that the proximity and sequence of these discussions in the preamble has caused confusion in the industry; some have concluded that, regardless of the first discussion and conclusion, biopsy needles might not constitute remuneration if the number of biopsy needles provided by a laboratory were to correlate to the number of biopsy specimens sent to the laboratory.

The commenter urged us to adopt the view that biopsy needles are surgical or medical devices, rather than items, devices, or supplies solely used for specimen collection purposes in all cases. The commenter noted that this interpretation would be consistent with statements made by the OIG that the free provision of biopsy needles from a laboratory to a physician would be suspect under the anti-kickback statute because the needles have independent value to the physician as a surgical device used in surgical procedures. (See the letter dated August 4, 1997, available on the OIG website at <http://www.dhhs.oig/gov>.) A second commenter concurred with this conclusion, and suggested that the same analysis should apply to other surgical or medical devices that may be used during a procedure to collect specimens, but have independent value to

physicians, such as snares and reusable aspiration and injection needles.

Response: We agree with the first commenter that the proximity and sequence of our discussion of this topic in the preamble might have been confusing. We wish to clarify our views on the “items, devices, and supplies” provision here. First, in enacting section 1877(h)(1)(C)(ii) of the Act, we believe that the Congress did not intend to allow laboratories to supply physicians with surgical instruments for free or below fair market value prices. Rather, we believe the Congress intended to include in this section items, supplies, and devices of low value, such as single use needles, vials, and specimen cups, that are primarily provided by laboratories to physicians to ensure proper collection of specimens for processing at the laboratory and that have little, if any, independent economic value to the physicians who receive them. In many cases, the cost of these items may already be included in the practice expense portion of the Medicare payment made to the physician. In addition, to the extent the items are reusable, they may have value unrelated to the collection of specimens for processing by the laboratory providing the items. The provision of such items for free or below fair market value poses a risk that the items may constitute compensation from the laboratories for the physician’s referrals and increase the risk of overutilization. Accordingly, biopsy needles and like devices, such as snares and reusable aspiration and injection needles, are categorically excluded from the items, devices, and supplies covered by section 1877(h)(1)(C)(ii) of the Act, although arrangements for providing such items may be structured to fit into the exception for payments by a physician for items and services to an entity if the items or services are furnished at a price that is consistent with fair market value. (See section 1877(e)(7) of the Act and § 411.357(i).) This view is consistent with the guidance published by the OIG noted in the preceding comment.

The discussion of the correlation of the number of supplies to the number of specimens sent to the laboratory has no application to biopsy needles and other devices that fall outside section 1877(h)(1)(C)(ii) of the Act. As to those single use, low value items, devices, and supplies that come within the scope of section 1877(h)(1)(C)(ii) of the Act, the fact that the number of supplies provided to a physician approximates the number of specimens sent by the physician to the laboratory providing

the supplies is merely one indicator that the supplies have been provided in connection with specimen collection for the entity providing the supplies. The numerical correlation is not a statutory or regulatory requirement. However, the provision of an excessive number of supplies creates an inference that the supplies are not provided solely to collect, transport, process, or store specimens for the entity providing them.

Comment: A commenter noted that certain supplies that are used in connection with the collection of specimens, such as gloves, can also be used by a physician for other purposes. Since the laboratory cannot guarantee that the gloves it supplies are used by the physician only for collecting specimens, the commenter recommended that the laboratory monitor the volume of the items supplied. The commenter asserted that if the number of gloves supplied equals, or is close to, the number needed for the collection of specimens by this physician, we should consider the conditions in the exception in section 1877(h)(1)(C)(ii) of the Act to have been met.

Response: While we recognize that sterile gloves are essential to the proper collection of specimens, we believe they are not items, devices, or supplies used solely to collect, transport, process, or store specimens. To be sure, sterile gloves are essential to the specimen collection process, but their main function is to prevent infection or contamination. Also, sterile gloves are fungible, general purpose supplies typically found in a physician's office and used for a wide range of examinations and procedures. We believe it would be impractical for physicians' offices to monitor and regulate the use of gloves so as to limit their use to the collection of specimens for the laboratory that provided them. Accordingly, we believe the provision of free gloves is remuneration subject to the general prohibition of section 1877 of the Act, in the absence of an applicable exception.

Comment: A commenter questioned how a laboratory should measure the volume of specimen collection supplies it provides to a new physician or group client with whom it has no experience. In such a situation, the commenter believes the laboratory should be allowed to rely on the anticipated volume of services, until an actual pattern of referral can be established, to meet the requirement that items furnished by the laboratory be consistent with the number of tests referred to the laboratory.

Response: As noted above, there is no explicit requirement in the statute that the volume of supplies provided by a laboratory correlate with the volume of specimens sent to the laboratory for processing. Rather, a correlation is one indicator that the provision of the supplies meets the requirement that they be used to collect, transport, process, or store specimens for the laboratory that provided them and that the supplies are not for the physician's general office use. We understand that a laboratory may not have a pattern of referrals on which to base the provision of items, devices, and supplies to a new physician or group practice client. In these instances, the laboratory may elect to provide supplies based on the number of tests typically ordered by physicians or group practices of like type and size in that community until the physician or group practice establishes a pattern of referrals with the laboratory sufficient to determine the appropriate number of supplies. The laboratory or physician should be prepared to demonstrate that the items, devices, or supplies were furnished based on a community standard and to describe the standard.

Comment: One commenter asked that we clarify how section 1877 of the Act applies to a clinical laboratory's provision of a phlebotomist to a physician, group practice, or ESRD facility without charge to the physician, group, or ESRD facility.

Response: Under section 1877(h)(1)(B) of the Act, remuneration includes "any remuneration, directly or indirectly, overtly or covertly, in cash or in kind," with the exception of certain items of potential value listed in section 1877(h)(1)(C) of the Act. The provision of personnel, such as a phlebotomist, does not fit in any category listed in section 1877(h)(1)(C). Thus, the provision of a phlebotomist, as described by the commenter, may constitute remuneration, and therefore create a compensation arrangement, for purposes of section 1877 of the Act. Whether a particular phlebotomist arrangement confers a benefit on a physician or group practice depends on the specific facts and circumstances. (The provision of a phlebotomist to an ESRD facility would not implicate section 1877 of the Act, unless the arrangement conferred a direct or indirect benefit on a physician or physician group; such laboratory-ESRD facility arrangements may implicate the anti-kickback statute.)

The OIG has issued a special fraud alert addressing the provision of free goods and services to physicians under the anti-kickback statute, 59 FR 242

(December 9, 1994). We believe the fraud alert is instructive here. Discussing the issue of laboratory phlebotomists placed in physicians' offices, it observes:

When permitted by State law, a laboratory may make available to a physician's office a phlebotomist who collects specimens from patients for testing by the outside laboratory. While the mere placement of a laboratory employee in the physician's office would not necessarily serve as an inducement prohibited by the anti-kickback statute, the statute is implicated when the phlebotomist performs additional tasks that are normally the responsibility of the physician's office staff. These tasks can include taking vital signs or other nursing functions, testing for the physician's office laboratory, or performing clerical services. Where the phlebotomist performs clerical or medical functions not directly related to the collection or processing of laboratory specimens, a strong inference arises that he or she is providing a benefit in return for the physician's referrals to the laboratory. In such a case, the physician, the phlebotomist, and the laboratory may have exposure under the anti-kickback statute. This analysis applies equally to the placement of phlebotomists in other health care settings, including nursing homes, clinics and hospitals. Furthermore, the mere existence of a contract between the laboratory and the health care provider that prohibits the phlebotomist from performing services unrelated to specimen collection does not eliminate the OIG's concern, where the phlebotomist is not closely monitored by his [or her] employer or where the contractual prohibition is not rigorously enforced.

Like the OIG, we believe that if the phlebotomist is purely performing laboratory functions for the laboratory that places the phlebotomist, then there would be no remuneration to the physician or group practice (that is, no compensation arrangement). Put another way, there would be no services to the physician or group for which they should pay. However, if the phlebotomist performs services that are not directly related to the collection or processing of laboratory specimens for the laboratory that has provided the phlebotomist, he or she may be providing a benefit to the physician or group practice, thus creating a compensation arrangement between the physician and the clinical laboratory that furnished the phlebotomist. Such arrangements may be structured to fit in an exception to section 1877 of the Act, such as the personal service arrangements exception, the fair market value exception, or the exception for payments by physicians for items or services.

Comment: Another commenter asked that we establish a clear standard governing the use by ESRD facilities of

personnel from a clinical laboratory. The commenter recommended that employees of clinical laboratories only be allowed to perform duties directly associated with collecting and preparing specimens, and making test results available to the ESRD facility. Activities involved in ESRD facility administration, patient care, or handling of specimens or data from other laboratories would not be allowed.

Response: As noted above, the provision of a phlebotomist to an ESRD facility would not implicate section 1877 of the Act unless the arrangement benefits a physician or physician group.

Comment: One commenter inquired whether a laboratory may provide medical waste disposal supplies and services to physicians free of charge. The commenter asserted that the services would be provided only for medical waste generated in connection with the collection, transportation, processing, or storage of specimens.

Response: Section 1877(h)(1)(C)(ii) of the Act excludes from the definition of a compensation arrangement remuneration that consists of "the provision of items, devices, or supplies that are used solely to—(I) collect, transport, process, or store specimens for the entity providing the item, device, or supply * * *." The provision does not specifically allow laboratories to furnish physicians and group practices with medical waste disposal supplies and services at no charge. However, we believe that supplies and the disposal of items used solely in connection with the collection of specimens for this clinical laboratory are part of the process the laboratory engages in when it collects, transports, and processes specimens. If a laboratory can provide a needle for collection and it can take away the specimen, we believe that the laboratory can also take away the needle and other items that are used in the process. However, we do not believe this exception covers the disposal of needles or other waste items that have been used by the physician practice for other purposes.

IX. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), agencies are required to provide a 30-day notice in the **Federal Register** and solicit public comment when a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that

we solicit comments on the following issues:

- Whether the information collection is necessary and useful to carry out the proper functions of the agency;
 - The accuracy of the agency's estimate of the information collection burden;
 - The quality, utility, and clarity of the information to be collected; and
 - Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.
- Therefore, we are soliciting public comment on each of these issues for the information collection requirements discussed below.

Section 411.352 Group Practice

Paragraph (d) requires that, except as provided in paragraphs (d)(2) and (d)(3) of this section, 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) must be furnished through the group and billed under a billing number assigned to the group; the amounts received must be treated as receipts of the group; and "patient care services" must be measured and documented by any reasonable means (including, but not limited to, time cards, appointment schedules, or personal diaries) or any alternative measure that is reasonable, fixed in advance of the performance of the services being measured, uniformly applied over time, verifiable, and documented.

While this requirement is subject to the PRA, the burden associated with it is exempt from the PRA because it meets the requirements set forth in 5 CFR 1320.3(b)(2) and/or (b)(3) and 5 CFR 1320.4(a).

