DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 411 and 424

[CMS–1810–IFC]

RIN 0938–AK67

Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II)

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule with comment period (Phase II of this rulemaking) incorporates into regulations the provisions concerning ownership and investment exceptions in paragraphs (c) and (d) and the compensation exceptions in paragraph (e) of section 1877 of the Social Security Act (the Act). Phase II also addresses comments concerning the reporting requirements in section 1877(f) of the Act.

Phase I (as defined below) addressed the majority of issues in implementing section 1877 of the Act. Phase II both addresses the remaining issues not addressed in Phase I and responds to public comments. In general, in response to public comments, the Department has attempted to reduce regulatory burden by broadening exceptions using the Secretary's discretionary authority under the statute to create exceptions that pose no risk of fraud or abuse. For the convenience of affected parties, we have set out the entire rule as previously promulgated, including the changes made by this rulemaking.

DATES: *Effective date:* This interim final rule is effective on July 26, 2004.

Comment date: We will consider comments on Phase II issues if we receive them at the appropriate address, as provided below, no later than 5 p.m. on June 24, 2004. Late filed comments will be considered to the extent practicable.

ADDRESSES: In commenting, please refer to file code CMS–1810–IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

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Please allow sufficient time for mailed comments to be timely received in the event of delivery delays.

If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) to one of the following addresses: Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room C5–14–03, 7500 Security Boulevard, Baltimore, MD 21244–1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

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All comments received before the close of the comment period are available for viewing by the public. After the close of the comment period, CMS posts all electronic comments received before the close of the comment period on its public Web site. To protect an individual's privacy and identity, a commenter may wish to omit his or her full name and address from the comment. We request that the commenter identify only his or her zip code. For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

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

SUPPLEMENTARY INFORMATION: *Submitting Comments:* We welcome comments from the public on all issues set forth in this rule to assist us in fully considering issues and developing policies. You can assist us by referencing the file code CMS–1810–IFC and the specific ''issue identifier'' that precedes the section on which you choose to comment.

Inspection of Public Comments: Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone (410) 786–7197.

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I. Background

Section 1877 of the Social Security Act (the Act), also known as the physician self-referral law: (1) Prohibits a physician from making referrals for certain ''designated health services'' (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship (ownership or compensation) unless an exception applies; and (2) prohibits the entity from filing claims with Medicare for those referred services, unless an exception applies. The statute establishes a number of specific exceptions and grants the Secretary the authority to create regulatory exceptions for financial relationships that pose no risk of fraud or abuse.

In reviewing the public comments received, the Department has endeavored to reduce the burden and prescriptive nature of the rule while applying the statute and maintaining the integrity of the regulatory framework. The Phase II rule exercises the Secretary's authority to create exceptions to accomplish this goal. In particular, the Phase II rule creates a new exception for community-wide health information systems. It also creates limited exceptions to allow physicians to refer to immediate family members in rural areas in certain circumstances when no other physician is available, and to exempt hospital payments to retain a physician who would otherwise leave a health professional shortage area.

This is Phase II of a bifurcated final rulemaking under section 1877 of the Act. The current version of section 1877, which applies to referrals for eleven DHS, has been in effect and subject to enforcement since January 1, 1995. Proposed regulations were published in 1998 at 63 FR 1659 (January 9, 1998) (the ''January 1998 proposed rule''). Phase I of the final rulemaking was published in the **Federal Register** on January 4, 2001 (66 FR 856) (''Phase I'') as a final rule with comment period.

The reasons for bifurcation of the rulemaking are explained in the Phase I preamble (66 FR 859–860). With two exceptions, the regulations published in Phase I became effective on January 4, 2002. Section 424.22(d), relating to home health services, became effective on April 6, 2001 (see our **Federal Register** notice dated February 2, 2001 (66 FR 8771)). We delayed the effective date of the final sentence of § 411.354(d)(1) relating to the definition of ''set in advance'' for one year from January 4, 2002 to January 6, 2003, in a **Federal Register** document published on December 3, 2001 (66 FR 60154). We further delayed the effective date of this sentence for an additional 6 months, until July 7, 2003, in a **Federal Register** document published on November 22, 2002 (67 FR 70322), and for an additional 6 months, until January 7, 2004, in a **Federal Register** document published on April 25, 2003 (68 FR 20347). We published another delay notice on December 24, 2003 (68 FR 74491), delaying that effective date until July 7, 2004.

Phase I covered—

- Sections 1877(a) and 1877(b) of the Act (the general prohibition and the exceptions applicable to both ownership and compensation arrangements);
- The statutory definitions at section 1877(h) of the Act;
- Certain additional regulatory definitions; and
- A number of new regulatory exceptions promulgated under section 1877(b)(4) of the Act.

Phase II covers—

- The remaining provisions of section 1877 of the Act;
- Additional regulatory definitions;
- Additional new regulatory exceptions promulgated under section 1877(b)(4) of the Act; and
- Responses to the public comments on the Phase I regulations.

We had intended to address in this Phase II rulemaking section 1903(s) of the Act, which applies section 1877 of the Act to referrals for Medicaid covered services and which we interpreted in the proposed rule at § 435.1012 and § 455.109. However, in the interest of expediting publication of these rules, we are reserving the Medicaid issue for a future rulemaking with one exception. In this rulemaking, we are amending the prepaid plans exception at § 411.356(c) to cover Medicaid managed care plans.

Phase II has a 90-day comment period and will become effective 120 days after the date of publication. Comments received on the Phase II rulemaking will be addressed in a separate **Federal Register** notice.

Phase I and Phase II of this rulemaking are intended to be read together as a unified whole. Among other things, Phase I contains a complete legislative and regulatory history (66 FR 857–859), which is not repeated here. Modifications or revisions to Phase I are clearly indicated in this Phase II preamble and corresponding regulations text. Unless otherwise expressly noted, to the extent the preamble in Phase II uses different language to describe a concept addressed in Phase I, our intent is to better explain or clarify a Phase I discussion, not to change its scope or meaning. For clarity and ease of access of the general public to the entire set of issues raised by the statute, we are republishing the regulatory text in its entirety. This Department has consistently worked to clarify and simplify the Phase I rules in response to comments, as well as to reduce the burden of the entire set of rules by exercising the Secretary's authority to create additional exceptions for financial relationships that pose no risk of fraud and abuse when all of the conditions of an exception are met. The Phase I and the Phase II rules, together, supersede the 1995 final rule (60 FR 41914), which has been applicable to referrals for clinical laboratory services.

As with Phase I, in developing Phase II of this rulemaking, we have carefully reconsidered the January 1998 proposed rule (63 FR 1659), given both the history and structure of section 1877 of the Act and the extensive comments we received to the January 1998 proposed rule, as well as the considerably smaller number of comments to the Phase I final rule. As with Phase I, we believe that Phase II of this rulemaking addresses many of the industry's primary concerns with the January 1998 proposed rule, is consistent with the statute's goals and directives, and protects beneficiaries of Federal health care programs. In particular, we have attempted to preserve the core statutory prohibition while providing sufficient flexibility to minimize the impact of the rule on many common business arrangements. For more detailed discussion of the criteria we have applied in evaluating regulatory options for Phase II, see 66 FR 859–863 of the Phase I rule.

This Phase II preamble is generally organized to track the statute. We first address the general prohibition, then the exceptions, then the definitions (although certain key definitions, such as ''group practice'' and ''isolated transaction'' are addressed in the discussions of the exceptions to which they mainly relate). Discussion of new regulatory exceptions follows (except that regulatory exceptions closely related to a statutory provision are discussed together with the statutory provision). Topics previously covered by Phase I are clearly indicated, along with cross-references to the relevant Phase I preamble pages and regulatory text. Topics new to Phase II are also clearly indicated, and, as in Phase I, each Phase II issue begins with summaries of the existing law, the January 1998 proposed rule, and the final rule. These summaries are intended to aid the reader in understanding the regulations. More detailed discussions of particular points are included in the responses to public comments for each topic.

II. The General Prohibition Under Section 1877 of the Act

(Section 1877(a) of the Act; Phase I—66 FR 863–875; § 411.353 and § 411.351)

Overall, the commenters to the Phase I rulemaking welcomed the additional clarity provided with respect to the general statutory prohibition, particularly with respect to the treatment of indirect compensation arrangements. However, we received a number of comments with respect to various aspects of the general prohibition. As in Phase I, the summaries of the public comments and our responses are divided into four parts:

A. General comments.

B. Comments related to whether a financial relationship exists between a referring physician and a designated health services entity (''DHS entity'').

C. Comments related to whether there has been a referral from a referring physician to a DHS entity.

D. Comments regarding the definition of ''consultation.''

A. General Comments

Comment: Many commenters praised the new regulations, particularly their clarity, flexibility, and focus on ''bright line'' rules. However, several stated that the regulations are still overly complex, lengthy, and burdensome. A physician organization asserted that the complexity discourages physicians from participating in the Medicare program.

Response: A certain amount of regulatory complexity is inevitable under a statutory scheme that encompasses the full panoply of physician financial arrangements with providers of eleven different types of health care services. The Phase I preamble attempted to provide clear explanations of the rules and to respond to approximately 13,000 public comments. Accordingly, it is somewhat lengthy. However, the Phase I regulations themselves constitute only 13 of the 108 pages published in the **Federal Register**. Moreover, while certain aspects of the statute and regulations involve detailed tests or standards, the overall statutory and regulatory scheme is straightforward. Most physician ownership in DHS entities is prohibited. Most physician compensation must be fair market value. We believe that the rule, like the statute, provides clear guidance for providers to comply demonstrably with the law.

Comment: The basic sanction under section 1877 of the Act is nonpayment for DHS referred by a physician with an improper financial relationship with the DHS entity. A home health agency commented that payment denial was not a sufficient deterrent to improper referrals and that referring physicians and hospitals that own or operate their own home health services need to be penalized.

Response: Section 1877(g) of the Act provides for two types of sanctions: nonpayment of claims for all violations and civil monetary penalties (CMPs) for knowing violations. Nonpayment applies to any DHS furnished to any Medicare patient under a prohibited referral. We believe the combination of nonpayment and CMPs is a strong deterrent.

Comment: A practicing physician objected to physicians being denied the right to own businesses to which they refer. The physician complained that the law compels referrals to businesses owned by persons who are not physicians and who do not have the skills or expertise to run them.

Response: As we explained in Phase I (66 FR 859), in enacting section 1877 of the Act, the Congress responded in part to a number of studies showing that physician ownership of certain types of facilities resulted in significantly higher utilization of those facilities by the physician-owners. While in some cases physician-owners may have been actively involved in the businesses, in others they were merely passive investors. The Congress created exceptions for certain physician-owned DHS entities, including providers in rural areas (section 1877(d)(2) of the Act), and for DHS provided within a physician's own office practice to the physician's patients (the in-office ancillary services exception in section 1877(b)(2) of the Act and § 411.355(b) of the regulations).

Comment: Several commenters requested that we enact various ''grace'' periods under the exceptions to accommodate situations in which parties to an arrangement: (1) Fall out of compliance with aspects of an exception

through events outside their control; or (2) are unable to comply with an exception for temporary periods of time.

Response: We are persuaded that a specified and limited exception for certain arrangements that have unavoidably and temporarily fallen out of compliance with other exceptions is warranted and consistent with the overall statutory scheme and the obligations the statute imposes on providers. Accordingly, using our authority at section 1877(b)(4) of the Act, we have incorporated into these regulations an exception at § 411.353(f) for certain arrangements that have fully satisfied another exception for at least 180 consecutive days, but have fallen out of compliance with the exception for reasons beyond the control of the DHS entity. Parties must take steps to rectify their noncompliance or otherwise comply with the statute as expeditiously as possible under the circumstances. The § 411.353(f) exception lasts up to 90 days and applies to DHS furnished during the exception period. By the end of the 90-day exception period, parties must either comply with another exception or have terminated their otherwise prohibited arrangement. It is in the provider's interest to document contemporaneously the reasons for the temporary noncompliance and the steps taken to rectify it. For example, this exception will allow rural providers that fall out of compliance with § 411.356(C)(2) through re-designation of a rural area as a non-rural area time to finish patients' existing courses of treatment or refer patients to other providers.

This new exception, at § 411.353(f), does not apply to arrangements that previously complied with the exceptions for non-monetary compensation up to $300 or incidental medical staff benefits. To provide otherwise would effectively negate the limits set in those exceptions. (In the case of non-monetary compensation, it is, of course, possible to be compliant in the next year, since the exception permits non-monetary compensation up to $300 annually.)

The new exception is *not* intended to allow DHS entities to file otherwise prohibited claims or bills when they purposefully take or omit to take actions or engage in conduct that causes their financial relationship to be noncompliant with an exception. The exception period is limited to 90 calendar days following the date of the initial event resulting in noncompliance with an exception and applies to DHS furnished during the exception period. The exception is intended to be used sparingly and may not be used by a DHS entity more often than once every three years with respect to referrals from the same referring physician. We believe this exception should address a number of situations that present special and temporary compliance problems, including conversion of publicly-traded companies to private ownership; loss of rural or health professional shortage areas (HPSA) designations; or delays in obtaining fully-signed copies of renewal agreements. As noted in section V.C below, we have also modified the group practice definition at § 411.352(d)(5) to address problems faced by group practices that fall out of compliance with elements of the definition when they add new members to the group. We have also interpreted the lease exceptions to permit holdover month-to-month leases for up to six months.

Comment: A commenter commended the Phase I regulations regarding referrals between physicians and their spouses, but submitted that the regulations did not go far enough in permitting certain cross-referrals between physicians who are family members. In the commenter's view, these referrals should be allowed whenever the referral arrangement would be permitted between non-family member physicians. For example, the commenter believed that if a physician could himself perform a designated health service under the in-office ancillary services exception, he should be permitted to refer to his spouse if she could also otherwise provide that service under the in-office ancillary services exception. According to the commenter, a physician would have no greater incentive to refer to his or her spouse if the physician could otherwise provide the designated health service under an exception. Thus, the commenter believes prohibiting cross-referrals unfairly penalizes two-physician families.

Response: The statute clearly provides that a physician may not make a referral to a DHS entity with which the physician (or an immediate family member) has a financial relationship, unless an exception applies. The change suggested by the commenter would contradict this clear statutory directive. However, as discussed in section V.B below, we are creating a new regulatory exception for some intra-family referrals that meet specific conditions.

B. When Is There a Financial Relationship Between the Referring Physician and the DHS Entity? (Phase I—66 FR 864; § 411.351, § 411.354, and § 411.357(p))

[If you choose to comment on issues in this section, please include the caption ''Financial Relationship Definition'' at the beginning of your comments.]

The existence of a financial relationship between the referring physician (or an immediate family member) and the entity furnishing DHS is the factual predicate 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 an immediate family member) in the DHS entity; or (2) a compensation arrangement between the referring physician (or an immediate family member) and the DHS entity. Any financial relationship between the referring physician and the DHS entity implicates the statute, even if the financial relationship is wholly unrelated to a designated health service payable by Medicare (for example, a financial relationship involving only private pay business). Unless the financial relationship fits into a statutory or regulatory exception, referrals and corresponding claims for DHS are prohibited. Section 411.354 addresses the circumstances under which a financial relationship exists.