Paragraph (i) requires that supporting documentation verifying the method used to calculate the profit shares or productivity bonus under paragraphs (i)(2) and (i)(3) of this section, and the resulting amount of compensation, must be made available to the Secretary upon request.

While this requirement is subject to the PRA, the burden associated with it is exempt from the PRA because it meets the requirements set forth in 5 CFR 1320.3(b)(2) and/or (b)(3) and 5 CFR 1320.4(a).

Section 411.354 Financial Relationship, Compensation, and Ownership or Investment Interest

Paragraph (d) requires that, when special rules are applied to compensation under section 1877 of the

Act and under these regulations in subpart J of this part, the compensation will be considered "set in advance" if the aggregate compensation or a time-based or per unit of service-based (whether per-use or per-service) amount is set in advance in the initial agreement, in writing, between the parties in sufficient detail so that it can be objectively verified, and meets the terms and conditions of this section.

While this requirement is subject to the PRA, the burden associated with it is exempt from the PRA because it meets the requirements set forth in 5 CFR 1320.3(b)(2) and/or (b)(3) and 5 CFR 1320.4(a).

Section 411.355 General Exceptions to the Referral Prohibition Related to Both Ownership/Investment and Compensation

Paragraph (e) requires that the relationship of the components of the academic medical center must be set forth in a written agreement that has been adopted by the governing body of each component.

While this requirement is subject to the PRA, the burden associated with it is exempt from the PRA because it meets the requirements set forth in 5 CFR 1320.3(b)(2) and/or (b)(3) and 5 CFR 1320.4(a).

Section 411.357 Exceptions to the Referral Prohibition Related to Compensation Arrangements

Paragraph (l) requires that compensation resulting from an arrangement between an entity and a physician (or an immediate family member) or any group of physicians (regardless of whether the group meets the definition of a group practice set forth in § 411.351) for the provision of items or services by the physician (or an immediate family member) or group practice to the entity, must be set forth in an agreement, be in writing, and meet the conditions of the section.

While this requirement is subject to the PRA, the burden associated with it is exempt from the PRA because it meets the requirements set forth in 5 CFR 1320.3(b)(2) and/or (b)(3) and 5 CFR 1320.4(a).

Paragraph (p) requires that, for indirect compensation arrangements, as defined in § 411.354(c)(2), the compensation described in § 411.354(c)(2)(ii) is part of an arrangement that is set out in writing and meets all of the conditions and requirements set forth in this section.

While this requirement is subject to the PRA, the burden associated with it is exempt from the PRA because it meets the requirements set forth in 5

CFR 1320.3(b)(2) and/or (b)(3) and 5 CFR 1320.4(a).

We have submitted a copy of this final rule to OMB for its review of the information collection requirements in §§ 411.352, 411.354, 411.355, and 411.357. These requirements are not effective until they have been approved by OMB.

If you have any comments on any of these information collection and record keeping requirements, please mail the original and 3 copies within 30 days of this publication date directly to the following:

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Allison Heron Eydt, HCFA Desk Officer; and Health Care Financing Administration, Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards, Room N2-14-26, 7500 Security Boulevard, Baltimore, MD 21244-1850, Attn: John Burke HCFA-1809.

X. Regulatory Impact Statement

A. Overall Impact

We have examined the impacts of Phase I of this rulemaking as required by Executive Order 12866 (September 1993, Regulatory Planning and Review) and the Regulatory Flexibility Act (RFA) (Pub. L. 96-354, enacted September 19, 1980). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more annually). We do not believe that Phase I of this rulemaking is a major rule that will have an economically significant effect. We have no way of determining with any certainty the aggregate amount of savings or costs Phase I of this rulemaking will impose, but do not believe it will approach \$100 million or more annually.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$5 million or less

annually. For purposes of the RFA, most physician practices are considered to be small entities. Individuals and States are not included in the definition of a small entity.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds. We do not believe Phase I of this rulemaking will have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in an expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$100 million. Phase I of this rulemaking will not have such an effect on the governments mentioned, and we do not believe the private sector costs will meet the \$100 million threshold.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We do not anticipate that Phase I of this rulemaking will have a substantial effect on State or local governments.

B. Anticipated Effects

We stated in the impact analysis in the January 1998 proposed rule that any estimate of the individual or aggregate economic impact of the provisions of the final rule would be purely speculative. We explained that we could not gauge with any certainty the number of physicians and entities that would be affected, or the extent of any changes they would have to make to comply with the rule. As we noted in the January 1998 proposed rule at 63 FR 1716, various studies have indicated that the degree of conflict of interest presented by a physician's investment in entities to which he or she refers patients is unknown. We pointed out that ownership information or information on the compensation arrangements between physicians and all of their immediate family members and the entities that furnish any of 11 DHS constitutes an enormous amount of

data that is continually subject to change. We also expected that the American Medical Association's declaration that self-referrals are unethical outside of a physician's practice, in conjunction with State laws restricting or qualifying self-referrals and the referral prohibition under section 1877 of the Act itself, have already 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 a furnishing entity would already be exempted under the statute.

We stated that, although the provisions in the rule do not lend themselves to a quantitative impact estimate, we did not anticipate that they would have a significant economic impact on a substantial number of small entities. We based this assessment on the many exceptions in the rule (including a broad exception for ownership in rural entities), as well as the actions parties can take to revise their business arrangements to avoid the referral prohibition. We still believe this to be the case. In fact, we expect that Phase I of this rulemaking will have a much smaller impact than the provisions that we proposed. However, because Phase I of this rulemaking may have significant effects on some health care practitioners, or be viewed as controversial, we wish to inform the public of what we regard as the possible major effects of Phase I of this rulemaking.

We stated in the January 1998 proposed rule that we expected that physicians who refer Medicare patients for DHS and entities that furnish DHS, including hospitals, would be the parties that are primarily affected by this rule. In response to comments on the January 1998 proposed rule, we have liberalized a wide variety of the provisions that could affect these parties. We have tried to create a more manageable regulation that includes "bright line" rules to help the health care community determine more easily when a physician's referrals are in compliance with the law. We have made numerous changes to the rule to try to mold it around existing business practices, and have attempted to reinterpret the law so that it has a more practical and realistic effect on physicians and the entities that provide DHS. The result, we believe, is an overall approach that should have far less impact on the business relationships of individuals and entities

than the provisions of the January 1998 proposed rule. We discuss below some of the major issues affecting physicians and furnishing entities. We also briefly discuss the effects of the rule on Medicare beneficiaries.

1. Effects on 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. A physician who has (or whose immediate family member has) a financial relationship with an entity that does not qualify for an exception is prohibited from referring Medicare patients to that entity for the provision of DHS. Also, when a physician with such a relationship makes a prohibited referral, there is a risk that the entity will receive no Medicare payment for those DHS. These provisions can have a significant effect on the business arrangements in which a physician will participate and the manner in which the physician will structure his or her practice.

The potential impact of the regulation on physicians and other individual parties was revealed to us by the voluminous comments from the public and health care community we received in response to the January 1998 proposed rule. In addition to specific complaints and objections, the commenters expressed a number of general concerns, including that the proposed regulation inappropriately intruded into the organization and delivery of medical care within physicians' offices; that the regulation in many respects was counter to our other longstanding policies on coverage and similar issues; that the rule was unclear in many areas and that in light of the severe penalty (that is, payment denial), "bright line" rules were essential; and that some aspects of the proposed rule, such as its treatment of indirect financial relationships, were administratively impractical or would have been prohibitively costly in terms of monitoring compliance.

We believe Phase I of this rulemaking substantially addresses the concerns raised by the commenters and yet is consistent with the statute. Phase I of this rulemaking clarifies the definitions of DHS; substantially broadens the in-office ancillary services exception (which allows physicians to refer within their own practices) by easing the criteria for qualifying as a group practice and conforming the supervision requirements to our coverage and other payment policies; permits shared facilities in the same building where physicians routinely provide services

that are neither Federal nor private pay DHS; excludes from the definition of "referral" services personally performed by the referring physician; expands the in-office ancillary services exception to cover certain DME provided to patients in physicians' offices; creates a new exception for compensation of faculty in academic medical centers; and clarifies when a managed care organization (MCO) is an entity furnishing DHS. All of these issues are described in greater detail elsewhere in the preamble, along with a number of lesser issues that could affect physicians.

2. Effects on Other Providers

As we stated above, Phase I of this rulemaking affects entities that furnish DHS by preventing them from receiving payment for services that they furnish as the result of a physician's prohibited referral. Entities can also be subject to various other sanctions, including fines and exclusion from Federal health care programs if they knowingly submit a claim in violation of the prohibition. We lack the data to determine the number of entities that could be affected by Phase I of this rulemaking. However, we believe they will be fewer in number than we had anticipated in the January 1998 proposed rule because, as we described above, physicians will have far more leeway to refer.

3. Effects on the Medicare and Medicaid Programs

Section 1877 of the Act was enacted primarily to address overutilization of health care services covered by Medicare. We have tried to focus Phase I of this rulemaking on financial relationships that may result in overutilization. We expect that Phase I of this rulemaking will result in savings to the program by providing physicians and entities with "bright line" rules on how to avoid the prohibited referrals that can result in overutilization of covered services. We cannot gauge with any certainty the extent of these savings to the program at this time. (We will discuss the effects on the Medicaid program in Phase II of this rulemaking.)

4. Effects on Beneficiaries

Some commenters thought the January 1998 proposed regulations exceeded our statutory authority and imposed unnecessary and costly burdens on physicians that would harm patient access to health care facilities and services. In Phase I of this rulemaking, we have tried to ensure that the rule will not adversely impact the medical care of Federal health care beneficiaries or other patients. Where we have determined that Phase I of this

rulemaking may impact current arrangements under which patients are receiving medical care, we have attempted to verify that there are other ways available to structure the arrangement, so that patients could continue to receive the care in the same location. In almost all cases, we believe Phase I of this rulemaking should not require substantial changes in delivery arrangements, although it may affect the referring physician's or group practice's ability to bill for the care.

In addition, we have significantly expanded the scope of services potentially included in the in-office ancillary services exception and thus readily available to a referring physician's patients by: (1) Making clear that outpatient prescription drugs may be "furnished" in the office, even if they are used by the patient at home; (2) explicitly permitting external ambulatory infusion pumps that are DME to be provided under the in-office ancillary services exception; (3) making clear that chemotherapy infusion drugs may be provided under the in-office ancillary services exception through the administration or dispensing of the drugs to patients in the physician's office; and (4) creating a new exception for certain items of DME furnished in a physician's office for the convenience of the physician's patients.

C. Alternatives Considered

In drafting the January 1998 proposed rule covering a physician's referrals for DHS, we attempted to interpret the statute strictly and literally. After reviewing the voluminous number of comments we received, we have considered many alternative ways to interpret the statute to accommodate the practical problems that commenters raised, while still fulfilling the intent of the law. For example, we revised the "same building" requirements in the in-office ancillary services exception to address commenters' concerns. Under section 1877(b)(2)(A)(ii)(I) of the Act, services qualify for the in-office ancillary services exception if they are furnished "in 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." In the January 1998 proposed rule, we made it clear that we regarded the building requirement of the in-office ancillary services exception, in combination with the supervision and billing requirements, as the Congress's attempt to circumscribe the exception so that it applies only to services provided within the referring physician's actual sphere

of practice. Without these requirements, physicians could refer to, and profit from, almost any entity, with the claim that somehow the referred services are "in-office" services that are being supervised from some remote place.

Notwithstanding, we now realize that our proposed definition of a "building" that attempted to define a building in architectural terms could cause practical problems for some physicians and that a clearer, "bright line" rule would be preferable. Accordingly, having considered the various alternatives suggested by the commenters, we concluded that for purposes of Phase I of this rulemaking, we would define a "building" as a structure with, or combination of structures that share, a single street address as assigned by the U.S. Postal Service. A building would be considered as one building for all suites or room numbers located inside that are required by the U.S. Postal Service to use the same street address, regardless of the suite number. Under Phase I of this rulemaking, suites used by the same group practice or solo physician in buildings with separate street addresses will be treated as separate buildings for the purposes of the in-office ancillary services exception. While we recognize that this mailing address rule may result in an occasional anomaly, we are persuaded that it creates a "bright line" rule that will be easy to apply and will produce fair results in the vast majority of cases.

We have also responded to the commenters' numerous concerns that the space in the building in which the DHS are provided must be adjacent to the space in which services that are not DHS are provided. We have revised the regulation so that an adjacent space is no longer necessary (subject to the dictates of any Medicare or Medicaid payment or coverage supervision rules). Shared facilities in the same building are now permitted to the extent they comply with the supervision, location, and billing requirements of the in-office ancillary services exception. However, because of the increased risk of abuse in this expansion, we felt that we could not protect DHS provided by mobile vans or other mobile facilities under the in-office ancillary services exception, except in very limited circumstances.

As these examples demonstrate, our approach in Phase I of this rulemaking was to address as many of the industry's concerns as possible. We considered a variety of suggestions and alternatives, selecting only those that were consistent with the statute's goals and directives, and that would protect Federal health care program beneficiaries' access to services.

D. Conclusion

For the reasons stated above, we are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined, and we certify, that Phase I of this rulemaking will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

In accordance with the provisions of Executive Order 12866, Phase I of this rulemaking was reviewed by the Office of Management and Budget.

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.

For the reasons set forth in the preamble, HCFA amends 42 CFR chapter IV 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).

Subpart A—General Exclusions and Exclusions of Particular Services

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 an HHA 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 the following: Federal providers or agencies (sections 1814(c) and 1835(d)); hospitals and physicians outside of the U.S. (sections 1814(f) and 1862(a)(4)); and hospitals and SNFs of the Indian Health Service (section 1880 of the Act). Section 1877

of the Act 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.

* * * * *

Subpart J—Physician Ownership of, and Referral of Patients or Laboratory Specimens to, Entities Furnishing Clinical Laboratory or Other Health Services

3. Section 411.350 is revised to read as follows:

§ 411.350 Scope of subpart.

(a) This subpart implements section 1877 of the Act, which generally prohibits a physician from making a referral under Medicare for 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 Medicare 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:

Centralized building means all or part of a building, including, for purposes of this definition only, a mobile vehicle, van, or trailer that is owned or leased on a full-time basis (that is, 24 hours per day, 7 days per week, for a term of not less than 6 months) by a group practice and that is used exclusively by the group practice. Space in a building or a

mobile vehicle, van, or trailer that is shared by more than one group practice, by a group practice and one or more solo practitioners, or by a group practice and another provider (for example, a diagnostic imaging facility) is not a centralized building for purposes of this rule. This provision does not preclude a group practice from providing services to other providers (for example, purchased diagnostic tests) in the group practice's centralized building. A group practice may have more than one centralized building.

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, including procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body, as specifically identified by the CPT and HCPCS codes posted on the HCFA web site, <http://www.hcfa.gov>, (and in annual updates published in the **Federal Register** and posted on the HCFA web site), except as specifically excluded on the HCFA web site and in annual updates. All services identified on the HCFA web site and in annual updates are clinical laboratory services for purposes of these regulations. Any service not specifically identified on the HCFA web site, as amended from time to time and published in the **Federal Register**, is not a clinical laboratory service for purposes of these regulations.

Consultation means a professional service furnished to a patient by a physician if the following conditions are satisfied:

(1) The physician's opinion or advice regarding evaluation and/or management of a specific medical problem is requested by another physician.

(2) The request and need for the consultation are documented in the patient's medical record.

(3) After the consultation is provided, the physician prepares a written report of his or her findings, which is provided to the physician who requested the consultation.

(4) With respect to radiation therapy services provided by a radiation oncologist, a course of radiation treatments over a period of time will be considered to be pursuant to a consultation, provided the radiation oncologist communicates with the

referring physician on a regular basis about the patient's course of treatment and progress.

Designated health services (DHS) means any of the following services (other than those provided as emergency physician services furnished outside of the U.S.), as they are defined in this section:

(1) Clinical laboratory services.

(2) Physical therapy, occupational therapy, and speech-language pathology services.

(3) Radiology and certain other imaging services.

(4) 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.

Except as otherwise noted in these regulations, the term "designated health services (DHS)" means only DHS payable, in whole or in part, by Medicare. DHS do not include services that are reimbursed by Medicare as part of a composite rate (for example, ambulatory surgical center services or SNF Part A payments), except to the extent the services listed in paragraphs (1) through (10) of this definition are themselves payable through a composite rate (that is, all services provided as home health services or inpatient and outpatient hospital services are DHS).

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

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

Entity means a physician's sole practice or a practice of multiple physicians or any other person, sole proprietorship, public or private agency or trust, corporation, partnership, limited liability company, foundation, not-for-profit corporation, or unincorporated association that furnishes DHS. For purposes of this definition, an entity does not include the referring physician himself or herself, but does include his or her medical practice. A person or entity is

considered to be furnishing DHS if it is the person or entity to which HCFA makes payment for the DHS, directly or upon assignment on the patient's behalf, except that if the person or entity has reassigned its right to payment to an employer pursuant to § 424.80(b)(1) of this chapter; a facility pursuant to § 424.80(b)(2) of this chapter; or a health care delivery system, including clinics, pursuant to § 424.80(b)(3) of this chapter (other than a health care delivery system that is a health plan (as defined in § 1000.952(l) of this title), and other than any managed care organization (MCO), provider-sponsored organization (PSO), or independent practice association (IPA) with which a health plan contracts for services provided to plan enrollees), the person or entity furnishing DHS is the person or entity to which payment has been reassigned. Provided further, that a health plan, MCO, PSO, or IPA that employs a supplier or operates a facility that could accept reassignment from a supplier pursuant to §§ 424.80(b)(1) and (b)(2) of this chapter is the entity furnishing DHS for any services provided by such supplier.

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 who are not otherwise in a position to generate business for the other party; 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 who are not otherwise in a position to generate business for the other party, 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. For purposes of

this section, a rental payment does not take into account intended use if it takes into account costs incurred by the lessor in developing or upgrading the property or maintaining the property or its improvements.

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 part 5 of this title).

Immediate family member or member of a physician's immediate family means husband or wife; birth 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.

"Incident to" services means those services that meet the requirements of section 1861(s)(2)(A) of the Act and section 2050 of the Medicare Carriers Manual (HCFA Pub. 14-3), Part 3—Claims Process. (Those wishing to subscribe to program manuals should contact either the Government Printing Office (GPO) or the National Technical Information Service (NTIS) at the following addresses: Superintendent of Documents, Government Printing Office, ATTN: New Orders, P.O. Box 371954, Pittsburgh, PA 15250-7954, Telephone (202) 512-1800, Fax number (202) 512-2250 (for credit card orders); or National Technical Information Service, Department of Commerce, 5825 Port Royal Road, Springfield, VA 22161, Telephone (703) 487-4630. In addition, individual manual transmittals and Program Memoranda can be purchased from NTIS. Interested parties should identify the transmittal(s) they want. GPO or NTIS can give complete details on how to obtain the publications they sell. Additionally, all manuals are

available at the following Internet address: <http://www.hcfa.gov/pubforms/progman.htm>.)

Inpatient hospital services means those services as defined in section 1861(b) of the Act and § 409.10(a) and (b) of this chapter and includes 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 of the U.S. and covered under the authority in section 1814(f)(2) of the Act and part 424, subpart H of this chapter, or emergency inpatient services provided by a nonparticipating hospital within the U.S., 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 part 405 of this chapter. 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. "Inpatient hospital services" do not include professional services performed by physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse midwives, and certified registered nurse anesthetists and qualified psychologists if Medicare reimburses the services independently and not as part of the inpatient hospital service (even if they are billed by a hospital under an assignment or reassignment).

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.

List of CPT/HCPCS Codes Used to Describe Certain Designated Health Services Under the Physician Referral Provisions (Section 1877 of the Social Security Act) means the list of certain designated health services under section

1877 of the Act initially posted on the HCFA web site and updated annually thereafter in an addendum to the physician fee schedule final rule and on the HCFA web site.

Member of the group means, for purposes of this rule, a direct or indirect physician owner of a group practice (including a physician whose interest is held by his or her individual professional corporation or by another entity), a physician employee of the group practice (including a physician employed by his or her individual professional corporation that has an equity interest in the group practice), a *locum tenens* physician (as defined in this section), or an on-call physician while the physician is providing on-call services for members of the group practice. A physician is a member of the group during the time he or she furnishes "patient care services" to the group as defined in this section. An independent contractor or a leased employee is not a member of the group. "*Locum tenens* physician" means a physician who substitutes (that is, "stands in the shoes") in exigent circumstances for a regular physician who is a member of the group, in accordance with applicable reassignment rules and regulations, including section 3060.7 of the Medicare Carriers Manual (HCFA Pub. 14-3), Part 3—Claims Process.

Outpatient hospital services means the therapeutic, diagnostic, and partial hospitalization services listed under sections 1861(s)(2)(B) and (C) of the Act; outpatient services furnished by a psychiatric hospital, as defined in section 1861(f) of the Act; and outpatient rural primary care hospital services, as defined in section 1861(mm)(3) of the Act. Emergency services covered in nonparticipating hospitals are excluded under the conditions described in section 1835(b) of the Act and subpart G of part 424 of this chapter. "Outpatient hospital services" includes services that a hospital provides for its patients that are furnished either by the hospital or by others under arrangements with the hospital. "Outpatient hospital services" do not include professional services performed by physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse midwives, certified registered nurse anesthetists, and qualified psychologists if Medicare reimburses the services independently and not as part of the outpatient hospital service (even if they are billed by a hospital under an assignment or reassignment).

Outpatient prescription drugs means all prescription drugs covered by Medicare Part B.

Parenteral and enteral nutrients, equipment, and supplies means the following services (including all HCPCS level 2 codes for these services):

(1) *Parenteral nutrients, equipment, and supplies*, meaning 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); and

(2) *Enteral nutrients, equipment, and supplies*, meaning 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).