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 an immediate family member) with no person or entity interposed between them (§ 411.354(a)(1)(2)). ''Indirect'' financial relationships—whether ownership or investment or compensation—exist where one or more persons or entities are interposed between the referring physician and the DHS entity. For indirect compensation arrangements, Phase I established a three part, ''bright line'' test that incorporated a knowledge element to protect DHS entities not in a position to know about or suspect an otherwise prohibited compensation arrangement with the referring physician. Phase I also established a corresponding new exception for indirect compensation arrangements. By

(1) defining the universe of ''indirect compensation arrangements'' that potentially triggers disallowance of claims and penalties; and (2) creating an exception for the subset of ''indirect compensation arrangements'' that will *not* trigger disallowance or penalties, we have structured the treatment of indirect compensation arrangements under section 1877 of the Act to parallel the treatment of direct compensation arrangements.

Most commenters were pleased with the specificity of § 411.354, which sets out rules for determining whether a financial relationship exists, and the accompanying discussion in the Phase I preamble (66 FR 864). While § 411.354 establishes rules for both direct and indirect financial relationships, very few comments addressed the rules for direct financial relationships. Rather, most comments addressed the definition of an indirect compensation arrangement at § 411.354(c)(2) and the interplay between that definition and the exception at § 411.357(p).

As discussed below, we are modifying the language of § 411.354 to address some of the concerns expressed by the commenters. These modifications include—

- Clarifying the meaning of direct and indirect *ownership* and affirming that common ownership of an entity does not create an *ownership* interest by one common investor in another;
- Clarifying the relationship between the ''indirect *compensation* arrangements'' definition and the ''volume or value'' and ''other business generated'' standards;
- Clarifying that a referring physician may be treated as ''standing in the shoes'' of his or her wholly-owned professional corporation (PC).

Summaries of the comments and our responses follow.

Comment: One commenter asked us to clarify that remuneration received as a result of an arrangement that does not fit in the definition of a ''financial relationship'' under § 411.354(a) does not implicate section 1877 of the Act.

Response: The commenter did not provide any specific examples of remuneration that would not result in a financial relationship. As a matter of law, section 1877 of the Act does not apply in the absence of a financial relationship as defined in § 411.354(a), but in the absence of specific examples, we find it difficult to identify any remuneration not covered by that definition.

Comment: A number of commenters found the definition of ''indirect compensation arrangement'' at § 411.354(c)(2) to be very complicated. One commenter stated that the definition was too broad and covered many arrangements that had not previously been subject to the statute. A national physician association emphasized that the physician community would need education as to the scope and application of the definition.

Response: The definition of ''indirect compensation arrangement'' at § 411.354(c)(2) requires three elements:

- Paragraph (c)(2)(i)—an unbroken chain of financial relationships (ownership or compensation) linking the referring physician to the DHS entity;
- Paragraph (c)(2)(ii)—aggregate compensation paid to the referring physician that varies with, or otherwise takes into account, the volume or value of referrals to, or other business generated for, the DHS entity; and
- Paragraph (c)(2)(iii)—knowledge by the DHS entity that the physician receives aggregate compensation that varies with, or otherwise takes into account, the volume or value of referrals to, or other business generated for, the DHS entity (using the same knowledge standard that applies under the False Claims Act (31 U.S.C. § 3729) and the Civil Monetary Penalties Law (section 1128A of the Act)).

With education and experience, we think DHS entities and referring physicians will be able to apply the test without difficulty. (We discuss further the application of the various elements in response to specific comments below.) We have made several technical revisions to clarify the intent of the exception.

We agree that the definition encompasses many arrangements that physicians and DHS entities claim not to have thought were covered by the statute. As we discussed in the Phase I preamble (66 FR 864), we believe that the knowledge element sufficiently and equitably sets the boundaries for the potential universe of prohibited arrangements.

Comment: Many commenters expressed confusion at the interplay between (1) the definition of ''indirect compensation arrangement'' at § 411.354(c)(2), which looks at whether the referring physician's aggregate compensation varies with, or otherwise takes into account ''the volume or value of referrals'' generated by the referring physician, and (2) § 411.354(d)(2), which describes when certain compensation (such as time-based and unit-of-service based payments) will be deemed not to take into account ''the volume or value of referrals,'' even though aggregate per unit compensation will always vary with the volume or value of referrals. (We received similar comments regarding § 411.354(d)(3) with respect to when compensation does not take into account ''other business generated between the parties.'') These provisions were discussed in the Phase I preamble (66 FR 876).

Specifically, under § 411.354(d)(2) and § 411.354(d)(3), time-based and unit-of-service based compensation is deemed not to take into account the volume or value of referrals or other business generated if the unit-based compensation: (i) Is fair market value for items or services actually provided; and (ii) does not vary over the term of the agreement in any manner that takes into account DHS referrals or other business generated by the referring physician. Some commenters questioned whether an indirect compensation arrangement exists at all if a referring physician receives time-based or unit-of-service based compensation that is fair market value and does not vary over the term of the agreement, that is, compensation that, by definition, does not take into account the volume or value of referrals or other business generated according to § 411.354(d)(2) and § 411.354(d)(3).

Similarly, the new exception for indirect compensation arrangements at § 411.357(p), like § 411.354(d)(2) and § 411.354(d)(3), does not look to aggregate compensation and incorporates a fair market value test. Given this, several commenters pointed out that the ultimate result would be the same whether time and unit-of-service based compensation arrangements are initially excluded from the definition of ''indirect compensation arrangement'' in § 411.354(c)(2) or included in the definition and then excepted by the new exception. One commenter proposed three options: (1) Retaining the indirect compensation arrangement definition in the final regulation and deleting the indirect compensation exception; (2) revising the indirect compensation arrangement definition by deleting the volume and value language; or (3) revising § 411.354(d)(2) and § 411.354(d)(3) to make clear that those provisions do not apply to the indirect compensation arrangements definition.

Response: An ''indirect compensation arrangement'' exists under § 411.354(c)(2) if the referring physician's aggregate compensation varies with, or otherwise takes into account, the volume or value of referrals or other business generated by the referring physician. Since time-based or unit-of-service based compensation will always vary with the volume or value of services when considered in the

aggregate, these compensation arrangements can constitute ''indirect compensation arrangements'' under § 411.354(c)(2), even if the individual time or unit-of-service based compensation is fair market value and otherwise complies with the language of § 411.354(d)(2) and § 411.354(d)(3).

We agree that the close similarity in the regulatory language between § 411.354(c)(2) and § 411.354(d)(2) and § 411.354(d)(3) can be clarified. We are modifying § 411.354(c)(2)(ii) to do so. Our intent is two-fold. First, we intend to include in the definition of ''indirect compensation arrangement'' any compensation arrangements (including time-based or unit-of-service based compensation arrangements) where the aggregate compensation received by the referring physician varies with, or otherwise takes into account, the volume or value of referrals or other business generated between the parties, regardless of whether the individual unit of compensation qualifies under § 411.354(d)(2) and § 411.354(d)(3). Second, we intend to exclude under the indirect compensation arrangement exception at § 411.357(p) that subset of indirect compensation arrangements where the compensation is fair market value and does not reflect the volume or value of referrals or other business generated and the other conditions of the exception are satisfied. Per unit compensation will meet this test if it complies with § 411.354(d)(2) and § 411.354(d)(3). While we agree that the ultimate result may be the same—time, unit-of-service, or other ''per click'' based arrangements are generally permitted if they are at fair market value without reference to referrals—we believe this construct more closely corresponds to the statutory treatment of direct compensation arrangements. Accordingly, we are clarifying § 411.354(c)(2)(ii).

It is important to bear in mind that, depending on the circumstances, fixed aggregate compensation can form the basis for a prohibited direct or indirect compensation arrangement. This will be the case if such fixed aggregate compensation takes into account the volume or value of referrals (for example, the fixed compensation exceeds fair market value for the items or services provided or is inflated to reflect the volume or value of a physician's referrals or other business generated). Section 411.354(d)(2) and § 411.354(d)(3) were not intended to remove the existing prohibition on fixed compensation arrangements that take into account the volume or value of referrals or other business generated between the parties. We have clarified the language in these sections to reflect the distinction.

Comment: The first element of an ''indirect compensation arrangement'' is an unbroken chain of financial relationships between the DHS entity and the referring physician. In Phase I, we explained that the links in the chain could be any form of financial relationship, whether excepted or not. Several commenters believe that there should be no indirect compensation arrangement if any financial relationship in the chain qualifies for an exception. One commenter pointed out that under section 1877(a)(2) of the Act, the definition of ''financial relationship'' excludes any financial relationship that fits in an exception. Thus, according to this commenter, the inclusion of an excepted financial relationship in a chain of financial relationships necessarily ''breaks'' the chain and precludes an indirect compensation arrangement. The commenter explained further that this result would make the application of the indirect compensation rules easier for DHS entities, especially hospitals, that have arrangements with group practices that employ, or contract with, referring physicians using compensation arrangements that fit in the employment, personal services contracts, or fair market value exceptions. Finally, the commenter suggested that, at a minimum, there should be no indirect financial relationship if every link in the chain qualifies for an exception.

Response: Section 1877(a)(2) of the Act excludes from the definition of ''financial relationship'' any ownership or compensation arrangement that fits in an exception. While the regulations are structured somewhat differently, they achieve the same result. The regulations define ''financial relationship'' in § 411.354(a) without limiting the term to unexcepted financial relationships. Exceptions are set forth in separate provisions of the regulations. Thus, the reference in the definition of ''indirect compensation arrangement'' to an unbroken chain of ''financial relationships'' as defined in § 411.354(a) includes both excepted and unexcepted relationships. A direct financial relationship can form a link in a chain of financial arrangements that creates an indirect compensation arrangement, even if the direct financial relationship qualifies for an exception. While it is very unlikely, we believe that a chain consisting entirely of excepted financial relationships could theoretically create an indirect compensation arrangement, if the remuneration paid to the referring physician is not fair market value or varies with, or otherwise takes into account, the volume or value of referrals or other business generated for the DHS entity by the referring physician. A more likely scenario is that the chain would either involve fair market value compensation that would qualify the relationship under the indirect compensation arrangement exception. We address the special issue of contracts with group practices in a subsequent response below.

Comment: A commenter asserted that ''indirect'' compensation under section 1877 of the Act means only non-monetary benefits that are incidental to a direct financial relationship, and that the Secretary exceeded his statutory authority by extending the regulations to other indirect compensation arrangements.

Response: The commenter provided no statutory support for its interpretation of section 1877 of the Act. Nor does the plain meaning of the term ''indirect'' support the commenter's view. The interpretation offered by the commenter would permit wholesale circumvention of section 1877 of the Act through the formal interposition of another person or entity between the referring physician and the DHS entity. The Congress clearly intended to prevent such schemes by including indirect compensation in the definition of remuneration in section 1877(b)(1)(B) of the Act. The Secretary has broad authority under sections 1102 and 1871 of the Act to promulgate regulations implementing any provision of the Act.

Comment: One commenter asked how far an indirect compensation arrangement could be traced along a chain of financial relationships created through common ownership.

Response: As with any indirect compensation arrangement, the chain of financial relationships can be of any length. As we discussed in the preamble to the Phase I rule (66 FR 864), the knowledge element in § 411.354(c)(2)(iii) limits the potential liability of a DHS entity involved in a distant, indirect compensation arrangement.

Comment: A number of commenters expressed the view that an indirect compensation arrangement should be excepted if any link in the chain fits in one of the exceptions for direct compensation arrangements. This issue was raised by group practices that contract to provide services to hospitals (or other DHS entities) or to lease space or equipment from DHS entities. For example, in the case of a services agreement between a hospital and a group practice, an indirect compensation arrangement is created

between the hospital and the contracting group practice's employee or investor physicians (that is, the referring physicians). Instead of looking to the indirect compensation exception in such circumstances, commenters proposed that the test be whether the compensation arrangement between the hospital and the group practice fits in a direct compensation exception. Commenters suggested that we use a similar rule for other indirect compensation arrangements involving referring physicians who are members of group practices, where the link in the chain closest to the referring physician is his or her compensation arrangement with his or her group practice. Commenters requested comparable relief with respect to physician-owned PCs. In the commenter's view, the fact that a physician practices through a wholly-owned PC should not convert a direct financial relationship with a DHS entity into an indirect relationship (that is, physician—PC—DHS entity).

Response: We do not agree that an indirect compensation arrangement should be excepted if any link in the chain complies with a direct compensation exception. As we explained in the Phase I preamble (66 FR 867), we are concerned that, in some situations, such a test would permit a middle entity to redirect compensation to referring physicians based upon the volume or value of referrals or other business generated by the physicians to the DHS entity (which is not the middle entity).

We recognize that it is not necessary to treat a referring physician as separate from his or her wholly-owned PC. We have revised the definition of referring physician in § 411.351 to reflect this clarification.

By way of example, under the Phase I regulations, if a hospital contracted with a referring physician's PC for the provision of services, the hospital would potentially have an indirect compensation arrangement with the referring physician for which the only available exception would be the indirect compensation arrangements exception. Under the revised regulations, the contract would create a direct compensation arrangement between the hospital and the referring physician.

We believe the revised regulations should make it simpler for physicians and others to evaluate their financial relationships and the application of exceptions under section 1877 of the Act.

We are not making any changes to the Phase I rule with respect to the issue of indirect compensation arrangements that are created when a group practice is an intervening entity in the chain between the DHS entity and referring physicians who are members of the group (for example, a hospital contracts with a group practice for services). The commenters' proposal that the regulations permit physicians to stand in the shoes of their group practices, thereby converting indirect arrangements to direct arrangements, is inconsistent with the compensation exceptions as drafted. We believe that the knowledge standard in the indirect compensation arrangements definition and exception adequately protects DHS entities. We solicit comments on this issue.

Comment: One commenter asked us to clarify the application of the indirect compensation arrangement rules to the situation in which a referring physician owns an interest in a hospital and the hospital contracts for services with a clinical laboratory to which the physician refers. In the preamble to the Phase I rule (66 FR 866), we indicated that there would be a chain of entities (referring physician—hospital—clinical lab). The commenter asked us whether that arrangement would fit in the indirect compensation arrangement definition and, if necessary, the indirect compensation exception.

Response: As commonly structured, the example would not create an indirect compensation arrangement. There would be an unbroken chain of financial relationships between the referring physician and the clinical laboratory (the DHS entity) via the hospital. However, an unbroken chain is only one of three elements required under the definition of indirect compensation arrangement. Section 411.354(c)(2)(ii) requires that the referring physician receives aggregate compensation that varies with, or otherwise takes into account, the volume or value of DHS referrals or other business generated by the referring physician for the DHS entity. Under § 411.354(c)(2)(ii), we look to the non-ownership or non-investment interest closest to the referring physician in the unbroken chain. That means that in the commenter's scenario, we would look to the contractual relationship between the hospital and the clinical laboratory. Absent unusual circumstances, the hospital would not receive *aggregate* compensation that reflects the volume or value of referrals, since the hospital would not be receiving any compensation from the clinical laboratory (assuming the contracted charges for laboratory services are fair market value). If, however, the contracted laboratory charges were less than fair market value, the arrangement could qualify as an indirect compensation arrangement between the referring physician and the clinical laboratory, provided the laboratory knew of, or had reason to suspect, the referring physician's ownership interest in the hospital. Because the payments would not be fair market value, the arrangement could not fit in the indirect compensation arrangements exception.