Patient care services means any tasks performed by a physician in the group practice that address the medical needs of specific patients or patients in general, regardless of whether they involve direct patient encounters; or generally benefit a particular practice. Patient care services 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, occupational therapy, and speech-language pathology services means those particular services identified by the CPT and HCPCS codes on the HCFA web site (and in annual updates published in the **Federal Register**). All services identified on the HCFA web site and in annual updates are physical therapy, occupational therapy, and speech-language pathology services for purposes of these regulations. Any service not specifically identified on the HCFA web site, as amended from time to time and published in the **Federal Register**, is not a physical therapy, occupational therapy, or speech-language pathology service for purposes of these regulations. The list of codes identifying physical therapy, occupational therapy, and speech-language pathology services

for purposes of these regulations includes the following:

(1) *Physical therapy services*, meaning those outpatient physical therapy services (including speech-language pathology services) described at section 1861(p) of the Act that are covered under Medicare Part A or Part B, regardless of who provides them, if the services include—

(i) Assessments, function tests and measurements of strength, balance, endurance, range of motion, and activities of daily living;

(ii) Therapeutic exercises, massage, and use of physical medicine modalities, assistive devices, and adaptive equipment;

(iii) Establishment of a maintenance therapy program for an individual whose restoration potential has been reached; however, maintenance therapy itself is not covered as part of these services; or

(iv) Speech-language pathology services that are for the diagnosis and treatment of speech, language, and cognitive disorders that include swallowing and other oral-motor dysfunctions.

(2) *Occupational therapy services*, meaning those services described at section 1861(g) of the Act that are covered under Medicare Part A or Part B, regardless of who provides them, if the services include—

(i) Teaching of compensatory techniques to permit an individual with a physical or cognitive impairment or limitation to engage in daily activities;

(ii) Evaluation of an individual's level of independent functioning;

(iii) Selection and teaching of task-oriented therapeutic activities to restore sensory-integrative function; or

(iv) Assessment of an individual's vocational potential, except when the assessment is related solely to vocational rehabilitation.

Physician means a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, or a chiropractor, as defined in section 1861(r) of the Act.

Physician in the group practice means a member of the group practice, as well as an independent contractor physician, during the time the independent contractor is furnishing patient care services (as defined in this section) to the group practice under a contractual arrangement with the group practice to provide services to the group practice's patients in the group practice's facilities. The contract must contain the same restrictions on compensation that apply to members of the group practice under § 411.352(g) (or the contract fits

in the personal services exception in § 411.357(d)), and the independent contractor's arrangement with the group practice must comply with the reassignment rules at § 424.80(b)(3) of this chapter (see also section 3060.3 of the Medicare Carriers Manual (HCFA Pub. 14-3), Part 3—Claims Process). Referrals from an independent contractor who is a physician in the group are subject to the prohibition on referrals in § 411.353(a), and the group practice is subject to the limitation on billing for those referrals in § 411.353(b).

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.

Prosthetics, Orthotics, and Prosthetic Devices and Supplies means the following services (including all HCPCS level 2 codes for these services that are covered by Medicare):

(1) *Orthotics*, meaning leg, arm, back, and neck braces, as listed in section 1861(s)(9) of the Act.

(2) *Prosthetics*, meaning artificial legs, arms, and eyes, as described in section 1861(s)(9) of the Act.

(3) *Prosthetic devices*, meaning devices (other than a dental device) listed in section 1861(s)(8) of the Act that replace all or part of an internal body organ, including colostomy bags, and one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens.

(4) *Prosthetic supplies*, meaning supplies that are necessary for the effective use of a prosthetic device (including supplies directly related to colostomy care).

Radiation therapy services and supplies means those particular services and supplies identified by the CPT and HCPCS codes on the HCFA web site and in annual updates published in the **Federal Register**. All services identified on the HCFA web site and in annual updates are *radiation therapy services and supplies* for purposes of these regulations. Any service not specifically identified on the HCFA web site, as amended from time to time and published in the **Federal Register**, is not a *radiation therapy service or supply* for purposes of these regulations. The list of codes for radiation therapy services and supplies identified on the HCFA web site and in annual updates is based on

section 1861(s)(4) of the Act and § 410.35 of this chapter but does not include nuclear medicine procedures.

Radiology and certain other imaging services means those particular services identified by the CPT and HCPCS codes on the HCFA web site and in annual updates published in the **Federal Register** (except as otherwise specifically excluded on the HCFA web site and in annual updates). All services identified on the HCFA web site and in annual updates are *radiology and certain other imaging services* for purposes of these regulations. Any service not specifically identified on the HCFA web site, as amended from time to time and published in the **Federal Register**, is not a *radiology or certain other imaging service* for purposes of these regulations. The list of *radiology and certain other imaging services* set forth on the HCFA web site and in annual updates includes the professional and technical components of any diagnostic test or procedure using x-rays, ultrasound, or other imaging services, computerized axial tomography, or magnetic resonance imaging, as covered under section 1861(s)(3) of the Act and §§ 410.32 and 410.34 of this chapter but does not include—

(1) X-ray, fluoroscopy, or ultrasonic procedures that require the insertion of a needle, catheter, tube, or probe through the skin or into a body orifice;

(2) Radiology procedures that are integral to the performance of, and performed during, nonradiological medical procedures; and

(3) Nuclear medicine procedures.

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, 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, but not including any designated health service *personally* performed or provided by the referring physician. A designated health service is not personally performed or provided by the referring physician if it is performed or provided by any other person, including, but not limited to, the referring physician's employees, independent contractors, or group practice members.

(ii) Except as provided in paragraph (2) of this definition, a request by a physician that includes the provision of

any designated health service for which payment may be made under Medicare, 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, but not including any designated health service *personally* performed or provided by the referring physician. A designated health service is not personally performed or provided by the referring physician if it is performed or provided by any other person including, but not limited to, the referring physician's employees, independent contractors, or group practice members.

(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 (whether the request for a consultation was made to a particular physician or to an entity with which the physician is affiliated); and

(ii) The tests or services are furnished by or under the supervision of the pathologist, radiologist, or radiation oncologist.

(3) Can be in any form, including, but not limited to, written, oral, or electronic.

Referring physician means a physician who makes a referral as defined in this section or who directs another person or entity to make a referral or who controls referrals made by another person or entity.

Remuneration means any payment or other benefit made directly or indirectly, overtly or covertly, in cash or in kind, except that the following are not considered remuneration for purposes of this section:

(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 (not including surgical 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.

Same building means a structure with, or combination of structures that share, a single street address as assigned by the U.S. Postal Service, excluding all exterior spaces (for example, lawns, courtyards, driveways, parking lots) and interior parking garages. For purposes of this rule, the "same building" does not include a mobile vehicle, van, or trailer.

5. Section 411.352 is added to read as follows:

§ 411.352 Group practice.

For purposes of this subpart, a group practice is a physician practice that meets the following conditions:

(a) *Single legal entity.* The group practice must consist of a single legal entity formed primarily for the purpose of being a physician group practice in any organizational form recognized by the State in which the group practice achieves its legal status, including, but not limited to, a partnership, professional corporation, limited liability company, foundation, not-for-profit corporation, faculty practice plan, or similar association. The single legal entity may be organized by any party or parties, including, but not limited to, physicians, health care facilities, or other persons or entities (including, but not limited to, physicians individually incorporated as professional corporations). The single legal entity may not be organized or owned (in whole or in part) by another medical practice that is an operating physician practice (regardless of whether the medical practice meets the conditions for a group practice under this section). For purposes of this rule, a single legal entity does not include informal affiliations of physicians formed substantially to share profits from referrals, or separate group practices under common ownership or control through a physician practice management company, hospital, health system, or other entity or organization. A group practice that is otherwise a

single legal entity may itself own subsidiary entities.

(b) *Physicians.* The group practice must have at least two physicians who are members of the group (whether employees or direct or indirect owners), as defined in this section.

(c) *Range of care.* Each physician who is a *member of the group*, as defined in § 411.351, must furnish 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.

(d) *Services furnished by group practice members.* (1) Except as provided in paragraphs (d)(2) and (d)(3) of this section, 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) must be furnished through the group and billed under a billing number assigned to the group, and the amounts received must be treated as receipts of the group. "Patient care services" must be measured by one of the following:

(i) The total time each member spends on patient care services documented by any reasonable means (including, but not limited to, time cards, appointment schedules, or personal diaries). (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 patient care services for the group.)

(ii) Any alternative measure that is reasonable, fixed in advance of the performance of the services being measured, uniformly applied over time, verifiable, and documented.

(2) The data used to calculate compliance with this "substantially all test" and related supportive documentation must be made available to the Secretary upon request.

(3) The "substantially all test" does not apply to any group practice that is located solely in an HPSA, as defined in § 411.351.

(4) For a group practice located outside of an HPSA (as defined in § 411.351), any time spent by a group practice member providing services in an HPSA should not be used to calculate whether the group practice has met the "substantially all test," regardless of whether the member's time in the HPSA is spent in a group practice, clinic, or office setting.

(5) During the "start up" period (not to exceed 12 months) that begins on the date of the initial formation of a new

group practice, a group practice must make a reasonable, good faith effort to ensure that the group practice complies with the requirement set forth in paragraph (d)(1) of this section as soon as practicable, but no later than 12 months from the date of the initial formation of the group practice. This paragraph (d)(5) does not apply when an existing group practice admits a new member or when an existing group practice reorganizes.

(e) *Distribution of expenses and income.* The overhead expenses of, and income from, the practice must be distributed according to methods that are determined before the receipt of payment for the services giving rise to the overhead expense or producing the income. Nothing in this rule prevents a group practice from adjusting its compensation methodology prospectively, subject to restrictions on the distribution of revenue from DHS under paragraph (i) of this section.

(f) *Unified business.* (1) The group practice must be a unified business having at least the following features:

(i) Centralized decision-making by a body representative of the group practice that maintains effective control over the group's assets and liabilities (including, but not limited to, budgets, compensation, and salaries).

(ii) Consolidated billing, accounting, and financial reporting.

(iii) Centralized utilization review.

(2) Location and specialty-based compensation practices are permitted with respect to revenues derived from services that are not DHS and may be permitted with respect to revenues derived from DHS under paragraph (i) of this section.

(g) *Volume or value of referrals.* No physician who is a member of the group practice directly or indirectly receives compensation based on the volume or value of referrals by the physician, except as provided in paragraph (i) of this section.

(h) *Physician-patient encounters.* Members of the group must personally conduct no less than 75 percent of the physician-patient encounters of the group practice.

(i) *Special rule for productivity bonuses and profit shares.* (1) A physician in a group practice may be paid a share of overall profits of the group, or a productivity bonus based on services that he or she has personally performed (including services "incident to" those personally performed services as defined in § 411.351), provided that the share or bonus is not determined in any manner that is directly related to the volume or value of referrals of DHS by the physician.

(2) "Overall profits" means the group's entire profits derived from DHS payable by Medicare or Medicaid or the profits derived from DHS payable by Medicare or Medicaid of any component of the group practice that consists of at least five physicians. The share of overall profits will be deemed *not* to relate directly to the volume or value of referrals if *one* of the following conditions is met:

(i) The group's profits are divided per capita (for example, per member of the group or per physician in the group).

(ii) Revenues derived from DHS are distributed based on the distribution of the group practice's revenues attributed to services that are not DHS payable by any Federal health care program or private payer.

(iii) Revenues derived from DHS constitute less than 5 percent of the group practice's total revenues, and the allocated portion of those revenues to each physician in the group practice constitutes 5 percent or less of his or her total compensation from the group.

(iv) Overall profits are divided in a reasonable and verifiable manner that is not directly related to the volume or value of the physician's referrals of DHS.

(3) A productivity bonus for personally performed services (including services "incident to" those personally performed services as defined in § 411.351) will be deemed *not* to relate directly to the volume or value of referrals of DHS if *one* of the following conditions is met:

(i) The bonus is based on the physician's total patient encounters or relative value units (RVUs). The methodology for establishing RVUs is set forth in § 414.22 of this chapter.

(ii) The bonus is based on the allocation of the physician's compensation attributable to services that are not DHS payable by any Federal health care program or private payer.

(iii) Revenues derived from DHS are less than 5 percent of the group practice's total revenues, and the allocated portion of those revenues to each physician in the group practice constitutes 5 percent or less of his or her total compensation from the group practice.

(iv) The bonus is calculated in a reasonable and verifiable manner that is not directly related to the volume or value of the physician's referrals of DHS.

(4) Supporting documentation verifying the method used to calculate the profit shares or productivity bonus under paragraphs (i)(2) and (i)(3) of this section, and the resulting amount of

compensation, must be made available to the Secretary upon request.

6. 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 direct or indirect financial relationship with an entity, or who has an immediate family member who has a direct or indirect financial relationship with the entity, may not make a referral to that entity for the furnishing of DHS for which payment otherwise may be made under Medicare. A physician's prohibited financial relationship with an entity that furnishes DHS is not imputed to his or her group practice or its members or its staff; however, a referral made by a physician's group practice, its members, or its staff may be imputed to the physician, if the physician directs the group practice, its members, or its staff to make the referral or if the physician controls referrals made by his or her group practice, its members, or its staff.

(b) *Limitations on billing.* An entity that furnishes DHS pursuant to 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 DHS performed pursuant to the prohibited referral.

(c) *Denial of payment.* Except as provided in paragraph (e) of this section, no Medicare payment may be made for a designated health service that is furnished pursuant to 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 this title.

(e) *Exception for certain entities.* Payment may be made to an entity that submits a claim for a designated health service if—

(1) The entity did not have actual knowledge of, and did not act in reckless disregard or deliberate ignorance of, the identity of the physician who made the referral of the designated health service to the entity; and

(2) The claim otherwise complies with all applicable Federal laws, rules, and regulations.

7. Section 411.354 is added to read as follows:

§ 411.354 Financial relationship, compensation, and ownership or investment interest.

(a) *Financial relationships.* (1) *Financial relationship* means—

(i) A direct or indirect ownership or investment interest (as defined in paragraph (b) of this section) in any entity that furnishes DHS; or

(ii) A direct or indirect compensation arrangement (as defined in paragraph (c) of this section) with an entity that furnishes DHS.

(2) A *direct* financial relationship exists if remuneration passes between the referring physician (or a member of his or her immediate family) and the entity furnishing DHS without any intervening persons or entities (not including an agent of the physician, the immediate family member, or the entity furnishing DHS).

(3) An *indirect* financial relationship exists under the conditions described in paragraphs (b)(5) and (c)(2) of this section.

(b) *Ownership or investment interest.* An ownership or investment interest may be through equity, debt, or other means, and includes an interest in an entity that holds an ownership or investment interest in any entity that furnishes DHS.

(1) An ownership or investment interest includes, but is not limited to, stock, partnership shares, limited liability company memberships, as well as loans, bonds, or other financial instruments that are secured with an entity's property or revenue or a portion of that property or revenue.

(2) An ownership or investment interest in a subsidiary company is neither an ownership or investment interest in the parent company, nor in any other subsidiary of the parent, unless the subsidiary company itself has an ownership or investment interest in the parent or such other subsidiaries. It may, however, be part of an indirect financial relationship.

(3) Ownership and investment interests do not include, among other things—

(i) An interest in a retirement plan;

(ii) Stock options and convertible securities until the stock options are exercised or the convertible securities are converted to equity (before this time they are compensation arrangements as defined in paragraph (c) of this section);

(iii) An unsecured loan subordinated to a credit facility (which is a compensation arrangement as defined in paragraph (c) of this section); or

(iv) An "under arrangements" contract between a hospital and an entity owned by one or more physicians (or a group of physicians) providing

DHS "under arrangements" to the hospital.

(4) An ownership or investment interest that meets an exception set forth in §§ 411.355 or 411.356 need not also meet an exception for compensation arrangements set forth in § 411.357 with respect to profit distributions, dividends, interest payments on secured obligations, or the like.

(5) *Indirect ownership or investment interest.* (i) An indirect ownership or investment interest exists if—

(A) Between the referring physician (or immediate family member) and the entity furnishing DHS there exists an unbroken chain of any number (but no fewer than one) of persons or entities having ownership or investment interests between them; and

(B) The entity furnishing DHS has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician (or immediate family member) has some ownership or investment interest (through any number of intermediary ownership or investment interests) in the entity furnishing the DHS.

(ii) The entity furnishing DHS need not know, or act in reckless disregard or deliberate ignorance of, the precise composition of the unbroken chain or the specific terms of the ownership or investment interests that form the links in the chain.

(c) *Compensation arrangement.* A compensation arrangement can be any arrangement involving remuneration, direct or indirect, between a physician (or a member of a physician's immediate family) and an entity. An "under arrangements" contract between a hospital and an entity providing DHS "under arrangements" to the hospital creates a compensation arrangement for purposes of these regulations.

(1) A compensation arrangement does not include any of the following:

(i) The portion of any business arrangement that consists solely of the remuneration described in section 1877(h)(1)(C) of the Act and in paragraphs (1) through (3) of the definition of the term "remuneration" in § 411.351. (However, any other portion of the arrangement may still constitute a compensation arrangement.)

(ii) Payments made by a consultant to a referring physician under § 414.65(e) of this chapter.

(2) *Indirect compensation arrangement.* An *indirect* compensation arrangement exists if—

(i) Between the referring physician (or a member of his or her immediate family) and the entity furnishing DHS there exists an unbroken chain of any number (but not fewer than one) of

persons or entities that have financial relationships (as defined in paragraph (a) of this section) between them (that is, each link in the chain has either an ownership or investment interest or a compensation arrangement with the preceding link);

(ii) The referring physician (or immediate family member) receives aggregate compensation from the person or entity in the chain with which the physician (or immediate family member) has a *direct* financial relationship that varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS. If the financial relationship between the physician (or immediate family member) and the person or entity in the chain with which the referring physician (or immediate family member) has a direct financial relationship is an ownership or investment interest, the determination whether the aggregate compensation varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS will be measured by the nonownership or noninvestment interest closest to the referring physician (or immediate family member). (For example, if a referring physician has an ownership interest in company A, which owns company B, which has a compensation arrangement with company C, which has a compensation arrangement with entity D that furnishes DHS, we would look to the aggregate compensation between company B and company C for purposes of this paragraph (c)(2)(ii)); and

(iii) The entity furnishing DHS has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician (or immediate family member) receives aggregate compensation that varies with, or otherwise reflects, the value or volume of referrals or other business generated by the referring physician for the entity furnishing the DHS.

(d) *Special rules on compensation.* The following special rules apply only to compensation under section 1877 of the Act and these regulations in subpart J of this part.

(1) Compensation will be considered "set in advance" if the aggregate compensation or a time-based or per unit of service-based (whether per-use or per-service) amount is set in advance in the initial agreement between the parties in sufficient detail so that it can be objectively verified. The payment amount must be fair market value compensation for services or items

actually provided, not taking into account the volume or value of referrals or other business generated by the referring physician at the time of the initial agreement or during the term of the agreement. Percentage compensation arrangements do not constitute compensation that is "set in advance" in which the percentage compensation is based on fluctuating or indeterminate measures or in which the arrangement results in the seller receiving different payment amounts for the same service from the same purchaser.

(2) Compensation (including time-based or per unit of service-based compensation) will be deemed not to take into account "the volume or value of referrals" if the compensation is fair market value for services or items actually provided and does not vary during the course of the compensation agreement in any manner that takes into account referrals of DHS.

(3) Compensation (including time-based or per unit of service-based compensation) will be deemed not to take into account "other business generated between the parties" so long as the compensation is fair market value and does not vary during the term of the agreement in any manner that takes into account referrals or other business generated by the referring physician, including private pay health care business.

(4) A physician's compensation may be conditioned on the physician's referrals to a particular provider, practitioner, or supplier, so long as the compensation arrangement—

(i) Is fixed in advance for the term of the agreement;

(ii) Is consistent with fair market value for services performed (that is, the payment does not take into account the volume or value of anticipated or required referrals);

(iii) Complies with an applicable exception under §§ 411.355 or 411.357; and

(iv) Complies with the following conditions:

(A) The requirement to make referrals to a particular provider, practitioner, or supplier is set forth in a written agreement signed by the parties.

(B) The requirement to make referrals to a particular provider, practitioner, or supplier does not apply if the patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the physician's judgement.

8. 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.* (1) Physician services as defined in § 410.20(a) of this chapter that are furnished—

(i) Personally by another physician who is a member of the referring physician's group practice or is a physician in the same group practice (as defined in § 411.351) as the referring physician; or

(ii) Under the supervision of another physician who is a member of the referring physician's group practice or is a physician in the same group practice (as defined in § 411.351) as the referring physician, provided that the supervision complies with all other applicable Medicare payment and coverage rules for the physician services.

(2) For purposes of paragraph (a) of this section, "physician services" includes only those "incident to" services (as defined in § 411.351) that are physician services under § 410.20(a) of this chapter.

(3) All other "incident to" services (for example, diagnostic tests, physical therapy) are outside the scope of paragraph (a) of this section.

(b) *In-office ancillary services.* Services (including certain items of durable medical equipment (DME), as defined in paragraph (b)(4) of this section, and infusion pumps that are DME (including external ambulatory infusion pumps), but excluding all other DME and parenteral and enteral nutrients, equipment, and supplies (such as infusion pumps used for PEN), 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) An individual who is supervised by the referring physician or by another physician in the group practice, provided the supervision complies with all other applicable Medicare payment and coverage rules for the services.

(2) They are furnished in one of the following locations:

(i) The same building (as defined in § 411.351), but not necessarily in the same space or part of the building, in which—

(A) The referring physician (or another physician who is a member of the same group practice) furnishes substantial physician services that are unrelated to the furnishing of DHS payable by Medicare, any other Federal

health care payer, or a private payer, even though the unrelated services may lead to the ordering of DHS;

(B) The physician services that are unrelated to the furnishing of DHS in paragraph (b)(2)(i)(A) of this section must represent substantially the full range of physician services unrelated to the furnishing of DHS that the referring physician routinely provides (or, in the case of a referring physician who is a member of a group practice, the full range of physician services that the physician routinely provides for the group practice); and

(C) The receipt of DHS (whether payable by a Federal health care program or a private payer) is not the primary reason the patient comes in contact with the referring physician or his or her group practice.