Comment: A commenter questioned whether the payment of a royalty by an equipment manufacturer to a physician inventor for a device implanted during surgeries performed by the physician inventor is permitted or whether that arrangement would create an indirect compensation relationship with the hospital that purchased the device. The commenter did not think that parties would be able to establish a fair market value for a unique invention.

Response: In the scenario described, the physician inventor would have an indirect compensation arrangement with the hospital in which the surgeries are performed (that is, the DHS entity (hospital) buys the invention from the manufacturer (the intermediary link in the chain), which pays the referring physician a royalty). However, as long as the royalty payment (the compensation link in the chain nearest the physician) is fair market value, the relationship should satisfy the indirect compensation exception at § 411.357(p). We see no reason that one cannot establish a fair market value for royalties, even on unique inventions.

Comment: A number of commenters questioned the discussion in the Phase I preamble that relates to ownership interests and indirect compensation arrangements (66 FR 867 and 870). Specifically, commenters questioned the statement that common ownership of an entity may create an indirect financial relationship between or among the common owners (66 FR 867). One commenter asked us to explain what type of financial relationship was created and when. Other commenters complained that the statement was inconsistent with other statements that common ownership did not create an indirect ownership interest in the common owners (66 FR 870). Several commenters stated that co-ownership of a non-DHS entity should not create any financial relationship between the owners.

Many commenters objected to the statement in the Phase I preamble that the direct compensation exceptions in section 1877 of the Act did not apply to indirect compensation arrangements. According to the commenters, all exceptions should be available,

regardless of whether the financial relationship is direct or indirect, and a DHS entity should be able to take advantage of any exception. A commenter asked whether a prohibited indirect *ownership* arrangement could be excepted if it satisfied the indirect *compensation* arrangement exception.

Response: An ownership or investment interest in an entity creates a financial relationship between the investor and the entity (if the entity has an ownership or investment interest in another entity, the investor may have an indirect ownership or investment interest in that further entity, and so on). Absent unusual circumstances, common owners of an entity will not, by virtue of their common ownership, have ownership or investment interests in each other. However, an indirect compensation arrangement may arise from their common ownership. Since an indirect compensation arrangement requires an unbroken chain of any financial relationships between the referring physician and the DHS entity, ownership or investment interests in a common entity count as links. In other words, common ownership does not itself create an indirect compensation arrangement as defined in § 411.354(c)(2) between co-owners; rather, the ownership or investment interests of the individual investors can satisfy the unbroken chain element of the three-part indirect compensation arrangement definition at § 411.354(c)(2). For example, if a DHS entity and a referring physician jointly own an entity, such co-ownership creates a chain of financial relationships linking the DHS entity to the referring physician: DHS entity—[ownership relationship]—owned entity—[ownership relationship]—referring physician. This chain is created regardless of the nature of the jointly owned entity.

However, even if an unbroken chain exists, the other elements of the definition at § 411.354(c)(2) still need to be satisfied to establish an indirect compensation arrangement (which could then be excepted under the indirect compensation exception, if applicable). In the preceding example, as long as the physician's *aggregate* return on his investment in the co-owned entity (including capital appreciation) did not vary or otherwise take into account the volume or value of referrals to, or other business generated for, the DHS entity (not the common venture), there would be no indirect compensation arrangement. We would expect this to be the case for most joint ownership of non-DHS entities. However, if the jointly owned entity is, for example, an imaging equipment leasing company co-owned by a hospital (the DHS entity) and a referring physician, the co-ownership may create an indirect compensation arrangement, since the physician's aggregate payout from the leasing company may vary with, or otherwise take into account, the volume of imaging business he or she generates for the hospital, assuming that the hospital contracts with the leasing company. Sufficient knowledge of the co-ownership is likely to exist in this circumstance to satisfy the knowledge standard at § 411.354(c)(2)(iii). If an indirect compensation arrangement exists, the relevant inquiry is whether the arrangement fits in the indirect compensation exception. In general, if the rental payment (frequently a ''per click'' payment) by the hospital to the leasing company is fair market value (and the ''per click'' fee does not vary over the term of the agreement) and does not otherwise reflect the volume or value of referrals, the indirect compensation arrangement would be excepted. Such arrangements could still violate the anti-kickback statute.

To address the commenters' concern, we are modifying § 411.354(b)(5)(i) and establishing new § 411.354(b)(5)(iii) and (b)(5)(iv) to make clear that common ownership does not establish an ownership or investment interest by one common investor in another common investor. An indirect ownership or investment interest requires an unbroken chain of direct ownership interests between the referring physician and the DHS entity such that the referring physician can be said to have an indirect ownership or investment interest in the DHS entity. In the preceding example, the referring physician has an ownership interest in the leasing company, but not in the hospital. (If, however, the leasing company owned an interest in a DHS entity, the physician would have an indirect ownership interest in that DHS entity).

If an indirect ownership or investment interest exists, it cannot be excepted under the indirect compensation exception in § 411.357(p). The Phase I preamble may have inadvertently suggested otherwise. We created a new exception for indirect compensation arrangements because none of the statutory compensation exceptions apply by their terms to these arrangements, and we believe that the Congress did not intend a wholesale prohibition on indirect compensation arrangements. The new indirect compensation arrangements exception conceptually follows the statutory exceptions applicable to direct compensation arrangements; in other words, we attempted to make the indirect compensation exception analogous to the existing exceptions. By contrast, the Congress clearly included indirect ownership or investment interests in the definition of ownership or investment interests to which the statute applies (section 1877(a)(2) of the Act) and created exceptions that can apply to those indirect interests. Thus, we have not created a separate exception for indirect ownership or investment interests. However, the definition of an ''indirect ownership or investment interest'' in § 411.354(b)(5)(i)(B) incorporates a knowledge element that should sufficiently limit the universe of prohibited ownership and investment interests so that most remote ownership or investment interests should not trigger the prohibition.

Comment: The indirect compensation exception includes a requirement that the compensation arrangement not violate the anti-kickback statute, section 1128B(b) of the Act (§ 411.357(p)(3)). One commenter wanted clarification as to which arrangement in the indirect compensation arrangement chain this provision referred.

Response: The relevant subject of the inquiry would be the entire arrangement, including all sources of remuneration, between the DHS entity and the referring physician (or group practice where applicable). This would include each link in the chain as well as the overall arrangement viewed as a whole.

Comment: One commenter asked us to clarify that compensation need not be ''set in advance'' under the indirect compensation exception.

Response: The indirect compensation exception does not include a ''set in advance'' requirement.

Comment: One commenter asked that the regulatory text be modified to expressly state that a DHS entity can rely on a certification from a physician that a known indirect compensation arrangement between the physician and another entity is at fair market value not taking into account the volume or value of referrals.

Response: While obtaining a certification may be an appropriate practice in some circumstances, we are not prepared to provide a blanket exception for reliance on certifications.

Comment: While most commenters welcomed the knowledge requirement in the definition of an indirect compensation arrangement in § 411.354(c)(2)(iii), a number of commenters had questions about the conditions under which a DHS entity

has a duty to inquire as to the existence of an indirect compensation arrangement with a referring physician (66 FR 865, 868). One commenter asserted that the knowledge element in the False Claims Act, 31 U.S.C. 3729, did not impose any duty to inquire. According to that same commenter, the preamble discussion seemed to impose a simple negligence standard. Others believed that the ''reason to suspect'' language was inconsistent with other statements that there was no duty to inquire on the part of the DHS entity (66 FR 865).

Response: The knowledge element used in § 411.354(c)(2)(iii) is the same as in the False Claims Act and the Civil Monetary Penalty Law (section 1128A of the Act): actual knowledge or reckless disregard or deliberate ignorance. As we explained in the Phase I preamble (66 FR 864), the phrase ''reason to suspect'' was simply intended as a convention to avoid repetition of the wordier ''actual knowledge or reckless disregard or deliberate ignorance'' standard. There is extensive case law applying the standard in the context of False Claims Act and the Civil Monetary Penalties Law. As stated in the Phase I preamble (66 FR 865), a DHS entity has no duty to inquire whether a referring physician receives aggregate compensation that varies with, or otherwise takes into account, referrals to, or other business generated for, the DHS entity unless facts or circumstances exist such that a failure to follow up with an inquiry would constitute deliberate ignorance or reckless disregard.

Comment: One commenter asked how the knowledge element in the definition of indirect compensation arrangements in § 411.354(c)(2)(iii) relates to the knowledge element in the sanctions sections 1877(g)(3) and (g)(4) of the Act (civil money penalties and exclusions).

Response: The standards are identical. However, the standard would be applied separately for each inquiry. In other words, whether an indirect compensation arrangement exists is a separate inquiry from whether a person has knowingly presented or caused to be presented an improper claim or bill for services or has knowingly entered into a circumvention arrangement. It is likely, however, that some facts would be relevant to both inquiries.

Comment: Several commenters, including a national physician professional association, questioned why the regulations only consider the DHS entity's knowledge. These commenters urged that physicians be protected under section 1877 of the Act if they do not have knowledge of the existence of a prohibited financial relationship.

Response: The statutory scheme already protects physicians from any liability in the absence of actual knowledge, reckless disregard, or deliberate ignorance. The basic statutory sanction is disallowance of claims or bills, which affects the DHS entity, not the referring physician. The new knowledge standards in § 411.354(c)(2)(iii) and § 411.354(b)(5)(i)(B) protect against this otherwise strict liability aspect of section 1877 of the Act. Under section 1877 of the Act, physicians are only subject to sanction under the civil monetary provisions of section 1877(g) of the Act. Those provisions already contain a comparable knowledge element.

Comment: One commenter asked that we clarify the statement in the Phase I preamble at 66 FR 866 that a distribution from an excepted ownership or investment interest is also excepted (and thus does not require recourse to a compensation exception), unless the distribution is a ''sham''. As an example, we posited a limited liability company that was losing money, but nonetheless made a distribution to physician investors after borrowing funds from a bank. The commenter suggested that the appropriate test should be whether the borrowing and distribution were lawful under applicable State law.

Response: We do not believe it is possible to establish a ''bright line'' test for determining whether a particular distribution is a ''sham'' in all cases. Rather, it will depend on the circumstances. The reference to possible ''sham'' distributions was intended to make clear that an excepted ownership or investment interest may not be used to shield payments that are not legitimately related to the ownership or investment interest (such as funneling additional remuneration to physicians as ostensible ''returns'' from an investment entity).

Comment: A physician organization questioned why a referring physician's investment interest in a subsidiary company should be considered an indirect ownership interest in the parent company if the subsidiary has any investment interest in the parent. The commenter thought the test should also require that the referring physician know that the investment interest exists.

Response: Our treatment of investment interests in subsidiaries that, in turn, have investment interests in parent companies is consistent with the general definition of indirect ownership and investment interests, described above. In short, in those circumstances, a physician investor in the subsidiary has an indirect investment interest in the parent. If the parent is a DHS entity, the physician may not refer patients to the parent for DHS and the parent may not file claims for those DHS, unless an exception applies. With respect to indirect ownership or investment interests, however, § 411.354(b)(5)(B) limits liability to those DHS entities that have actual knowledge of, or act in reckless disregard or deliberate ignorance of, the existence of an indirect ownership or investment interest by the referring physician in the DHS entity. In other words, although the physician need not have knowledge to trigger the prohibition, the DHS entity must have some reason to suspect the existence of the indirect ownership or investment interest. This regulatory scheme does not adversely impact physicians who do not have knowledge; non-payment of claims affects only the DHS entity, and imposition of CMPs (the sanction applicable to physicians under section 1877 of the Act) only applies to *knowing* violations.

Comment: One commenter asked us to clarify that, if a referring physician's direct ownership or investment interest in a DHS entity would be protected under an exception, then a similar indirect ownership or investment interest of the physician in that same DHS entity would be excepted.

Response: The commenter is correct. For example, if a physician has an investment interest in a company that, in turn, owns an interest in a hospital in Puerto Rico, the physician's indirect investment interest in the Puerto Rico hospital is excepted under § 411.356(c)(3).

Comment: One commenter questioned our conclusion that stock options and convertible securities create a compensation arrangement, rather than an ownership or investment interest (§ 411.354(b)(3)(ii)). The commenter pointed out that options and securities can be purchased on the open market and are not just received pursuant to employment.

Response: We are persuaded that the commenter is correct and are modifying the definition of ownership or investment interest. The determination as to whether stock options and convertible securities create ownership or investment interests or compensation arrangements depends on the method of acquisition. If the options or securities are originally purchased or received for money or in return for a capital contribution in whole or in part, they will be considered ownership or investment interests. If they are received

as compensation for services, they will be considered compensation until the time that they are exercised, at which time they become an ownership or investment interest.

Comment: One commenter objected to treating loans secured by the property of an entity as an ownership interest in the entity (§ 411.354(b)(1)).

Response: Section 1877(a)(2) of the Act states that an ownership or investment interest may be through equity, debt, or other means. The rule adopted in Phase I for secured loans accommodated the industry's desire for a ''bright line'' rule in this area. However, we agree with the commenter that loans or bonds that are secured by, or otherwise linked to, a particular piece of equipment or the revenue of a department or other discrete hospital operations should not be considered an ownership interest in the whole hospital, but only in a part or subdivision of the hospital. Therefore, the whole hospital exception would not apply.

C. When Does a Physician Make a Referral? (Section 1877(h)(5) of the Act; Phase I—66 FR 871; § 411.351)

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. The regulations define ''referral'' in § 411.351.

In Phase I, we excluded from the definition of ''referral'' services performed personally by the referring physician, but included services provided by a physician's employees, co-workers, or independent contractors. We made clear that referrals can occur in a wide variety of formats—written, oral, or electronic—depending on the particular service. Moreover, referrals can be direct or indirect. Phase I also added a new regulatory exception at § 411.353(e) 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). Under this exception, a claim by a DHS entity may be paid for purposes of section 1877 of the Act if the entity did not know of, or have reason to suspect, the identity of the physician making the indirect or oral referral.

Comments to the Phase I rule on referrals and our responses follow. We are making no major changes to the final rule in this area.

Comment: A number of commenters urged that the definition of referral exclude services that are performed ''incident to'' a physician's personally performed services or that are performed by a physician's employees. According to the commenters, such services are integral to the physician's services. Another commenter suggested that services by licensed professionals that are separately billable should be considered referrals, but services that are only billable as part of a physician's service should not be considered referrals. One commenter suggested the appropriate test should be whether there is significant physician involvement in the provision of a service.

Response: This is an issue about which we specifically solicited comments in the Phase I rulemaking. After careful consideration of the comments and the issues raised, we are adhering to our original determination that ''incident to'' services performed by others, as well as services performed by a physician's employees, are referrals within the meaning of section 1877 of the Act. As discussed in the Phase I preamble (66 FR 871–872), this interpretation is consistent with the statute as a whole. A blanket exclusion for services that are ''incident to'' a physician's services or are performed by a physician's employees would, for example, substantially swallow the in-office ancillary services exception. As a practical matter, although ''incident to'' services and employee services are included in the definition of ''referrals'' for purposes of section 1877 of the Act, many of those referrals will fit in the in-office ancillary services or another exception. This approach to the definition of ''referral'' is consistent with the statutory scheme, which allows productivity bonuses for ''incident to'' services under the in-office ancillary services exception, but not under other exceptions. A ''substantial involvement'' test would be vague and impracticable.

Comment: A group representing allergists and immunologists requested clarification that no referral occurs when a physician prepares an antigen and furnishes it to a patient. Another commenter requested clarification that there is no referral if a physician personally refills an implantable pump. Yet another commenter requested clarification that there is no referral if a physician personally provides durable medical equipment (DME) to a patient.

Response: The commenters are correct. There is no ''referral'' if a physician personally performs a designated health service. However, as noted above, there is a referral if the designated health service is provided by someone else. In many cases, these referrals will qualify for an exception.

Comment: A commenter sought clarification that no referral occurs when a physician personally performs services in a hospital, even if the hospital bills for the services pursuant to an assignment.

Response: If a physician personally performs the services, there is no referral, regardless of whether the physician bills the program directly or another entity bills pursuant to an assignment. However, technical components associated with a physician's personally performed services in a hospital are referrals to which section 1877 of the Act applies (66 FR 871).

Comment: One commenter suggested that the application of section 1877 of the Act to referrals within a physician's medical practice is inconsistent with the Office of the Inspector General's interpretation of the anti-kickback statute, section 1128B(b) of the Act. The commenter suggested that there exists a blanket exception for such referrals under the anti-kickback statute.

Response: As we discussed more thoroughly in the Phase I preamble (66 FR 863), section 1877 of the Act is a separate statute from the anti-kickback statute and must be applied separately. We do not perceive any inconsistency, however, in the treatment of referrals within a physician's medical practice. Like section 1877 of the Act, the anti-kickback statute contains no blanket exception for such referrals (contrary to the commenter's suggestion). Some arrangements may be protected by a statutory or regulatory safe harbor under the anti-kickback statute. (42 CFR 1001.952)

Comment: One commenter requested clarification as to whether services ordered by a nurse practitioner or other licensed professional will be considered to have been referred by a physician in the same group practice.

Response: In determining whether an independent health professional's referral to a DHS entity should be attributed to the physician, all the facts

and circumstances surrounding the referral and the relationship of the independent health professional and the physician must be considered. As we indicated in the Phase I preamble (66 FR 872), our concern is that physicians could attempt to circumvent section 1877 of the Act by funneling referrals through nonphysician practitioners. The relevant inquiry is whether the physician has controlled or influenced the nonphysician's referral such that the referral should properly be considered the physician's referral. We are changing the regulation text accordingly to reflect Phase I preamble language.

Comment: An imaging center commented that physicians do not refer patients to imaging centers, but only order tests. The commenter also stated that many radiology procedures have similar sounding names, and a patient may not know the difference between procedures if he or she is given an oral referral and may unwittingly request a designated health service rather than a service that is not a designated health service. The commenter also stated that, if a patient self-referred to an imaging center, a report would usually be sent to the patient's physician, whether the physician made the referral or not.

Response: Contrary to the commenter's assertion, in many instances physicians do refer patients to entities that furnish imaging services. The determination whether a particular patient has been referred by a particular physician for a designated health service within the meaning of section 1877 of the Act would depend on the facts and circumstances. While we are unclear about the commenter's statement concerning patients, we note that imaging centers are in a position to ensure compliance with section 1877 of the Act by structuring any financial arrangement with a referring physician or immediate family member (or potential referring physician or immediate family member) to fit in an exception.

Comment: A commenter objected to the application of section 1877 of the Act to referrals for hospital and other Medicare Part A services. According to the commenter, the statutory definition of ''referral'' in section 1877 of the Act only applies to items or services ''for which payment may be made under Part B.''

Response: As we discussed in the January 1998 proposed rule (63 FR 1691–1692), section 1877(h)(5) of the Act contains two parts defining ''referral''. The first part, section 1877(h)(5)(A) of the Act, defines a referral to include the request by a physician for an item or service for which payment may be made under Part B, including the request for a consultation with another physician (and any test or procedure ordered by, or to be performed by, or under the supervision of, that other physician). The second part, section 1877(h)(5)(B) of the Act, covers the request or establishment of a plan of care by a physician that includes the provision of a designated health service. Although this second part is not drafted in Medicare-specific terms and could be interpreted to include any designated health service, we interpreted it to cover only DHS that may be covered under Medicare. This would include DHS, such as hospital and home health care services, that are covered under Medicare Part A. We noted in 1998 that we were aware of no rationale for the broader reach of ''referral'' under the first part (a request for any Part B item or service) than the second (a request for a designated health service). We therefore took the position—which we affirm here—that the first part relating to Part B items and services should be limited to referrals for DHS.

Comment: An association for nursing facilities objected to the concept of imputed or oral referrals. According to the association, the regulations will inhibit communications between physicians and patients by restricting a physician's ability to share information about DHS entities freely with patients. The association suggested that the regulations protect any physician who provides patients with accurate information about all appropriate DHS entities and discloses his or her financial relationships with any of those DHS entities.

Response: Section 1877 of the Act embodies a congressional determination to discourage physicians from having financial relationships with DHS entities to which they refer Medicare patients. Neither the statute nor the regulations burdens any physician-patient communications except those communications in which the physician refers to those DHS entities with which the physician has a prohibited financial relationship. Although disclosure of financial interests to patients informs patients of the potential conflict of interest, we do not believe, nor does the statute contemplate, that such disclosure adequately protects against improper referrals or overutilization. If DHS entities and physicians insist on entering into financial relationships, they can protect themselves by structuring the relationships to fit in one of the exceptions. The commenter's proposed exception would swallow the statute and inhibit enforcement.

Comment: A hospital association requested that the ''innocent entity'' exception at § 411.353(e), which protects DHS entities that do not have knowledge of the identity of the referring physician, be expanded to protect DHS entities that do not have knowledge of the existence of a financial relationship with the referring physician. In particular, the commenter was concerned that it may be difficult for DHS entities to know if they have financial relationships with immediate family members of referring physicians.

Response: Knowledge of the existence of a financial relationship is an element of the definition of an ''indirect compensation arrangement''. (66 FR 864) Absent the requisite knowledge, no indirect compensation arrangement is established. This aspect of the definition should address many of the commenter's concerns. We recognize that no comparable knowledge limitation applies to direct financial relationships, including direct financial relationships with referring physicians' family members. The statute clearly contemplates a strict liability bar on direct financial relationships with immediate family members. The exception proposed by the commenter would effectively negate the statutory prohibition.

Comment: A number of commenters asked that we expand the protection of the ''innocent entity'' exception at § 411.353(e) to referring physicians.

Response: As discussed above, referring physicians have no liability under section 1877 of the Act unless they knowingly cause an improper claim or bill to be submitted or knowingly engage in a circumvention scheme.

D. Definition of ''Consultation'' (Section 1877(h)(5) of the Act; Phase I—66 FR 873; § 411.351)

The definition of a ''referral'' at section 1877(h)(5) of the Act includes DHS provided in accordance with a consultation with another physician, including DHS performed or supervised by the consulting physician or any DHS ordered by the consulting physician. Section 1877(h)(5)(c) of the Act creates a narrow exception for a small subset of services provided or ordered by certain specialists in accordance with a consultation requested by another physician. These include requests by a pathologist for clinical laboratory services or pathological examination services; a radiologist for diagnostic radiology services; or a radiation oncologist for radiation therapy. To qualify, the services must be furnished by, or under the supervision of, the

pathologist, radiologist, or radiation oncologist in accordance with a consultation requested by another physician.

In Phase I, we broadly interpreted a ''consultation'' for purposes of determining when an entity with which a pathologist, diagnostic radiologist, or radiation oncologist has an otherwise prohibited financial relationship will be permitted to submit a claim to Medicare for DHS ordered by those physicians (66 FR 873). The ''consultation'' definition in this rule is not intended to, nor does it, apply to other Medicare coverage or payment rules relating to consultations. Moreover, neither section 1877(h)(5)(C) of the Act, nor the definition of ''consultation'' at § 411.351, protects referrals from the physician requesting the consultation to a DHS entity with which the requesting physician has a prohibited financial relationship (66 FR 875 of Phase I preamble).

The Phase I rule adopted the following criteria to identify a consultation for purposes of section 1877 of the Act:

- 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.
- The request and need for the consultation is documented in the patient's medical record.
- 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.
- 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 furnished 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.

We have modified the final rule slightly to accommodate concerns raised by consulting physicians in group practices and by radiation oncologists who furnish services that are ancillary and integral to radiation therapy services. Otherwise, we have made no major changes to the Phase I rule. Comments to the Phase I definition of ''consultation'' and our responses are related below.

Comment: Several commenters questioned the level of supervision required for radiological procedures. Another asked us to affirm that it is sufficient to provide the level of supervision required by the Clinical Laboratory Improvement Amendments of 1988 (CLIA) (Pub. L. 100–578, October 31, 1988). One professional association asked us to clarify that the services need not be supervised by the consulting radiologist, but could be supervised by another physician in the consulting radiologist's group practice.

Response: Nothing in this rulemaking establishes any particular level of supervision for any particular services. The supervision necessary to come within the various exceptions that include a supervision requirement, as well as the definition of ''consultation'' in section 1877(h)(5)(C) of the Act, is the level of supervision otherwise required by the applicable Medicare payment and coverage rules for the specific service (66 FR 872). In § 411.351, the definition of ''referral'' in paragraph (2)(ii) provides that the DHS must be furnished ''by or under the supervision of the pathologist, radiologist, or radiation oncologist.'' We agree that supervision by a pathologist, radiologist, or radiation oncologist in the same group practice as the consulting pathologist, radiologist, or radiation oncologist, respectively, would be appropriate and consistent with the overall statutory scheme and structure. We have modified the regulation accordingly. Where applicable Medicare payment and coverage rules permit, the supervision required under section 1877(h)(5)(C) of the Act may be provided by a physician in the same group practice.

Comment: Section 1877(h)(5)(C) of the Act applies to requests by radiation oncologists for ''radiation therapy.'' Several professional associations representing radiologists and imaging centers requested that we interpret ''radiation therapy'' to include other DHS performed as part of the radiation therapy treatment. According to the commenters, computerized axial tomography (CT), magnetic resonance imaging (MRI) and ultrasound services are often integral and necessary to the provision of radiation therapy. The commenters indicated that in many cases the in-office ancillary services exception at section 1877(b)(2) of the Act and § 411.355(b) will not cover these ancillary services.

Response: We agree with the commenters that the exception for radiation oncologists who request radiation therapy services would fail its intended purpose if it did not also protect necessary and integral ancillary services requested, and appropriately supervised, by the radiation oncologist. We have modified the regulations accordingly. We believe this interpretation effectuates the statutory intent. Moreover, it is consistent with the existing exception in section 1877(h)(5)(C) of the Act for diagnostic radiology services (including CT, MRI, and ultrasound) requested by a radiologist.

Comment: One commenter objected that the consultation definition at § 411.351 requires the consulting physician to produce a written report. According to the commenter, most consulting physicians do not prepare written reports.

Response: Current Medicare rules governing payment and coverage for consultation services require a written report. Moreover, no other commenter, including the many physician associations, objected to the requirement. Since we believe that preparation of a written report is the general practice and consistent with Medicare program rules, and the commenter provided no evidence to support his assertion, we are retaining the written report requirement.

Comment: One commenter requested that we expand section 1877(h)(5)(C) of the Act to cover cardiologists who interpret echocardiograms under financial arrangements that are comparable to those that exist when a radiologist interprets a radiological ultrasound.

Response: An echocardiogram ordered and read by a cardiologist is not a service integral to a consultation by a specialist within the meaning of section 1877(h)(5)(C) of the Act. Under section 1877(h)(5)(C) of the Act, the Congress specifically excepted three narrow categories of physicians who provide specific services pursuant to consultations. The statutory language is very specific and reflects congressional intent that the exception be narrow. We do not have the authority to extend this exception to other specialists. Moreover, there is a substantial difference between a radiologist ordering diagnostic radiology tests pursuant to a request for a consultation and a cardiologist ordering an echocardiogram. In the former situation, the ordering and interpretation of the procedure is the physician's primary specialty; in the latter, the echocardiogram is ancillary to the cardiologist's primary medical practice, the treatment of the heart. In other words, an echocardiogram ordered by a cardiologist is no different from any other designated health service test ordered by other physicians who are not pathologists, radiologists, and radiation oncologists; if the physician has a financial interest in the furnishing of the test, section 1877 of the Act is implicated.

Comment: One commenter stated that some patients self-refer to radiation oncologists for brachytherapy, which is then provided by an entity with which the radiation oncologist has a financial relationship. Since there is no referral from another physician, the consultation exception in section 1877(5)(C) of the Act is not available. Moreover, according to the commenters, the in-office ancillary services exception in section 1877(b)(2) of the Act and § 411.355(b) is often unavailable for these referred services, because patients primarily come to the radiation oncologist or his or her entity only for radiation therapy services. Thus, the services cannot meet § 411.355(b)(2)(i) of the in-office ancillary services exception in Phase I, which required that excepted services be provided in a building where the referring physician (or another member of the referring physician's group practice) furnishes substantial physician services unrelated to the furnishing of DHS or in a centralized building owned or operated by the physician's group practice on a full-time basis. The commenter wondered whether, in these circumstances, it would be appropriate for the radiation oncologist to refer the patient to a urologist who might then refer the patient back to the radiation oncologist.

Response: While we recognize the problem identified by the commenter, the proposed solution would be an inappropriate circumvention. Rather, we believe the changes to the in-office ancillary services exception described in this Phase II preamble in section V.B.4 address the commenter's concerns. These changes should enable most radiation oncologists to provide radiation therapy services to self-referred patients under the in-office ancillary services exception.

III. Physician Compensation Under Section 1877 of the Act (Phase I—66 FR 875)

Section 1877 of the Act provides different exceptions for core physician compensation based on whether the physicians are physicians in a group practice (in connection with the in-office ancillary services and physician services exceptions), employees, or independent contractors. The terms of the statutory exceptions vary. In addition, the Phase I regulations implemented new regulatory exceptions for fair market value compensation paid to employees or independent contractors and compensation for certain academic physicians.

Many comments addressed the issue of physician compensation under section 1877 of the Act. We have provided detailed responses to these comments in the relevant sections of this preamble. However, some issues relate to more than one exception. We summarize those aspects of physician compensation here. This discussion supplements the discussion of physician compensation in section IV of the Phase I preamble (66 FR 875).

A common thread in many of the comments was the observation that physician compensation arrangements are structured in various ways for legitimate reasons and that the form of the arrangement (for example, employment or personal services contract) should not constrain the structure of the compensation (for example, percentage-based compensation, productivity bonuses, or physician incentive plans). In short, many commenters thought that there should be only one set of conditions applicable to physician compensation, and that the same rules should apply to group practices, employees, and independent contractors, as well as under the fair market value and academic medical center exceptions. As explained below, we have tried to minimize the differences, consistent with the statute.