(ii) A centralized building (as defined in § 411.351) that is used by the group practice for the provision of some or all of the group practice's clinical laboratory services.

(iii) A centralized building (as defined in § 411.351) that is used by the group practice for the provision of some or all of the group practice's DHS (other than clinical laboratory services).

(3) They must be 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) The group practice if the supervising physician is a "physician in the group" (as defined at § 411.351) under a billing number assigned to the group practice.

(iv) An entity that is wholly owned by the performing or supervising physician or by that physician's group practice under the entity's own billing number or under a billing number assigned to the physician or group practice.

(v) An independent third party billing company acting as an agent of the physician, group practice, or entity specified in paragraphs (b)(3)(i) through (b)(3)(iv) of this section under a billing number assigned to the physician, group practice, or entity, provided the billing arrangement meets the requirements of § 424.80(b)(6) of this chapter. For purposes of this paragraph (b)(3), a group practice may have, and bill under, more than one Medicare billing number, subject to any applicable Medicare program restrictions.

(4) For purposes of paragraph (b) of this section, DME covered by the in-office ancillary services exception means canes, crutches, walkers and folding manual wheelchairs, and blood

glucose monitors, that meet the following conditions:

(i) The item is one that a patient requires for the purposes of ambulating, uses in order to depart from the physician's office, or is a blood glucose monitor (including one starter set of test strips and lancets, consisting of no more than 100 of each). A blood glucose monitor may be furnished only by a physician or employee of a physician or group practice that also furnishes outpatient diabetes self-management training to the patient.

(ii) The item is furnished in a building that meets the "same building" requirements in the in-office ancillary services exception as part of the treatment for the specific condition for which the patient-physician encounter occurred.

(iii) The item is furnished personally by the physician who ordered the DME, by another physician in the group practice, or by an employee of the physician or the group practice.

(iv) A physician or group practice that furnishes the DME meets all DME supplier standards located in § 424.57(c) of this chapter.

(v) The arrangement does not violate the anti-kickback statute, section 1128B(b) of the Act, or any law or regulation governing billing or claims submission.

(vi) All other requirements of the in-office ancillary services exception in paragraph (b) of this section are met.

(5) A designated health service is "furnished" for purposes of paragraph (b) of this section in the location where the service is actually performed upon a patient or where an item is dispensed to a patient in a manner that is sufficient to meet the applicable Medicare payment and coverage rules.

(6) *Special rule for home care physicians.* In the case of a referring physician whose principal medical practice consists of treating patients in their private homes, the "same building" requirements of paragraph (b)(2)(i) of this section are met if the referring physician (or a qualified person accompanying the physician, such as a nurse or technician) provides the DHS contemporaneously with a physician service that is not a designated health service provided by the referring physician to the patient in the patient's private home. For purposes of paragraph (b)(5) of this section, a private home does not include a nursing, long-term care, or other facility or institution.

(c) *Services furnished by an organization (or its contractors or subcontractors) to enrollees.* Services furnished by an organization (or its

contractors or subcontractors) to enrollees of one of the following prepaid health plans (not including services provided to enrollees in any other plan or line of business offered or administered by the same organization):

(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, which set forth qualifying conditions for Medicare contracts; enrollment, entitlement, and disenrollment under Medicare contracts; Medicare contract requirements; and change of ownership and leasing of facilities: effect on Medicare contracts.

(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 HMO (within the meaning of section 1310(d) of the Public Health Service Act).

(5) A coordinated care plan (within the meaning of section 1851(a)(2)(A) of the Act) offered by an organization in accordance with a contract with HCFA under section 1857 of the Act and part 422 of this chapter.

(d) *Clinical laboratory services furnished in an ambulatory surgical center (ASC) or end-stage renal disease (ESRD) facility, or by a hospice* if payment for those services is included in the ASC rate, the ESRD composite rate, or as part of the per diem hospice charge, respectively.

(e) *Academic medical centers.* (1) Services provided by an academic medical center if all of the following conditions are met:

(i) The referring physician—
(A) Is a *bona fide* employee of a component of the academic medical center on a full-time or substantial part-time basis. ("Components" of an academic medical center means an affiliated medical school, faculty practice plan, hospital, teaching facility, institution of higher education, or departmental professional corporation.);

(B) Is licensed to practice medicine in the State;

(C) Has a *bona fide* faculty appointment at the affiliated medical school; and

(D) Provides either substantial academic or substantial clinical

teaching services for which the faculty member receives compensation as part of his or her employment relationship with the academic medical center.

(ii) The total compensation paid for the previous 12-month period (or fiscal year or calendar year) from all academic medical center components to the referring physician is set in advance and, in the aggregate, does not exceed fair market value for the services provided, and is not determined in a manner that takes into account the volume or value of any referrals or other business generated by the referring physician within the academic medical center.

(iii) The academic medical center must meet all of the following conditions:

(A) All transfers of money between components of the academic medical center must directly or indirectly support the missions of teaching, indigent care, research, or community service.

(B) The relationship of the components of the academic medical center must be set forth in a written agreement that has been adopted by the governing body of each component.

(C) All money paid to a referring physician for research must be used solely to support *bona fide* research.

(iv) The referring physician's compensation arrangement does not violate the anti-kickback statute, section 1128B(b) of the Act.

(2) The "academic medical center" for purposes of this section consists of—

(i) An accredited medical school (including a university, when appropriate);

(ii) An affiliated faculty practice plan that is a 501(c)(3) or (c)(4) of the Internal Revenue Code nonprofit, tax-exempt organization under IRS regulations (or is a part of such an organization under an umbrella designation); and

(iii) One or more affiliated hospital(s) in which a majority of the hospital medical staff consists of physicians who are faculty members and a majority of all hospital admissions are made by physicians who are faculty members.

(f) *Implants in an ASC.* Implants, including, but not limited to, cochlear implants, intraocular lenses, and other implanted prosthetics, implanted prosthetic devices and implanted DME that meet the following conditions:

(1) The implant is furnished by the referring physician or a member of the referring physician's group practice in a Medicare-certified ASC (under part 416 of this chapter) with which the referring physician has a financial relationship.

(2) The implant is implanted in the patient during a surgical procedure

performed in the same ASC where the implant is furnished.

(3) The arrangement for the furnishing of the implant does not violate the Federal anti-kickback statute, section 1128B(b) of the Act.

(4) Billing and claims submission for the implants complies with all Federal and State laws and regulations.

(5) The exception set forth in this paragraph (f) does not apply to any financial relationships between the referring physician and any entity other than the ASC in which the implant is furnished to and implanted in the patient.

(g) *EPO and other dialysis-related outpatient prescription drugs furnished in or by an ESRD facility.* EPO and other dialysis-related outpatient prescription drugs that are identified by the CPT and HCPCS codes on the HCFA web site, <http://www.hcfa.gov>, and in annual updates published in the **Federal Register** and that meet the following conditions:

(1) The EPO and other dialysis-related drugs are furnished in or by an ESRD facility. For purposes of this paragraph, "furnished" means that the EPO or drugs are either administered or dispensed to a patient in or by the ESRD facility, even if the EPO or drugs are furnished to the patient at home. "Dialysis-related drugs" means certain drugs required for the efficacy of dialysis, as identified on the HCFA web site and in annual updates.

(2) The arrangement for the furnishing of the EPO and other dialysis-related drugs does not violate the Federal anti-kickback statute, section 1128B(b) of the Act.

(3) Billing and claims submission for the EPO and other dialysis related drugs complies with all Federal and State laws and regulations.

(4) The exception set forth in this paragraph (g) does not apply to any financial relationships between the referring physician and any entity other than the ESRD facility that furnishes the EPO and other dialysis-related drugs to the patient.

(h) *Preventive screening tests, immunizations, and vaccines.*

Preventive screening tests, immunizations, and vaccines that are covered by Medicare and identified by the CPT and HCPCS codes included on the HCFA web site and in annual updates published in the **Federal Register** and that meet the following conditions:

(1) The preventive screening tests, immunizations, and vaccines are subject to HCFA-mandated frequency limits.

(2) The preventive screening tests, immunizations, and vaccines are

reimbursed by Medicare based on a fee schedule.

(3) The arrangement for the provision of the preventive screening tests, immunizations, and vaccines does not violate the Federal anti-kickback statute, section 1128B(b) of the Act.

(4) Billing and claims submission for the preventive screening tests, immunizations, and vaccines complies with all Federal and State laws and regulations.

(5) To qualify under this exception, the preventive screening tests, immunizations, and vaccines must be covered by Medicare and must be listed on the HCFA web site and in annual updates.

(i) *Eyeglasses and contact lenses following cataract surgery.* Eyeglasses and contact lenses that are covered by Medicare when furnished to patients following cataract surgery that meet the following conditions:

(1) The eyeglasses or contact lenses are provided in accordance with the coverage and payment provisions set forth in § 410.36(a)(2)(ii) and § 414.228 of this chapter, respectively.

(2) The arrangement for the furnishing of the eyeglasses or contact lenses does not violate the Federal anti-kickback statute, section 1128B(b) of the Act.

(3) Billing and claims submission for the eyeglasses or contact lenses complies with all Federal and State laws and regulations.

9. In § 411.357, paragraph (j) is added and reserved, and paragraphs (k), (l), (m), (n), (o), and (p) are added to read as follows:

§ 411.357 Exceptions to the referral prohibition related to compensation arrangements.

* * * * *

(j) [Reserved]

(k) *Non-monetary compensation up to \$300.* Compensation from an entity in the form of items or services (not including cash or cash equivalents) that does not exceed an aggregate of \$300 per year, if all of the following conditions are satisfied:

(1) The compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician.

(2) The compensation may not be solicited by the physician or the physician's practice (including employees and staff members).

(3) The compensation arrangement does not violate the Federal anti-kickback statute, section 1128B(b) of the Act.

(l) *Fair market value compensation.* Compensation resulting from an

arrangement between an entity and a physician (or an immediate family member) or any group of physicians (regardless of whether the group meets the definition of a group practice set forth in § 411.351) for the provision of items or services by the physician (or an immediate family member) or group practice to the entity, 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.

(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 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 or any other business generated by the referring physician.

(4) It involves a transaction that is commercially reasonable (taking into account the nature and scope of the transaction) and furthers the legitimate business purposes of the parties.

(5) It meets a safe harbor under the anti-kickback statute in § 1001.952 of this title, has been approved by the OIG under a favorable advisory opinion issued in accordance with part 1008 of this title, or does not violate the anti-kickback provisions in section 1128B(b) of the Act.