First, the statute permits group practices to divide revenues among their physicians in ways that are very different from the ways other DHS entities are permitted to share revenues with employed or independent contractor physicians. The statute recognizes the differences between physicians in a group dividing income derived from their own joint practice and a hospital (or other entity) paying a physician employee or contractor who generates substantial income for the facility that would not ordinarily be available to a physician group. In effect, group practices receive favored treatment with respect to physician compensation: they are permitted to compensate physicians in the group, regardless of status as owner, employee, or independent contractor, for ''incident to'' services and indirectly for other DHS referrals. This preference is statutory.

Second, outside of the group practice/in-office ancillary services context, we have tried to equalize the most important conditions in the other main physician compensation exceptions (employment, personal services, fair market value, and academic medical centers). Under these exceptions in the regulations, physicians can be paid on a percentage of revenues or collections for personally performed services; receive a productivity bonus on any personally performed services; and participate in a physician incentive plan related to health plan enrollees. These issues are explained in more detail below and in the discussions of the relevant exceptions.

- Percentage compensation arrangements. Commenters representing independent contractors argued that the statute and regulations unfairly restrict the kinds of compensation that independent contractor physicians can receive when compared to the compensation permitted for group practice physicians and employed physicians. In particular, the personal service arrangements and the fair market value exceptions (key exceptions for independent contractors) both contain a ''set in advance'' requirement not present in the statutory group practice definition or employment exception.

In Phase I, we interpreted ''set in advance'' to preclude most percentage compensation arrangements. As discussed below in section IV, we have modified our interpretation of ''set in advance'' to permit some percentage compensation if the methodology for calculating the compensation is set in advance and does not change over the course of the arrangement in any manner that reflects the volume or value of referrals or other business generated by the referring physician. As a result, like their group practice and employee counterparts, independent contractor physicians can receive certain limited forms of percentage compensation under section 1877 of the Act. The same is true for academic physicians under the academic medical centers exception, which also contains the ''set in advance'' requirement.

- Productivity bonuses. A second concern for independent contractors is the availability of productivity bonuses under section 1877 of the Act. While the personal service arrangements, employment, fair market value, and academic medical centers exceptions all restrict compensation that is determined based on the volume or value of DHS referrals, the personal service arrangements, fair market value, and academic medical centers exceptions further restrict compensation that is determined based on the volume or value of ''other business generated.'' Moreover, the employment exception contains a provision that expressly permits productivity bonuses to be paid to employed physicians for services they personally perform. Independent contractor physicians have noted that the statute and regulations make no comparable provision for productivity bonuses for work personally performed by independent contractors.

We partially addressed this issue in the Phase I rulemaking. There, we defined ''referral'' under the statute to include only DHS referrals and to *exclude* personally performed DHS. In short, personally performed work -DHS or otherwise—is not considered a ''referral'' under section 1877 of the Act. (*See* § 411.351.) Thus, a productivity bonus based on personally performed work would not be based on the volume or value of ''referrals.''

The personal service arrangements, fair market value, and academic medical centers exceptions bar compensation that takes into account ''other business generated'' by the referring physician. (In the January 1998 proposed rule, we had proposed adding by regulation a similar restriction to the employment exception, but we are not adopting that proposal.) In Phase I, we interpreted ''other business generated'' to include any health care business, including private pay business (*See* § 411.354(d)(3)). Many commenters construed this definition to encompass personally performed services, including a physician's professional services. That was not our intent, nor do we believe it to have been the intent of the Congress. We have clarified the regulations at § 411.354(d)(3) to reflect that ''other business generated'' does not include personally performed services. It does, however, include any corresponding technical component of a service that is billed by the DHS entity.

The result of these interpretations is that all physicians, whether employees, independent contractors, or academic medical center physicians, can be paid productivity bonuses based on work they personally perform. As discussed above, consistent with the statutory scheme, group practices also may pay physicians in the group, whether independent contractors or employees, productivity bonuses based on ''incident to'' services, as well as indirect bonuses and profit shares that may include DHS revenues, provided the distribution methodology meets certain conditions. As noted above, this additional latitude for group practices is statutory.

• Physician incentive plans and other risk-sharing arrangements. A further perceived inconsistency raised by some commenters involves payments to physicians under risk-sharing arrangements. The statutory personal service arrangements exception contains an express provision allowing independent contractor physicians to be compensated under a physician incentive plan with respect to services provided to individuals enrolled with the entity making the payments. The group practice, employee, fair market value, and academic medical center exceptions do not contain comparable language. Notwithstanding, in Phase I, we established a new regulatory exception at § 411.357(n) for compensation under a risk-sharing arrangement for services furnished to enrollees of a commercial or employer-provided health plan. The new exception applies to payments made directly or through a subcontractor. The new exception is available for all qualifying risk-sharing arrangements, whether the physician is a member of a group practice, employed, an independent contractor physician, or an academic medical center physician. (The prepaid plans exception at § 411.355(c) protects referrals of DHS furnished to enrollees of Medicare and Medicaid managed care plans.) The risk sharing arrangements exception is discussed in Phase I at 66 FR 912 through 914. Also, in this Phase II, we have clarified that payments made by downstream subcontractors may be protected under the physician incentive plan provision of the personal service arrangements exception.

In sum, we have modified the regulations to clarify that independent contractor and academic medical center physicians, like their group practice and employed counterparts, can be paid using certain forms of percentage compensation and can receive productivity bonuses based on personally performed services. Moreover, the regulations permit group practice, employed, and academic medical center physicians, like independent contractors, to be paid under risk-sharing arrangements. We believe these changes substantially address the concerns raised by the commenters.

Despite these modifications, the terms and conditions of the statutory and regulatory exceptions differ with respect to physician compensation. For the convenience of the public, we are providing the following chart briefly summarizing key provisions. Readers are cautioned that the exceptions contain additional conditions not summarized here. (In the chart below, those sections referred to as 1877 refer to section 1877 of the Social Security Act; those sections referred to as 411 refer to § 411 of the Code of Federal Regulations.)

Terms of exception	Group practice physicians [1877(h)(4); 411.352]	Bona Fide employment [1877(e)(2); 411.357(c)]	Personal service arrangements [1877(e)(3); 411.357(d)]	Fair market value [411.357(1)]	Academic medical centers [411.355(e)]
Must compensation be ''fair market value''?	No	Yes—1877(e)(2)(B)(i)	Yes—1877(e)(3)(A)(v).	Yes—411.357(1)(3)	Yes—411.355(e)(1)(ii).
Must compensation be ''set in advance''?	No	No	Yes—1877(e)(3)(A)(v).	Yes—411.357(1)(3)	Yes—411.355(e)(1)(ii).
Scope of ''volume or value'' restriction.	DHS referrals—1877(h)(4)(A)(iv).	DHS referrals—1877(e)(2)(B)(ii).	DHS referrals or other business—1877(e)(3)(A)(v).	DHS referrals or other business—411.357(1)(3).	DHS referrals or other business—411.355(e)(1)(ii).
Scope of productivity bonuses allowed.	Personally performed services and ''incident to'', plus indirect—1877(h)(4)(B)(i).	Personally performed services—1877(e)(2).	Personally performed services—411.351 (''referral'') and 411.354(d)(3).	Personally performed services—411.351 (''referral'') and 411.354(d)(3).	Personally performed services—411.351 (''referral'') and 411.354(d)(3).
Are overall profit shares allowed?	Yes—1877(h)(4)(B)(i)	No	No	No	No.
Written agreement required?	No	No	Yes, minimum 1 year term.	Yes (except for employment), no minimum term.	Yes, written agreement(s) or other document(s).

Terms of exception	Group practice physicians [1877(h)(4); 411.352]	Bona Fide employment [1877(e)(2); 411.357(c)]	Personal service arrangements [1877(e)(3); 411.357(d)]	Fair market value [411.357(1)]	Academic medical centers [411.355(e)]
Physician incentive plan (PIP) exception for services to plan enrollees?	No, but risk-sharing arrangement exception at 411.357(n) may apply.	No, but risk-sharing arrangement exception at 411.357(n) may apply.	Yes, and risk-sharing arrangement exception at 411.357 may also apply.	No, but risk-sharing arrangement exception at 411.357(n) may apply.	No, but risk sharing arrangement exception at 411.357(n) may apply.

General comments on physician compensation and our responses follow.

Comment: Several commenters asked whether a physician's personally performed services would be included as ''other business generated between the parties.''

Response: Personally performed services are not considered ''other business generated'' for purposes of these regulations. This interpretation is consistent with the exclusion of personally performed services from the definition of ''referral'' at § 411.351. The regulations have been revised to clarify that personally performed services do not count as other business generated for the DHS entity. However, the technical component corresponding to a physician's personally performed service would be considered other business generated for the entity.

Comment: A number of exceptions, including the personal service arrangements, office and equipment rental, fair market value, and academic medical center exceptions, require that compensation be ''set in advance.'' Many commenters urged us to abandon our position that percentage compensation arrangements based on fluctuating or indeterminate measures or which result in the seller receiving different payment amounts for the same services from the same purchaser are not ''set in advance'' for purposes of section 1877 of the Act. This was of particular concern to academic medical centers and hospitals, which argued that percentage compensation is commonplace in their physician compensation arrangements. They also pointed out that, under the statute, group practices are not subject to the ''set in advance'' restriction when paying profit shares or productivity bonuses to group practice physicians, nor are employers so restricted in their payments to employed physicians under the employee exception.

Response: As noted in section I above, we delayed until January 7, 2004, the effective date of the last sentence of § 411.354(d)(1), which contained the percentage compensation limitation, so we could reconsider our position without unduly upsetting existing percentage compensation arrangements. Upon further consideration, we are persuaded that our original position was overly restrictive. We are deleting the last sentence of § 411.354(d)(1) as promulgated in the Phase I final rule. Instead, we are modifying the ''set in advance'' definition at § 411.354(d)(1) to clarify that the formula for calculating percentage compensation must be established with specificity prospectively, must be objectively verifiable, and may not be changed over the course of the agreement between the parties based on the volume or value of referrals or other business generated by the referring physician. We are clarifying the regulations text to make clear that compensation is ''set in advance'' if it is set in an agreement before the services for which payment is being made are rendered. As explained above, the different treatment of group practice physicians is part of the statutory scheme. We address the specific circumstances of academic medical centers further in section XII.A below.

Comment: One commenter requested clarification that the set in advance and fair market value tests in § 411.354(d)(1) are separate tests.

Response: The commenter is correct. Compensation must be both ''set in advance'' and ''fair market value.'' We have clarified the regulation by deleting the second sentence of § 411.354(d)(1), which states that a ''set in advance'' payment must be fair market value not taking referrals or other business into account. This concept is already contained in § 411.354(d)(2) and (d)(3), as well as in the individual exceptions.

IV. The ''Volume or Value'' Standards Under Section 1877 of the Act (Phase I—66 FR 876; § 411.354)

Many of the exceptions in section 1877 of the Act include a requirement that 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 Phase I (66 FR 876), we interpreted the statute as permitting time-based or unit-of-service based payments, even when the physician receiving the payment has generated the payment through a DHS referral, as long as the individual payment is set at fair market value at the inception of the arrangement and does not subsequently change during the term of the arrangement in any manner that takes into account DHS referrals. For those exceptions that also restrict payments that take into account ''other business generated between the parties,'' we interpreted the language to mean that the payments also may not take into account any other business, including non-Federal health care business, generated by the referring physician. We interpreted the phrase ''generated between the parties'' to mean business generated by the referring physician. As discussed in the preceding section, we have interpreted ''other business generated'' to make clear that it excludes personally performed services (but includes corresponding technical components).

In short, we interpreted section 1877 of the Act to establish a straightforward test that compensation arrangements should be at fair market value for the work or service performed or the equipment or space leased. We indicated that we would apply our interpretation of the volume or value standard uniformly to all provisions under section 1877 of the Act and part 411 where the language appears. The ''other business generated'' restriction applies only to those exceptions in which it expressly appears.

In Phase I, we also concluded that, in certain situations, compensation arrangements that require physicians to refer to particular DHS entities would be permitted under section 1877 of the Act, if the compensation is set in advance, is consistent with fair market value (without regard to anticipated or required referrals), otherwise complies with an applicable exception, and complies with certain conditions ensuring patient choice, insurer choice, and a physician's independent medical judgement. In response to comments, we are clarifying that this provision, codified at § 411.354(d)(4), applies only to employment, managed care, and

personal services arrangements and only if (i) the required referrals relate solely to the physician's services covered under the arrangement; and (ii) the referral requirement is reasonably necessary to effectuate the legitimate purposes of the compensation relationship.

Comments to the Phase I rule on the ''volume or value'' standards and our responses follow.

Comment: Two commenters requested that we clarify that per-use or per unit-of-service based payment methodologies do not vary with the volume or value of referrals or other business generated within the meaning of the regulations. One of the commenters asked that the regulatory text be modified to make this clear.

Response: Section 411.354(d)(2) and § 411.354(d)(3) clearly state that time-based and unit-of-service based compensation will be deemed not to take into account the volume or value of referrals or other business generated between the parties *as long as* the time-based or unit-of-service based compensation is fair market value for services or items actually provided and the compensation does not vary during the course of the compensation agreement in any manner that takes into account referrals of DHS (or, in the case of § 411.354(d)(3), other business generated by the referring physician, including private pay health care business). We consider per-use payments (also known as ''per click'') payments to be unit-of-service based compensation. When viewed in the aggregate (for example, for purposes of the indirect compensation arrangement definition at § 411.354(c)(2)), unit-of-service based compensation is likely to vary or otherwise reflect the volume or value of DHS referrals or other business generated, as applicable.

In reviewing the regulatory text, we discovered that the language ''for services or items actually provided'' appears in § 411.354(d)(2), but not correspondingly in § 411.354(d)(3); this was a technical oversight and has been corrected. We are also clarifying § 411.354(d)(3) by changing the phrase ''during the term of the agreement'' to ''during the course of the compensation agreement'' to conform to the language used in § 411.354(d)(2). We intended these provisions to be comparable.

Comment: A number of commenters questioned the discussion of the ''volume or value'' standard as applied in the context of the indirect compensation arrangement definition at § 411.354(c) and the indirect compensation arrangements exception at § 411.357(p).

Response: As discussed above at section II.B, the use of very similar language in the indirect compensation arrangement definition, indirect compensation arrangments exception, and the explanations of the ''volume or value'' and ''other business generated'' standards at § 411.354(d)(2) and § 411.354(d)(3) raised unnecessary questions, and we have revised the regulations. For purposes of determining whether an indirect compensation arrangement exists under the definition at § 411.354(c), the inquiry is whether the aggregate compensation to the referring physician reflects the volume or value of DHS referrals or other business generated by the referring physician, even if individual time-based or unit-of-service based payments would otherwise be permissible (that is, the payments are fair market value at inception and do not vary over the term of the agreement). In short, many time-based or unit-of-service based fee arrangements will involve aggregate compensation that varies based on volume or value of services and thus will be ''indirect compensation arrangements'' under § 411.354(c). However, in determining whether these arrangements fit into the indirect compensation arrangements exception at § 411.357(p), which does not include an aggregate requirement, the relevant inquiry is whether the individual payments are fair market value not taking into account the volume or value of referrals or other business generated by the referring physician (and do not change after inception). In other words, the issue is whether the time-based or unit-of-service based fee is fair market value and not inflated to compensate for the generation of business. As noted above, we have revised § 411.354(c)(2)(ii) to clarify the application of the ''volume or value'' standards in § 411.354(d) to indirect compensation arrangements.

Comment: A commenter asked whether a per-use or per unit-of-service based methodology that incorporated decreasing payments as volume increased would be permitted. According to the commenter, these payment methodologies often more accurately reflect fair market value for equipment leases because they spread fixed costs over the term of the lease.

Response: Payments of the sort described by the commenter would be reviewed on a case-by-case basis. There may be circumstances, particularly in the context of equipment leases, in which payments that decrease as volume increases most accurately reflect fair market value and do not take into account the volume or value of referrals or other business generated for purposes of section 1877 of the Act. For example, to the extent the declining payments are fair market value and based on costs, rather than volume, they would be permitted. It is our understanding that these declining payment arrangements primarily occur in the context of equipment leases, where the costs allocable to the equipment decline over time.

Comment: In Phase I, we determined that the volume or value standard would not be implicated by an otherwise acceptable compensation arrangement solely because the arrangement required the physician to refer to a particular provider as a condition of payment, as long as certain conditions were satisfied (66 FR 878). Several commenters objected to permitting employers to require employees to refer to specific DHS entities, notwithstanding the conditions imposed under § 411.354(d)(4). Commenters representing competitor entities that are not part of integrated health systems objected to our position on required referrals, believing themselves to be competitively disadvantaged by our rule.

Response: In limited circumstances, required referrals are a reasonable and appropriate aspect of certain health care business arrangements that should not, in and of themselves, implicate section 1877 of the Act. Notwithstanding, we are persuaded by the commenters that § 411.354(d)(4) is overly broad and could permit required referrals beyond those that are reasonable and appropriate. We are modifying § 411.354(d)(4) to permit only those required referrals that are related to the services a physician performs while acting under his or her arrangement with an entity, such as when an employer requires its employees, when working in their capacity as employees, to refer to employer-affiliated entities or when a managed care organization requires its network providers, when treating enrollees, to refer to other network providers. Thus, § 411.354(d)(4) will apply to employment, managed care, and other contractual arrangements that include required referrals only to the extent those referrals relate to the physician's services that are covered under the contractual arrangement and the referral requirement is reasonably necessary to effectuate the legitimate purposes of the compensation relationship. For example, an entity that employs or contracts with a physician on a part-time basis to provide services to the entity cannot condition the employment or contract—or any compensation under

the employment or contract-on referrals of the physician's private practice business (for example, patients seen by the physician when he or she is not working part-time for the entity). As we cautioned in Phase I, mandatory referral arrangements could still implicate the anti-kickback statute, depending on the facts and circumstances.

Comment: Several commenters asked us to clarify whether the rules set out in § 411.354(d) are requirements or simply ''safe harbors.'' One commenter sought confirmation of the following interpretation: a promotional item offered free of charge to referring and non-referring physicians alike would not violate the ''volume or value of referrals'' standard, even though it would not qualify under § 411.354(d) because it was not sold at fair market value.

Response: The provisions at § 411.354(d) are intended to be ''deeming'' or ''safe harbor'' provisions. In other words, there may be some situations not described in § 411.354(d) where an arrangement does not take into account the volume or value of referrals. The promotional giveaway arrangement described by the commenter might not take the volume or value of referrals into account if the promotional item were offered to all physicians in a community (but not, for example, if the giveaway were limited to all members of a particular medical staff in the community). The arrangement still creates a financial relationship with the referring physicians that would need to comply with an exception. Apart from the non-monetary compensation up to $300 or hospital medical staff incidental benefits exceptions, other potentially applicable exceptions require that compensation be fair market value.

V. Exceptions Applicable to Ownership and Compensation Arrangements (Section 1877(b) of the Act; Phase I—66 FR 879; § 411.355)

A. Physician Services Exception (Section 1877(b)(1) of the Act; Phase I—66 FR 879; § 411.355(a))

Section 1877(b)(1) of the Act specifies that the general prohibition 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. We are making no modifications to the Phase I rule for this exception.

Comment: We received one comment on this provision. A group practice of allergists objected to the inclusion of antigens as an outpatient prescription drug in the final rule. According to the commenter, the provision of antigens is paid as a physician service and is defined as a physician service in the Act. The group asked that we clarify that the provision of antigens is a physician service covered by § 411.355(a) or, in the alternative, that the furnishing of such antigens by a physician in his office is not a referral when he or she personally furnishes the antigens to the patient.

Response: The commenter is correct that providing antigens is a physician service and that the provision of antigens may qualify under the physician services exception at § 411.355(a). Moreover, under the final rule, personally performed services are not considered referrals to an entity. Finally, we note that the provision of antigens will frequently qualify under the in-office ancillary services exception, which also covers physician services that are DHS.

B. In-Office Ancillary Services Exception (Section 1877(b)(2) of the Act; Phase I—66 FR 880; § 411.355(b))

[If you choose to comment on issues in this section, please include the caption ''In-Office Ancillary Services Exception'' at the beginning of your comments.]

A detailed discussion of the in-office ancillary services exception appears in the Phase I preamble. In general, the exception regulates physicians' ordering of DHS in the context of their own practices. The exception is designed to protect the in-office provision of certain DHS that are truly ancillary to the medical services being provided by the physician practice.

The Phase I rule made significant changes to the January 1998 proposed rule, which was generally criticized as overly restrictive. In response to a large volume of comments to the January 1998 proposed rule, we modified the types of services that could qualify for protection under the exception, the level of physician supervision required to qualify, the kinds of physicians that could provide the requisite supervision, and the locations where the services could be provided. While the overwhelming majority of the comments to the Phase I rule strongly supported the changes, some commenters raised concerns about aspects of the Phase I rule, particularly the building requirements. We have simplified the building tests as described in section V.B.4 of this preamble. We have made a number of other minor changes.

As in Phase I, comments and responses to the in-office ancillary services exception are divided into five sections: general comments, covered DHS, supervision requirements, building requirements, and billing requirements.

1. General Comments (§ 411.355(b))

Several commenters objected to the easing of the requirements for meeting the in-office ancillary services exception. In particular, a number of physical and occupational therapy organizations complained that physicians would use the exception to expand the scope of the services they provide within their practices and thus capture additional revenues from their own referrals. These commenters suggested tightening various elements of § 411.355(b).

As we explained more fully in the Phase I preamble (66 FR 880), we believe the final rule reflects the balance that the Congress sought between regulating physician financial relationships and not unduly interfering with the practice of medicine.

2. Covered Designated Health Services (Phase I—66 FR 881; § 411.355(b))

The in-office ancillary services exception in section 1877(b)(2) of the Act covers all DHS except durable medical equipment (DME) (other than infusion pumps) and parenteral and enteral nutrients, equipment, and supplies. In Phase I, we used the statutory authority at section 1877(b)(4) of the Act to expand the scope of DHS potentially included in the in-office ancillary services exception by—

(1) Clarifying that outpatient prescription drugs may be ''furnished'' in the office, even if they are used by the patient at home;

(2) Permitting external ambulatory infusion pumps that are DME to be provided under the in-office ancillary services exception;

(3) Clarifying 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.

We are making no further changes to the DHS covered by the in-office ancillary services exception in Phase II.

Comment: Many commenters approved of the modification made in § 411.355(b)(4) to permit physicians to

furnish crutches, canes, walkers, and manual folding wheelchairs to patients who need assistance in ambulating in order to depart from the physician's office. Several physician organizations commended the modifications, but suggested that the regulatory language should not be specific as to the items covered. An association for DME suppliers expressed concern that the provision of folding manual wheelchairs might discourage patients from receiving more appropriate chairs and suggested we only permit physicians to loan wheelchairs.

Response: It is unlikely that the provision of a folding wheelchair will deter a patient from receiving a more appropriate wheelchair on a long-term basis. In general, with the exception of infusion pumps, the statute expressly excludes DME from the in-office ancillary services exception. Given this statutory directive, we think a specific and limited list of permitted items is appropriate. While we recognize that specificity limits future flexibility, we do not anticipate significant changes in the equipment that might be permitted in the future.

Comment: A DME supplier association asked us to clarify the provision in § 411.355(b)(4)(iv) that physicians or group practices that furnish DME under the in-office ancillary services exception must meet all DME supplier standards in § 424.57(c). Specifically, the commenter asked whether physicians must apply for a supplier number from the National Supplier Clearinghouse. If not, the commenter asked how the DME will be billed to ensure that payment is made at the DME regional carrier (DMERC) rates.

Response: Certification of a physician or physician group as a provider of Medicare services does not authorize that physician or group to bill Medicare for DME. Rather, the physician or physician group must obtain a Medicare certification as a DME Prosthethic, Orthotics and Supplies (DMEPOS) supplier under the DMEPOS fee schedule. Given this payment rule, if a physician or group intends to furnish and bill Medicare for DME under the in-office ancillary services exception, the physician or group would need to obtain a supplier number.

3. Direct Supervision (Section 1877(b)(2)(A)(i) of the Act; Phase I—66 FR 885; § 411.355(b)(1))

The in-office ancillary services exception includes a requirement that the DHS be provided personally by: (i) The referring physician; (ii) a physician who is a member of the same group practice as the referring physician; or (iii) individuals ''directly supervised'' by the physician or another physician ''in the group practice'' (section 1877(b)(2)(A)(i) of the Act). In the Phase I final rule, we interpreted ''directly supervised'' to mean that the supervision meets the physician supervision requirements under applicable Medicare payment or coverage rules for the specific service at issue. We interpreted physicians ''in the group practice'' to include owners of the group practice, employees of the group practice, and independent contractors who, while not ''members of the group,'' contract to provide services to the group's patients in the group's facilities pursuant to an arrangement that 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 (CMS Pub. 14–3), Part 3—Claims Process.

Commenters were generally pleased with the Phase I interpretation of the ''supervision'' requirement, and we are making no significant changes to the rule. Comments to the Phase I rule and our responses follow.

Comment: In the Phase I final rule, we interpreted the ''direct supervision'' requirement in section 1877(b)(1) of the Act to mean that supervision must be provided at the level necessary to meet the Medicare program payment and coverage rules applicable to the particular designated health service being furnished. (See § 411.355(b)(1)(iii)). While several commenters approved of this general approach, they objected to various aspects of the current supervision standards in the payment and coverage rules. For example, several commenters objected to the fact that ''incident to'' services require a very high level of supervision.

Response: This regulation is not the appropriate vehicle for addressing concerns with the supervision requirements in current coverage and payment rules and policies. This regulation addresses supervision of services only insofar as it is relevant to determining whether there is a prohibited financial relationship or a prohibited referral. In that regard, we have simply tied this regulatory scheme to the payment and coverage supervision standards. If those rules change in the future, those changes would similarly apply, prospectively, under these regulations.

Comment: A physician organization asked that we modify the language of § 411.355(b)(1)(iii) from ''*another* physician in the group practice'' (emphasis added) to ''*a* physician in the group practice.'' According to the commenter, the proposed change more clearly reflects that a solo practitioner can furnish DHS through a shared facility in the same building. In the commenter's view, the current language implies that the referring physician must be in a group practice.

Response: The regulatory language cited by the commenter is identical to the statutory language. However, to forestall any confusion, we have clarified the regulatory text to make clear that the language ''another physician in the group practice'' is not intended to mean that the referring physician must be in a group practice. Under the regulations, a solo practitioner may provide DHS through a shared facility, as long as the supervision, location, and billing requirements of the in-office ancillary services exception are satisfied. The supervision requirement referenced by the commenter requires that the services be furnished personally by an individual supervised by:

(1) The referring physician *or,* in the alternative if applicable; (2) another physician in the referring physician's group practice. (Under other sections of the regulation, in-office ancillary services may also be furnished personally by the referring physician or a member of his or her same group practice (§ 411.355(b)(1)(i) and § 411.355(b)(1)(ii))). Thus, a solo practitioner can satisfy the first alternative and provide the necessary supervision himself or herself. (The level of supervision that the practitioner must provide is dictated by the applicable Medicare coverage and payment rules for the service.)

Comment: Several physical therapists and a professional association representing physical and occupational therapists urged us to require personal supervision under § 411.355(b)(1). The professional association specifically requested clarification of the following issues:

- When physical therapists work in a physician office, is the physician required to bill ''incident to'' for those services? Would the standards of Medicare Carrier's Manual 2050 apply?
- Does the level of supervision required in the physician's office differ depending on whether a physical therapist has his or her own provider number?
- Can a group practice own a rehabilitation agency and bill through it? What is the supervision requirement?
- If a group practice owns a comprehensive outpatient rehabilitation facility (CORF), and the physicians who own the practice refer patients for

physical therapy, what are the supervision requirements?

According to the commenter, if physicians can own these kinds of facilities without providing direct supervision, the intent of section 1877 of the Act would be circumvented.

Response: As explained in the Phase I preamble (66 FR 885–886), we have concluded that section 1877 of the Act should not subject physicians to supervision standards that differ from the standards for Medicare payment and coverage for the services provided. Thus, for example, services billed ''incident to'' will require the level of supervision applicable under the ''incident to'' rules. Services that require only low-level general supervision are subject to that lower level of supervision for purposes of section 1877 of the Act. As noted above, these regulations under section 1877 of the Act do not, in the first instance, establish the supervision requirements applicable to particular services, nor are they an appropriate vehicle for doing so.

Similarly, group practices must comply with all existing billing and claims submission rules. These regulations do not change any of those existing rules, nor is this an appropriate place to address other rules. Strictly for purposes of meeting the in-office ancillary services exception, the referred DHS must be billed in a manner that satisfies § 411.355(b)(3) (discussed below).

4. The Building Requirements (Section 1877(b)(2)(A)(ii) of the Act; Phase I—66 FR 887; § 411.355(b)(2))

Under the in-office ancillary services exception, DHS must be furnished to patients in the same building where the referring physicians provide their regular medical services, *or,* in the case of a group practice, in a central building, provided certain conditions are satisfied (section 1877(b)(2)(A)(ii) of the Act). As the Phase I preamble notes, the building requirements help ensure that the DHS qualifying for the exception are truly ancillary to the physician's core medical office practice and are not provided as part of a separate business enterprise.

In the Phase I final rule, we adopted the suggestion of some commenters and defined a ''building'' as 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 and interior parking garages. Under this test, a building can include a skilled nursing or other facility or a patient's private home, provided all other conditions of the in-office ancillary services exception are satisfied. A mobile van or trailer is not considered a building or a part of a building for purposes of section 1877 of the Act (*see* § 411.351). We are retaining the Phase I definition.

We are also retaining without substantive change the Phase I ''centralized building'' test for group practices under the in-office ancillary services exception. To prevent abuse of off-site DHS arrangements, such as part-time MRI or CAT scan rentals, Phase I provided that the group practice must have full-time, exclusive ownership or occupancy of the centralized space. While many commenters objected to this requirement, we are not changing the rule.