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

(m) *Medical staff incidental benefits.* Compensation in the form of items or services (not including cash or cash equivalents) from a hospital to a member of its medical staff when the item or service is used on the hospital's campus, if all of the following conditions are met:

(1) The compensation is offered to all members of the medical staff without regard to the volume or value of referrals or other business generated between the parties.

(2) The compensation is offered only during periods when the medical staff members are making rounds or

performing other duties that benefit the hospital or its patients.

(3) The compensation is provided by the hospital and used by the medical staff members only on the hospital's campus.

(4) The compensation is reasonably related to the provision of, or designed to facilitate directly or indirectly the delivery of, medical services at the hospital.

(5) The compensation is consistent with the types of benefits offered to medical staff members—

(i) By other hospitals within the same local region; or

(ii) If no such hospitals exist within the same local region, by comparable hospitals in comparable regions.

(6) The compensation is of low value (that is, less than \$25) with respect to each occurrence of the benefit (for example, each meal given to a physician while he or she is serving patients who are hospitalized must be of low value).

(7) The compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated between the parties.

(8) The compensation arrangement does not violate the Federal anti-kickback provisions in section 1128B(b) of the Act.

(n) *Risk sharing arrangements.* Compensation pursuant to a risk-sharing arrangement (including, but not limited to, withholds, bonuses, and risk pools) between a managed care organization or an independent physicians association and a physician (either directly or indirectly through a subcontractor) for services provided to enrollees of a health plan, provided that the arrangement does not violate the Federal anti-kickback statute, section 1128B(b) of the Act, or any law or regulation governing billing or claims submission. For purposes of this paragraph (n), "health plan" and "enrollees" have the meanings ascribed to those terms in § 1001.952(l) of this title.

(o) *Compliance training.* Compliance training provided by a hospital to a physician (or the physician's immediate family member) who practices in the hospital's local community or service area, provided the training is held in the local community or service area. For purposes of this paragraph (o), "compliance training" means training regarding the basic elements of a compliance program (for example, establishing policies and procedures, training of staff, internal monitoring, reporting) or specific training regarding the requirements of Federal health care programs (for example, billing, coding,

reasonable and necessary services, documentation, unlawful referral arrangements).

(p) *Indirect compensation arrangements.* Indirect compensation arrangements, as defined in § 411.354(c)(2), if all of the following conditions are satisfied:

(1) The compensation received by the referring physician (or immediate family member) described in § 411.354(c)(2)(ii) is fair market value for services and items actually provided not taking into account the value or volume of referrals or other business generated by the referring physician for the entity furnishing DHS.

(2) The compensation arrangement described in § 411.354(c)(2)(ii) is set out in writing, signed by the parties, and specifies the services covered by the arrangement, except in the case of a *bona fide* employment relationship between an employer and an employee, in which case the arrangement need not be set out in a written contract, but must be for identifiable services and be commercially reasonable even if no referrals are made to the employer.

(3) The compensation arrangement does not violate the anti-kickback statute or any laws or regulations governing billing or claims submission.

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).

Subpart B—Certification and Plan of Treatment Requirements

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 section 1877 of the Act, which sets forth general exceptions to the referral prohibition related to both ownership/investment and compensation; exceptions to the referral prohibition

related to ownership or investment interests; and exceptions to the referral prohibition related to compensation arrangements.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare-Hospital Insurance; Program No. 93.774, Medicare-Supplementary Medical Insurance Program; and Program No. 93.778, Medical Assistance Program)

Dated: October 6, 2000.

Michael M. Hash,

Acting Administrator, Health Care Financing Administration.

Dated: October 16, 2000.

Donna E. Shalala,

Secretary.

Note: The following attachment will not appear in the Code of Federal Regulations.

Attachment

List of CPT¹/HCPCS Codes Used To Describe Certain Designated Health Services Under the Physician Referral Provisions (Section 1877 of the Social Security Act)

Clinical Laboratory Services

Include CPT codes for all clinical laboratory services in the 80000 series, except *Exclude* CPT codes for the following blood component collection services:

86890 Autologous blood process
86891 Autologous blood, op salvage
86915 Bone marrow/stem cell prep
86927 Plasma, fresh frozen
86930 Frozen blood prep
86931 Frozen blood thaw
86932 Frozen blood freeze/thaw
86945 Blood product/irradiation
86950 Leukocyte transfusion
86965 Pooling blood platelets
86985 Split blood or products

Include HCPCS level 2 codes for other clinical laboratory services:

G0001 Drawing blood for specimen
G0026 Fecal leukocyte examination
G0027 Semen analysis
G0103 Psa, total screening
G0107 CA screen; fecal blood test
G0123 Screen cerv/vag thin layer
G0124 Screen c/v thin layer by MD
G0141 Scr c/v cyto, autosys and md
G0143–G0145 Scr c/v cyto, thinlayer, rescr
G0147 Scr c/v cyto, automated sys
G0148 Scr c/v cyto, autosys, rescr
P2028 Cephalin flocculation test
P2029 Congo red blood test
P2031 Hair analysis
P2033 Blood thymol turbidity
P2038 Blood mucoprotein

P3000 Screen pap by tech w md supv
P3001 Screening pap smear by phys
P7001 Culture bacterial urine
P9612 Catheterize for urine spec
P9615 Urine specimen collect mult
Q0111 Wet mounts/w preparations
Q0112 Potassium hydroxide preps
Q0113 Pinworm examinations
Q0114 Fern test
Q0115 Post-coital mucous exam

Physical Therapy/Occupational Therapy/Speech-Language Pathology

Include the following CPT codes for the physical therapy/occupational therapy/speech-language pathology services in the 97000 series:

97001 Pt evaluation
97002 Pt re-evaluation
97003 Ot evaluation
97004 Ot re-evaluation
97010 Hot or cold packs therapy
97012 Mechanical traction therapy
97014 Electric stimulation therapy
97016 Vasopneumatic device therapy
97018 Paraffin bath therapy
97020 Microwave therapy
97022 Whirlpool therapy
97024 Diathermy treatment
97026 Infrared therapy
97028 Ultraviolet therapy
97032 Electrical stimulation
97033 Electric current therapy
97034 Contrast bath therapy
97035 Ultrasound therapy
97036 Hydrotherapy
97039 Physical therapy treatment
97110 Therapeutic exercises
97112 Neuromuscular reeducation
97113 Aquatic therapy/exercises
97116 Gait training therapy
97124 Massage therapy
97139 Physical medicine procedure
97140 Manual therapy
97150 Group therapeutic procedures
97504 Orthotic training
97520 Prosthetic training
97530 Therapeutic activities
97532 Cognitive skills development
97533 Sensory integration
97535 Self care mngmt training
97537 Community/work reintegration
97542 Wheelchair mngmt training
97545 Work hardening
97546 Work hardening add-on
97703 Prosthetic checkout
97750 Physical performance test
97799 Physical medicine procedure

Include CPT codes for physical therapy/occupational therapy/speech-language pathology services *not* in the 97000 series:

64550 Apply neurostimulator
90901 Biofeedback train, any meth
90911 Biofeedback peri/uro/rectal
92506 Speech/hearing evaluation
92507–92508 Speech/hearing therapy
92510 Rehab for ear implant

92526 Oral function therapy
93797 Cardiac rehab
93798 Cardiac rehab/monitor
94667–94668 Chest wall manipulation
94762 Measure blood oxygen level
95831 Limb muscle testing, manual
95832 Hand muscle testing, manual
95833–95834 Body muscle testing, manual
95851–95852 Range of motion measurements
96105 Assessment of aphasia
96110 Developmental test, lim
96111 Developmental test, extend
96115 Neurobehavior status exam

Include HCPCS level 2 codes for the following physical therapy/occupational therapy/speech-language pathology services:

G0193 Endoscopic study swallow functn
G0194 Sensory testing endoscopic stud
G0195 Clinical eval swallowing funct
G0196 Eval of swallowing with radioopa
G0197 Eval of pt for prescip speech devi
G0198 Patient adaption & train for spe
G0199 Reevaluation of patient use spec
G0200 Eval of patient prescip of voice p
G0201 Modi for training in use voice pro
Q0086 Physical therapy evaluation/

Radiology

Include the following radiology and certain other imaging services in the CPT 70000 series:

70100–70110 X-ray exam of jaw
70120–70130 X-ray exam of mastoids
70134 X-ray exam of middle ear
70140–70150 X-ray exam of facial bones
70160 X-ray exam of nasal bones
70190–70200 X-ray exam of eye sockets
70210–70220 X-ray exam of sinuses
70240 X-ray exam, pituitary saddle
70250–70260 X-ray exam of skull
70300–70310 X-ray exam of teeth
70320 Full mouth x-ray of teeth
70328 X-ray exam of jaw joint
70330 X-ray exam of jaw joints
70336 Magnetic image, jaw joint
70350 X-ray head for orthodontia
70355 Panoramic x-ray of jaws
70360 X-ray exam of neck
70370 Throat x-ray & fluoroscopy
70371 Speech evaluation, complex
70380 X-ray exam of salivary gland
70450 CT head/brain w/o dye
70460 CT head/brain w/dye
70470 CT head/brain w/o&w dye
70480 CT orbit/ear/fossa w/o dye
70481 CT orbit/ear/fossa w/dye
70482 CT orbit/ear/fossa w/o&w dye