We are, however, substantially revising the ''same building'' test under the in-office ancillary services exception to provide greater flexibility and a clearer rule. The same building test in the statute requires that the building be one in which the referring physician (or a member of his or group practice) furnishes physician services unrelated to the furnishing of DHS. In the Phase I rule, we interpreted this standard as requiring the referring physician (or another physician who is a member of the same group practice) to furnish in the same building ''substantial'' physician services unrelated to the furnishing of DHS.

We defined the phrase ''physician services unrelated to the furnishing of DHS'' using a three-part test (the ''Phase I three-part test''). First, ''physician services unrelated to the furnishing of DHS'' was defined to mean physician services that are neither Federal nor private pay DHS, even if the physician services lead to the ordering of a designated health service. Second, we required that the physician services unrelated to the furnishing of DHS that are 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). Third, we added a requirement that the DHS furnished in the building must be furnished to patients whose primary reason for coming in contact with the referring physician (or his or her group practice) is the receipt of physician services unrelated to the furnishing of DHS. The Phase I three-part test was intended so that parties could not use the same building test to circumvent the intent of the statute that the in-office ancillary services exception be limited to services that are truly ''in-office'' and related to the physician's core medical services to his or her patients.

A number of commenters raised concerns about the Phase I three-part test. Some found it unclear or insufficiently ''bright line''. For example, some commenters wanted further guidance on the meaning of the ''substantial physician services'' and ''primary reason'' elements. Commenters representing practitioners in specialty groups that primarily provide DHS, such as radiology or oncology, suggested that the Phase I three-part test was unduly restrictive and precluded them from using the in-office ancillary services exception.

In addition, since publication of the Phase I final rule, we have become concerned that the Phase I three-part test might be susceptible to abuse. In particular, we are concerned that the test would allow physicians to implement arrangements in which DHS are insufficiently tied to the referring physician's core medical practice and are, in essence, separate business enterprises. For example, under the Phase I three-part test, a group practice might lease space at an off-site imaging facility, provide physician services there one day a week, and then provide nothing but imaging services the remainder of the week without any involvement or presence of the group practice physicians at the site. These types of arrangements would not be consistent with the intent of the ''same building'' requirement in the statute, and we had not intended to permit them.

For all of these reasons, we have developed three new, alternative tests that are more straightforward, afford physicians greater flexibility, and are less susceptible to abuse. Only one of the three tests needs to be satisfied to meet the ''same building'' requirement. All three tests are available to solo practitioners, as well as group practices. These new tests replace the Phase I three-part test in its entirety. We believe that virtually all legitimate arrangements that complied with the Phase I three-part test should qualify under one of the new tests, as will many arrangements that had difficulty meeting the Phase I three-part test. Arrangements that may have complied with the Phase I three-part test, but do not meet any of the new tests, should be restructured (or unwound) prior to the effective date of this regulation.

Under the first new test, at § 411.355(b)(2)(i)(A), a designated health service is furnished in the ''same building'' if the building is one in which the referring physician or his or her group practice (if applicable) has an

office that is normally open to their patients at least 35 hours per week, and the referring physician or one or more members of his or her group regularly practices medicine and furnishes physician services to patients in that office at least 30 hours per week. Some of the services must be physician services that are unrelated to the furnishing of DHS, whether Federal or private pay, although the unrelated physician services may lead to the ordering of DHS. This new test should address the concerns expressed by radiologists, oncologists, and others whose practices primarily consist of furnishing DHS. Conceptually, this test generally describes buildings that are the principal place of practice for physicians or their groups.

Under the second new test, at § 411.355(b)(2)(i)(B), a designated health service is furnished in the ''same building'' if the building is one in which the referring physician or his or her group practice has an office that is normally open to their patients at least 8 hours per week, and the referring physician regularly practices medicine and furnishes physician services to his or her patients in that office at least 6 hours per week (including some physician services unrelated to the furnishing of DHS). In this test, services provided by members of the referring physician's group practice do not count toward the 6-hour threshold. In addition, the building must be one in which the patient receiving the designated health service usually sees the referring physician or other members of his or her group practice (if the physician practices in a group practice). Conceptually, this test generally describes a building where a referring physician practices medicine at least 1 day per week and that is the principal place in which the physician's patients receive physician services.

Under the third new test, at § 411.355(b)(2)(i)(C), a designated health service is furnished in the ''same building'' if the building is one in which the referring physician or his or her group practice has an office that is normally open to their patients at least 8 hours per week, and the referring physician or a member of his or her group practice (if any) regularly practices medicine and furnishes physician services to patients at least 6 hours per week in that office (including some physician services unrelated to the furnishing of DHS). In addition, the referring physician must be present and order the designated health service in connection with a patient visit during the time the office is open in the building or the referring physician or a member of his or her group practice (if any) must be present while the designated health service is furnished during the time the office is open in the building. This test requires presence in the building, but not necessarily in the same space or part of the building. Conceptually, this test generally describes buildings in which referring physicians (or group practice members, if any) provide physician services to patients at least 1 day per week and the DHS are ordered during a patient visit or the physicians are present during the furnishing of the designated health service.

Under all of these tests, referring physicians or group practices must have offices in the building that are normally open to their patients a requisite number of hours per week. This standard is not intended to preclude occasional weeks in which the office is open fewer hours (for example, during vacation periods). In addition, under all three tests, referring physicians (or for § 411.355(b)(2)(i)(A) and § 411.355(b)(2)(i)(C), their group practice members) must regularly practice medicine and furnish physician services for a minimum number of hours per week in that office. This standard is not intended to preclude use of the in-office ancillary services exception by physicians or group practices that have unfilled appointment slots, cancellations, or other occasional gaps in the furnishing of services such that they do not actually provide the requisite number of hours of physician services in particular weeks. Rather, they must regularly (that is, in the customary, usual, and normal course) practice medicine and furnish physician services in the building for the minimum number of hours. In addition, consistent with the statute, the tests require that ''some'' of the physician services be unrelated to the furnishing of DHS. We are not requiring any particular threshold amount of physician services unrelated to the furnishing of DHS—''some'' should be interpreted in its common sense meaning. For purposes of establishing compliance with the ''same building'' test, we do not interpret the statute to mean that the physician services must be entirely disconnected from subsequent furnishing of DHS. A stricter interpretation would be inconsistent with the Congress' intent to create an exception that allows physicians to conduct their medical practices in their own offices for their own patients. Moreover, in the context of this exception, we are concerned that a stricter interpretation could potentially adversely impact the delivery of patient care. Therefore, as in Phase I, we are defining ''physicians' services unrelated to the furnishing of DHS'' to mean physician services that are neither Federal nor private pay DHS, even if the physician services lead to the ordering of a designated health service (for example, a physical examination that leads to the ordering of a clinical laboratory test or an x-ray). The provision of interpretations and reads of diagnostic or other tests will not be considered physicians' services unrelated to the furnishing of DHS for purposes of this rule.

Finally, we are making several minor modifications to the building requirements described in the responses to comments below. Moreover, we are revising the regulations to make clear that physicians and group practices may purchase the technical components of mobile services (which are not buildings for purposes of the in-office ancillary services exception) and bill for them pursuant to § 414.50 and the purchased diagnostic testing rules at section 3060 of the Medicare Carriers Manual (as amended or replaced from time to time).

Comments to the Phase I building requirements follow, along with our responses.

Comment: A number of commenters objected to using the post office street address to determine whether DHS are being provided in the same building as the physician's practice. Some commenters suggested various alternative tests, including same ''strip mall'', same ''campus'', ''adjacent buildings'', and several others. One commenter said that the decision as to location of the DHS was frequently controlled by the landlord, not the physician.

Response: Any bright line test in this area will produce aberrant results in some circumstances. Nevertheless, a bright line test for ''same building'' is essential given the significance of the in-office ancillary services exception and, in particular, the significance of the building tests. The post office address test was proposed by commenters to the January 1998 proposed rule (66 FR 888). None of the tests proffered by the Phase I commenters, nor any other test proposed in comments to the January 1998 proposed rule, is sufficiently definite to establish a ''bright line'' test. Any specific listing of types of building configurations would invariably cover some situations but omit others. The postal address test, while imperfect, provides a clear, fair, easily-applied standard. Moreover, as we explained in Phase I (66 FR 889), the easing of the supervision standards under the

exception elevates the importance of meaningful building requirements in ensuring that the in-office ancillary services exception protects those DHS that are truly ancillary to the physician's office practice and not those that are essentially a separate business enterprise.

Comment: A number of commenters objected to the exclusion of services furnished in mobile vans or other facilities not permanently affixed to the building. These commenters stated that mobile equipment was cost-efficient and offered convenience to patients, especially in rural areas. One commenter asked why we were prohibiting physicians from purchasing the technical component of these mobile services. Another commenter asked that we clarify that mobile equipment that can be moved into a building can qualify for the in-office ancillary exception.

Response: As we stated in the Phase I preamble (66 FR 891), part-time rentals of DHS equipment are precisely the arrangements that section 1877 of the Act was designed to restrict. Mobile equipment that is placed inside a building qualifies for the exception if it is located and used inside the ''same building'' (that is, not in the garage or an internal loading dock or parking garage). (In this regard, we have modified the rule consistent with our original intent in Phase I, to clarify that internal loading docks are not considered the ''same building''.) The special circumstances of rural area providers are addressed by the rural exception at section 1877(d)(2) of the Act (§ 411.356(c)(1)), discussed in more detail below at VII.B.

It was not our intent to prohibit physicians and group practices from purchasing diagnostic tests under the purchased diagnostic testing rules § 414.50 and in section 3060 of the Medicare Carriers Manual (Reassignment) (as amended or replaced from time to time). Upon further review, however, we have concluded that the Phase I rule did not adequately provide for the furnishing of those services. The purchased diagnostic tests rules permit physicians or groups to bill Medicare for purchased diagnostic tests, as long as they do not mark up the charge for the test, and they accept the lowest of the physician fee schedule, the physician's actual charge, or the supplier's net charge to the physician or group as payment in full for the test, even if assignment is not accepted. Having considered various options for addressing this issue in this interim final rule with comment period, we have determined that the best approach would be to exclude physicians (or group practices) who bill for purchased diagnostic tests in accordance with Medicare rules from the definition of ''entity'' under § 411.351, which otherwise defines an ''entity'' as the party that bills Medicare for the DHS. Conceptually, this approach reflects the substance of a purchased diagnostic test transaction, in which another entity actually furnishes the test, but passes the responsibility for billing Medicare on to the physician, who is precluded from profiting.

Comment: In response to comments to the January 1998 proposed rule, the Phase I rule included a special provision under the in-office ancillary services exception for services provided by physicians (including services provided by qualified persons accompanying those physicians) whose principal medical practice involves treating patients in their private residences (§ 411.355(b)(6)). Under § 411.355(b)(6), the ''same building'' test is met if DHS are provided in a private home contemporaneously with a physician service that is not a designated health service. A private home does not include a nursing, long-term care, or other facility or institution. We solicited comments as to whether additional special rules might be appropriate. Two commenters urged us to expand the exception to cover more locations and to ease the other restrictions so that more physicians could qualify. One commenter objected to the requirement that the physician's principal medical practice consist of home care; the commenter stated that the requirement was unnecessary and limited the applicability of the exception. The commenter suggested that a physician should qualify if his or her medical group spent more than 50 percent of the group's practice time outside of the office setting, including travel time, preparation, and follow up. The same commenter asked us to clarify that the requirement that the services be contemporaneous does not require the physician's presence during the furnishing of the designated health service.

Response: While we understand that relaxing the standards would result in more physicians qualifying under the special rule for home care physicians, the commenters apparently misunderstood our intent. Simply put, we intended to create a narrow rule for a particular group of specialty physicians who otherwise would generally be precluded from using the in-office ancillary services exception because they would have no ''building'' that could qualify as the place in which they furnish DHS under the exception. Restricting the special rule to physicians who principally practice in the home care field is designed to insure that the patient's home is, in fact, the physician's real locus of practice. The special rule is specifically limited to private residences, not nursing or other facilities.

The commenter is correct that the contemporaneous requirement does not require the physician to be present throughout the furnishing of the designated health service. However, the physician must be present in the patient's private residence at the inception of the designated health service. This presence requirement is necessary to limit the exception to services truly furnished as part of the referring physician's ''office'' medical practice.

Comment: One commenter asked us to clarify that residences in independent living facilities and assisted living facilities qualify as private homes. The commenter observed that some assisted living facilities have examination rooms that physicians use to treat residents. The commenter asked whether DHS furnished in such rooms would qualify as services furnished in the patient's residence.

Response: We agree that private residences in independent living facilities and assisted living facilities should qualify as private homes for purposes of the special rule. We will consider a residence in an independent living facility or assisted living facility to be ''private'' if the patient occupies the premises as his or her residence, through ownership or lease (by the patient or a relative or friend on the patient's behalf), and has the right to exclude others from the premises. The use of common examination rooms in those facilities is more problematic. For example, in some cases, assisted living facilities are conjoined with nursing facilities, and a case-by-case evaluation would be required to determine whether a shared examination room is part of the nursing facility or the assisted living facility. On balance, we prefer a clear rule in this area, and thus would not consider a common examination room to be a private residence.

Comment: Many commenters objected to the requirements in the ''same building'' test that (i) the referring physician (or another physician in his or her group practice) furnish substantial physician services unrelated to the furnishing of DHS in the same building (§ 411.355(b)(2)(i)(A)); and (ii) those unrelated services represent the full range of services that the referring physician routinely provides (or, for a

referring physician in a group practice, the full range of services that the physician routinely provides for the group practice) (§ 411.355(b)(2)(i)(B)).

These commenters described these requirements as vague, both with respect to the quantity of services that are not DHS that must be performed in the building and the kinds of services that are not DHS that qualify. Moreover, the commenters objected to the requirement in § 411.355(b)(2)(i)(C) that the receipt of DHS not be the primary reason the patient comes into contact with the referring physician or the group practice. Commenters pointed out that the latter requirement was particularly problematic for physicians in certain specialties, such as radiology and oncology, where much of their practice consists of furnishing DHS. Commenters suggested a number of replacements for the term ''substantial,'' including ''any,'' ''more than incidental,'' ''10 percent,'' and ''significant,'' and requested clarification as to the application of the ''primary reason'' test to oncology and radiology practices.

Response: The statute requires that the DHS be furnished in the ''same building'' where the referring physician (or a member of his or her group practice) furnishes ''physicians'' services unrelated to the furnishing of DHS.'' The requirements referenced by the commenters were intended to ensure that DHS furnished under the in-office ancillary services exception are truly ancillary to the delivery of physician services and that the exception is sufficiently circumscribed to prevent abuse, particularly since the exception, as revised in the Phase I rule, permits certain shared facilities.