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70486	CT maxillofacial w/o dye	72170-72190	X-ray exam of pelvis	74230	Cinema x-ray, throat/esoph
70487	CT maxillofacial w/dye	72191	CT angiograph pelv w/o&w dye	74240-74245	X-ray exam, upper gi tract
70488	CT maxillofacial w/o&w dye	72192	CT pelvis w/o dye	74246-74249	Contrst x-ray uppr gi tract
70490	CT soft tissue neck w/o dye	72193	CT pelvis w/dye	74250	X-ray exam of small bowel
70491	CT soft tissue neck w/dye	72194	CT pelvis w/o&w dye	74290	Contrast x-ray, gallbladder
70492	CT sft tsue nck w/o & w/dye	72195	MRI pelvis w/o dye	74291	Contrast x-rays, gallbladder
70496	CT angiography, head	72196	MRI pelvis w/dye	74710	X-ray measurement of pelvis
70498	CT angiography, neck	72197	MRI pelvis w/o&w dye	75552	Heart MRI for morph w/o dye
70540	MRI orbit/face/neck w/o dye	72200-72202	X-ray exam sacroiliac joints	75553	Heart MRI for morph w/dye
70542	MRI orbit/face/neck w/dye	72220	X-ray exam of tailbone	75554	Cardiac MRI/function
70543	MRI orbit/fac/nck w/o&w dye	73000	X-ray exam of collar bone	75555	Cardiac MRI/limited study
70544	MR angiography head w/o dye	73010	X-ray exam of shoulder blade	75635	CT angio abdominal arteries
70545	MR angiography head w/dye	73020-73030	X-ray exam of shoulder	76000	Fluoroscope examination
70546	MR angiograph head w/o&w dye	73050	X-ray exam of shoulders	76006	X-ray stress view
70547	MR angiography neck w/o dye	73060	X-ray exam of humerus	76010	X-ray, nose to rectum
70548	MR angiography neck w/dye	73070-73080	X-ray exam of elbow	76020	X-rays for bone age
70549	MR angiograph neck w/o&w dye	73090	X-ray exam of forearm	76040	X-rays, bone evaluation
70551	MRI brain w/o dye	73092	X-ray exam of arm, infant	76061-76062	X-rays, bone survey
70552	MRI brain w/dye	73100-73110	X-ray exam of wrist	76065	X-rays, bone evaluation
70553	MRI brain w/o&w dye	73120-73130	X-ray exam of hand	76066	Joint(s) survey, single film
71010-71022	Chest x-ray	73140	X-ray exam of finger(s)	76090	Mammogram, one breast
71023	Chest x-ray and fluoroscopy	73200	CT upper extremity w/o dye	76091	Mammogram, both breasts
71030	Chest x-ray	73201	CT upper extremity w/dye	76092	Mammogram, screening
71034	Chest x-ray and fluoroscopy	73202	CT uppr extremity w/o&w dye	76093	Magnetic image, breast
71035	Chest x-ray	73206	CT angio upr extrm w/o&w dye	76094	Magnetic image, both breasts
71100	X-ray exam of ribs	73218	MRI upper extremity w/o dye	76100	X-ray exam of body section
71101	X-ray exam of ribs/chest	73219	MRI upper extremity w/dye	76101	Complex body section x-ray
71110	X-ray exam of ribs	73220	MRI uppr extremity w/o&w dye	76102	Complex body section x-rays
71111	X-ray exam of ribs/chest	73221	MRI joint upr extrem w/o dye	76120	Cinematic x-rays
71120-71130	X-ray exam of breastbone	73222	MRI joint upr extrem w/ dye	76125	Cinematic x-rays add-on
71250	CT thorax w/o dye	73223	MRI joint upr extr w/o&w dye	76150	X-ray exam, dry process
71260	CT thorax w/dye	73500-73510	X-ray exam of hip	76370	CAT scan for therapy guide
71270	CT thorax w/o&w dye	73520	X-ray exam of hips	76375	3d/holograph reconstr add-on
71275	CT angiography, chest	73540	X-ray exam of pelvis & hips	76380	CAT scan follow-up study
71550	MRI chest w/o dye	73550	X-ray exam of thigh	76390	Mr spectroscopy
71551	MRI chest w/dye	73560	X-ray exam of knee, 1 or 2	76400	Magnetic image, bone marrow
71552	MRI chest w/o&w dye	73562	X-ray exam of knee, 3	76499	Radiographic procedure
71555	MRI angio chest w or w/o dye	73564	X-ray exam, knee, 4 or more	76506	Echo exam of head
72010-72020	X-ray exam of spine	73565	X-ray exam of knees	76511-76512	Echo exam of eye
72040-72052	X-ray exam of neck spine	73590	X-ray exam of lower leg	76513	Echo exam of eye, water bath
72069	X-ray exam of trunk spine	73592	X-ray exam of leg, infant	76516-76519	Echo exam of eye
72070-72074	X-ray exam of thoracic spine	73600-73610	X-ray exam of ankle	76536	Echo exam of head and neck
72080-72090	X-ray exam of trunk spine	73620-73630	X-ray exam of foot	76604	Echo exam of chest
72100-72120	X-ray exam of lower spine	73650	X-ray exam of heel	76645	Echo exam of breast(s)
72125	CT neck spine w/o dye	73660	X-ray exam of toe(s)	76700-76705	Echo exam of abdomen
72126	CT neck spine w/dye	73700	CT lower extremity w/o dye	76770-76775	Echo exam abdomen back wall
72127	CT neck spine w/o&w dye	73701	CT lower extremity w/dye	76778	Echo exam kidney transplant
72128	CT chest spine w/o dye	73702	CT lwr extremity w/o&w dye	76800	Echo exam spinal canal
72129	CT chest spine w/dye	73706	CT angio lwr extr w/o&w dye	76805-76815	Echo exam of pregnant uterus
72130	CT chest spine w/o&w dye	73718	MRI lower extremity w/o dye	76816	Echo exam follow-up/repeat
72131	CT lumbar spine w/o dye	73719	MRI lower extremity w/dye	76818	Fetl biophys profil w/stress
72132	CT lumbar spine w/dye	73720	MRI lwr extremity w/o&w dye	76819	Fetl biophys profil w/o str
72133	CT lumbar spine w/o&w dye	73721	MRI joint of lwr extre w/o d	76825-76828	Echo exam of fetal heart
72141	MRI neck spine w/o dye	73722	MRI joint of lwr extr w/dye	76830	Echo exam, transvaginal
72142	MRI neck spine w/dye	73723	MRI joint lwr extr w/o&w dye	76831	Echo exam, uterus
72146	MRI chest spine w/o dye	73725	MR ang lwr ext w or w/o dye	76856-76857	Echo exam of pelvis
72147	MRI chest spine w/dye	74000-74020	X-ray exam of abdomen	76870	Echo exam of scrotum
72148	MRI lumbar spine w/o dye	74022	X-ray exam series, abdomen	76872	Echo exam, transrectal
72149	MRI lumbar spine w/dye	74150	CT abdomen w/o dye	76873	Echograp trans r, pros study
72156	MRI neck spine w/o&w dye	74160	CT abdomen w/dye	76880	Echo exam of extremity
72157	MRI chest spine w/o&w dye	74170	CT abdomen w/o&w dye	76885-76886	Echo exam, infant hips
72158	MRI lumbar spine w/o&w dye	74175	CT angio abdom w/o&w dye	76970	Ultrasound exam follow-up
		74181	MRI abdomen w/o dye	76977	Us bone density measure
		74182	MRI abdomen w/dye	76999	Echo examination procedure
		74183	MRI abdomen w/o&w dye		<i>Include</i> the following CPT codes for echocardiography and vascular ultrasound:
		74185	MRI angio, abdom w or w/o dy		
		74210	Contrst x-ray exam of throat		
		74220	Contrast x-ray, esophagus		

93303-93304 Echo transthoracic
 93307-93308 Echo exam of heart
 93320-93321 Doppler echo exam,
 heart, if used in conjunction with
 93303-93308
 93325 Doppler color flow add-on, if
 used in conjunction with 93303-
 93308
 93875-93882 Extracranial study
 93886-93888 Intracranial study
 93922-93924 Extremity study
 93925-93926 Lower extremity study
 93930-93931 Upper extremity study
 93965-93971 Extremity study
 93975-93979 Vascular study
 93980-93981 Penile vascular study
 93990 Doppler flow testing

Include miscellaneous other HCPCS
 level 2 codes for radiology and certain
 other imaging services:

G0050 Residual urine by ultrasound
 G0131-132 CT scan, bone density
 study
 G0188 Xray lwr extrmty-full lngth
 R0070 Transport portable x-ray
 R0075 Transport port x-ray multipl

Radiation Therapy Services and Supplies

Include CPT codes for all radiation
 therapy services and supplies in the
 CPT 70000 series:

77261-77263 Radiation therapy
 planning
 77280-77295 Set radiation therapy
 field
 77299 Radiation therapy planning
 77300-77315 Radiation therapy dose
 plan
 77321 Radiation therapy port plan
 77326-77328 Radiation therapy dose
 plan
 77331 Special radiation dosimetry
 77332-77334 Radiation treatment
 aid(s)
 77336-77370 Radiation physics
 consult
 77399 External radiation dosimetry
 77401-77416 Radiation treatment
 delivery

77417 Radiology port film(s)
 77427 Radiation tx management, x5
 77431 Radiation therapy management
 77432 Stereotactic radiation trmt
 77470 Special radiation treatment
 77499 Radiation therapy management
 77520 Proton trmt, simple w/o comp
 77522 Proton trmt, simple w/comp
 77523 Proton trmt, intermediate
 77525 Proton treatment, complex
 77600-77620 Hyperthermia treatment
 77750 Infuse radioactive materials
 77761 Apply intrcav radiat simple
 77762 Apply intrcav radiat interm
 77763 Apply intrcav radiat compl
 77776 Apply interstit radiat simpl
 77777 Apply interstit radiat inter
 77778 Apply iterstit radiat compl
 77781-77784 High intensity
 brachytherapy

77789 Apply surface radiation
 77790 Radiation handling
 77799 Radium/radioisotope therapy

Include CPT codes for radiation
 therapy classified elsewhere:

31643 Diag bronchoscope/catheter
 50559 Renal endoscopy/radiotracer
 55859 Percut/needle insert, pros
 61770 Incise skull for treatment
 61793 Focus radiation beam

Preventive Screening Tests, Immunizations and Vaccines

The following CPT and HCPCS codes
 are excluded under § 411.355(h) as
 screening tests:

76092 Mammogram, screening
 76977 Us bone density measure
 G0103 Psa, total screening
 G0107 CA screen; fecal blood test
 G0123 Screen cerv/vag thin layer
 G0124 Screen c/v thin layer by MD
 G0141 Scr c/v cyto,autosys and md
 G0143-G0145 Scr c/v cyto, thin layer,
 rescr
 G0147 Scr c/v cyto, automated sys
 G0148 Scr c/v cyto, autosys, rescr
 P3000 Screen pap by tech w md supv
 P3001 Screening pap smear by phys

The following CPT codes are
 excluded under § 411.355(h) as
 vaccines:

90657 Flu vaccine, 6-35 mo, im
 90658 Flu vaccine, 3 yrs, im
 90659 Flu vaccine, whole, im
 90732 Pneumococcal vacc, adult/ill
 90744 Hepb vacc ped/adol 3 dose im
 90746 Hep b vaccine, adult, im
 90747 Hepb vacc, ill pat 4 dose im
 90748 Hep b/hib vaccine, im

Drugs Used by Patients Undergoing Dialysis

The following HCPCS codes are
 excluded under § 411.355(g) as EPO and
 other dialysis related outpatient
 prescription drugs furnished in or by an
 ESRD facility:

J0635 Calcitriol injection
 J0895 Deferoxamine meslyate inj
 J1750 Iron dextran
 J2915 NA Ferric Gluconate Complex
 J2997 Alteplase recombinant
 Q9920 Epoetin with hct <=20
 Q9921 Epoetin with hct = 21
 Q9922 Epoetin with hct = 22
 Q9923 Epoetin with hct = 23
 Q9924 Epoetin with hct = 24
 Q9925 Epoetin with hct = 25
 Q9926 Epoetin with hct = 26
 Q9927 Epoetin with hct = 27
 Q9928 Epoetin with hct = 28
 Q9929 Epoetin with hct = 29
 Q9930 Epoetin with hct = 30
 Q9931 Epoetin with hct = 31
 Q9932 Epoetin with hct = 32
 Q9933 Epoetin with hct = 33
 Q9934 Epoetin with hct = 34
 Q9935 Epoetin with hct = 35
 Q9936 Epoetin with hct = 36
 Q9937 Epoetin with hct = 37
 Q9938 Epoetin with hct = 38
 Q9939 Epoetin with hct = 39
 Q9940 Epoetin with hct >= 40

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