As explained in detail above, we agree that the Phase I three-part test did not adequately take into account the nature of certain speciality practices, such as oncology and radiology, that inherently involve the furnishing of substantial DHS and relatively limited physician services unrelated to the furnishing of DHS. We have addressed those concerns, among others, by replacing the Phase I three part test with three new tests, one of which applies to any building in which a physician's practice (whether solo or group) is normally open for business 35 hours per week and in which the physician (or, if applicable, members of his or her group) regularly practices medicine and furnishes physician services to patients at least 30 hours per week. Some part of the physician services must be physician services unrelated to the furnishing of DHS, even if the physician services lead to the ordering or furnishing of DHS. We are no longer requiring that the physician services unrelated to the furnishing of DHS be ''substantial.'' We believe that radiology, oncology, and other specialty practices that primarily provide DHS to their patients will be able to meet the lower threshold of providing ''some'' unrelated services in the revised regulations.

We note that interpretations or reads of tests are generally DHS and will not count as physician services unrelated to the furnishing of DHS.

Comment: One commenter asked us to clarify that, in § 411.355(b)(2)(i)(B) of Phase I, the physician services unrelated to the furnishing of DHS can be provided by the referring physician or by another physician who is a member of the same group practice.

Response: The commenter is correct, although the test will be superseded as of the effective date of these regulations by the new building tests described above. However, for referrals and claims filed during the period between the effective date of Phase I (January 4, 2002) and the effective date of Phase II, the Phase I building test would apply.

Comment: Several commenters suggested that the Phase I three part test in § 411.355(b)(2) should count only DHS payable by Medicare or Medicaid.

Response: We disagree. The purpose of the same building test is to determine the location where the physician or group practice is practicing medicine so as to ascertain whether the DHS are truly ancillary to the referring physician's core medical practice and furnished in the same building as the referring physician's (or his or her group's) core medical practice. Consistent with this purpose, physicians should be providing in the building that is the subject of the inquiry at least some physician services that are unrelated to the furnishing of any DHS, whether Federal or private pay. In other words, the fact that a physician or group provides private pay x-rays in a building is insufficient to establish that the provision of DHS is ancillary to the physician's or group's core office medical practice. We have incorporated this concept in the three new same building tests described above.

Comment: Several commenters asked us to clarify that the primary purpose element of the Phase I three-part test does not preclude a referral of a patient to a group practice or to a physician for DHS from a physician who is not in the group.

Response: Unless the outside physician has a financial relationship with the group or physician to whom the patient is referred, a referral for a designated health service to a physician or group practice by an outside physician would not implicate section 1877 of the Act. As noted previously, we are eliminating the primary purpose element in the new Phase II regulations.

Comment: Many commenters commended our decision to permit shared facilities in the same building provided the parties comply with the supervision, location, and billing requirements of the in-office ancillary services exception. Several commenters urged us to permit shared facilities that are not located in the same building. Many commenters objected to the requirement in the centralized building test (66 FR 889) that the building be owned or leased by the group practice on a full-time basis and used exclusively by the group practice, thus excluding shared off-site facilities under the centralized building test. Some commenters observed that the full-time, exclusive use requirement unduly favored large group practices over small ones.

Response: We are not persuaded to change the regulations regarding shared off-site facilities. As discussed in greater detail in the Phase I preamble (66 FR 888), we believe that section 1877 of the Act is directed at arrangements that enable physicians to profit from referrals to free-standing DHS that are not ancillary to their medical practices. For the reasons given in the Phase I preamble (66 FR 888–893), we believe the final Phase I regulation strikes the proper balance with respect to shared facilities.

Comment: Several commenters objected to our decision to permit group practices to have more than one centralized facility.

Response: We discern no reason to restrict group practices to a single centralized building, nor does the statutory language compel that result. We believe the requirement that any centralized building must be owned or leased 24 hours per day, 7 days per week, for at least six months, and used exclusively by the group practice should adequately protect against abuse.

5. The Billing Requirement (Section 1877(b)(2)(B) of the Act; Phase I—66 FR 893; § 411.355(b)(3))

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 that 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. In addition, under the Phase I rule, the group practice may bill if the physician is a ''physician in the group practice'' under the group practice's billing number. (This interpretation corrected a statutory anomaly and conformed the billing requirement to the corresponding statutory supervision requirements.) As with the other requirements in the in-office ancillary services exception, the billing requirements serve to directly associate the ancillary services for which self-referrals will be permitted with the physician's core medical practice. The billing requirement is a threshold rule for determining whether a designated health service furnished by a physician practice may be billed or claimed. The bill or claim itself must still comply with all other applicable billing and claims submission laws, regulations, and policies.

Comment: One commenter asked that we interpret the billing requirement to permit a shared facility to bill under its own billing number.

Response: We decline to adopt the commenter's suggestion. The billing arrangement proposed by the commenter clearly falls outside of the statutory requirement. Moreover, the proposal would undermine the role of the billing requirement in ensuring that the excepted furnishing of DHS closely relates to a physician's core medical practice.

Comment: The same commenter interpreted the final regulations as permitting physicians to bill ''incident to'' for DHS that only require general supervision, even though the ''incident to'' billing rules require ''direct supervision''. Another commenter asked whether physical therapy services had to be directly supervised by a physician if the services are billed by a physician or a group practice.

Response: The commenter misapprehends the scope of these regulations. The regulations under section 1877 of the Act do not establish or authorize any billing practice that is not in full compliance with other applicable Medicare coverage and payment rules. The billing requirement set forth in these regulations is for the purpose of determining whether a designated health service fits within the in-office ancillary services exception such that, as a threshold matter, a claim or bill for the service may be submitted at all by a physician or group practice. If a claim or bill may be submitted, it must still comply with all applicable Medicare payment and coverage rules (including, for example, the ''incident to'' rules).

Comment: A professional association for physical therapists asked the following questions:

- If a physical therapist employed by a physician practice furnishes services, bills using the physical therapy provider number, and then reassigns payment to the group practice, are the billing requirements met?
- Would a rehabilitation agency, which is owned by physicians, and has its own billing number, be considered a wholly owned entity for billing purposes?
- Can physicians own a physical therapy private practice office and bill through the provider number of that office?
- When a designated health service is billed by an entity wholly owned by a group practice, do the Medicare conditions of participation applicable to the wholly owned entity determine the applicable level of supervision or do the supervision requirements related to group practice billing apply?

Response: With respect to the first question, we assume it is directed at services provided after March 1, 2003, as prior to that date, services by an employed physical therapist had to be billed as ''incident to'' services. Billing by a physical therapist under his or her own billing number does not satisfy the billing requirement of section 1877(b)(2)(B) of the Act, which requires that the service be billed by the performing physician, the supervising physician, the group practice *using a number assigned to the group*, or an entity wholly owned by the performing or supervising physician or the group practice. However, if the physical therapist reassigns his or her right to payment to the group, and the group bills using its own billing number (with the physical therapist's number indicated on the bill), then the billing requirement would be met. As to the second and third questions, the rehabilitation facility or physical therapy practice would be considered wholly owned if it is owned 100 percent by the physician group practice; 100 percent by the performing physician; or 100 percent by the supervising physician. A wholly owned entity can bill using its own billing number (*See* § 411.355(b)(3)(iv)). With respect to the last question, the supervision must meet the requirements applicable to the billing submitted to the Medicare program.

C. Group Practice Definition (Section 1877(h)(4)) of the Act; Phase I—66 FR 894; § 411.352)

[If you choose to comment on issues in this section, please include the caption ''Group Practice Definition'' at the beginning of your comments.]

The Phase I rulemaking addressed the definition of a ''group practice'' under section 1877(h)(4) of the Act (the regulatory definition appears at § 411.352). Most commenters commended the changes made in Phase I. In particular, the final rule incorporated significant additional flexibility for group practices. We are making no major changes to that definition in Phase II. We have modified the ''primary purpose'' test to make clear that the relevant inquiry is the current operation of the group practice and have eliminated the requirement for centralized utilization review under the ''unified business'' test. We have revised the special rules on profit shares and productivity bonuses to make clear that the ''safe harbors'' are deeming provisions. We have also made certain modifications to address particular concerns raised by group practices operating across State lines, group practices employing part-time physicians, and existing group practices adding new members.

Comments on the Phase I group practice definition and our responses follow.

Comment: Two commenters asked us to clarify the application of the single legal entity rule in § 411.352(a) to a group practice that has offices in more than one contiguous State and thus operates through ''mirror'' entities with identical ownership and governance.

Response: As long as both entities are absolutely identical as to ownership, governance, and operation, the States in which the group is operating are contiguous, and the group uses multiple legal entities solely to comply with jurisdictional licensing laws, we will consider the two entities to be a single legal entity. We have modified the regulation accordingly. We note that, as a whole, the States in which the group operates need to be contiguous, but each State need not be contiguous with every other State.

Comment: A number of commenters objected to the requirement in § 411.352(a) that the single legal entity must be formed primarily for the purpose of being a physician group practice. According to the commenters, the purpose at the time of formation is irrelevant, as long as the entity is currently operated primarily as a physician group practice.

Response: We agree with the commenters that the relevant inquiry should be whether the group currently is operating primarily for the purpose of being a physician practice. We have

revised the rule accordingly. We want to iterate, however, that an entity that has a substantial purpose other than operating a physician group practice, such as operating a hospital, will not qualify. Thus, hospitals that employ two or more physicians are not physician ''group practices'' for purposes of section 1877(h)(4) of the Act and are not eligible under the in-office ancillary services exception. A hospital may own or acquire a separate physician group practice that qualifies under section 1877(h)(4) of the Act and would be eligible under the in-office ancillary services exception.

Comment: One commenter asked us to clarify that a group practice can meet the definition at § 411.352 if it is owned by a medical group, as long as the medical group that owns it no longer provides medical services. Some commenters asked us to reconsider our position that the single legal entity requirement is not met if a group practice is owned by another functioning medical group.

Response: Under § 411.352(a), defunct medical groups no longer providing medical services can own or operate a medical practice that qualifies as a ''group practice'' for purposes of section 1877(h)(4) of the Act. In this regard, we have clarified the third sentence in § 411.352(a) to read: ''The single legal entity may be organized or owned (in whole or in part) by another medical practice, provided that the other medical practice is not an operating physician practice (and regardless of whether the medical practice meets the conditions for a group practice under this section).'' We stand by our determination that a group practice owned by other functioning medical groups cannot meet the single legal entity requirement; to conclude otherwise would insufficiently protect against sham group practice arrangements or physicians forming groups substantially for the purpose of profiting from DHS referrals.

Comment: Several commenters objected to our determination that, for purposes of section 1877(h)(4) of the Act, a hospital cannot form a group practice of its employed physicians without organizing them into a separate entity.

Response: As we explained in the Phase I preamble (66 FR 898–899), treating a ''group'' of hospital-employed physicians as a ''group practice'' for purposes of section 1877(h)(4) of the Act would stretch the meaning of a ''group practice'' too far. It would enable hospitals that employ two or more physicians to use the in-office ancillary services exception inappropriately to protect virtually all inpatient and outpatient hospital services. We do not believe that the Congress intended the in-office ancillary services exception, which focuses on services provided by physician practices, to be used to exempt hospital services from the scope of section 1877 of the Act. Under the ''group practice'' definition, a hospital may legally organize, own, or operate a group practice that is a separate legal entity; however, the hospital itself (or other facility or entity the primary purpose of which is something other than the operation of a physician group practice) cannot be a group practice for purposes of section 1877(h)(4) of the Act. Hospitals that employ physicians can appropriately structure their arrangements with physicians to fit in the employment exception.

Comment: Some commenters urged that a foundation-model physician practice should be allowed to qualify as a ''group practice'' under section 1877(h)(4) of the Act.

Response: It is our understanding that ''foundation-model'' physician practices exist in a variety of forms, depending on jurisdiction and other factors (including, for example, whether a particular State bars the corporate practice of medicine). Given the variety of foundation-model arrangements, it would be difficult to craft a uniform definition of a foundation-model group. Moreover, the personal services arrangements exception corresponds more closely to the contractual arrangements that typically establish foundation-model physician practices. Indeed, the legislative history reflects congressional intent to apply the personal services exception to foundations. (H.R. Conf. Report No. 103–213 at 814 (1993) (''The conferees intend that this exception would apply to payments made by a non-profit Medical Foundation under a contract with physicians to provide health care services and which conducts medical research [sic].'')) Thus, as explained in Phase I (66 FR 897), foundation-model practices should use the personal service arrangements exception. We believe the modifications we are making to that exception in this Phase II will address the commenters' concerns and offer adequate protection for DHS referrals within most foundation-model group structures. This determination does not preclude particular foundations or foundation-model practices that, in fact, meet the single legal entity test from qualifying as a group practice and using the in-office ancillary services exception.

Comment: Section 1877(h)(4) of the Act requires that a ''group practice'' consist of ''2 or more physicians.'' Several commenters asked that we clarify whether the ''2 or more physicians'' test is met if a group consists of one full-time physician and one part-time employed physician or independent contractor physician. The commenters interpreted the Phase I preamble as requiring that the second physician be a full-time, rather than part-time, employee. The commenters viewed this requirement as conflicting with § 411.352(b), which requires that the group have two physicians who are ''members of the group'' (as defined in § 411.351), whether as employees or direct or indirect owners. The commenters pointed out that, under the ''members of the group'' test, a physician with only token ownership in the group could qualify as a member of the group. Given this relatively expansive test for ''members of the group,'' the commenters discerned no reason for the ''2 or more physicians'' test to require that the second physician be a full-time employee.

Response: The list of examples of acceptable group practice structures in the Phase I preamble (66 FR 897) is illustrative, not exhaustive, of the kinds of arrangements that could qualify under the group practice definition. We agree with the commenters' interpretation that the physicians counted for the ''2 or more physicians'' test can be part-time employed physicians. The group practice would still need to satisfy the remaining conditions of § 411.352. This interpretation is consistent with the language of § 411.352(b), and we are therefore making no textual change.

However, with respect to independent contractor physicians, we are not expanding § 411.352(b) to permit them to fulfill the ''2 or more physicians'' test. Independent contractors are not group practice ''members'' under § 411.351. A large number of commenters to the January 1998 proposed rule, as well as commenters to the Phase I rule, opposed including independent contractors in the definition of ''member of the group'' because of concerns about meeting certain of the statutory group practice tests (66 FR 900). Accordingly, we excluded those physicians from being group practice members, but included them in the definition of ''physicians in the group practice,'' a resolution consistent with the comment letters and the statutory language. To count non-member physicians in the ''2 or more physicians'' test would effectively expand the group practice definition to groups with *no* physician members (that is, groups with 2 or more independent contractors), a result inconsistent with the statute. That expansion would

enable physicians to nullify the various tests in section 1877(h)(4) of the Act related specifically to group practice members. For example, the ''75 percent physician-patient encounters'' test in section 1877(h)(4)(A)(v) of the Act, which requires that members of the group conduct at least 75 percent of the group practice's physician-patient encounters, would be meaningless.

Comment: One commenter asked that we reconsider permitting group practices to elect to treat independent contractors as members for purposes of determining compliance with §§ 411.352(d) and (h) (the 75 percent ''substantially all'' and ''75 percent physician-patient encounters'' tests, respectively).

Response: We are not persuaded that a change is warranted or feasible. As we indicated in the Phase I preamble (66 FR 900), an election process would impose an administrative burden on groups without significant corresponding benefit, given the overall design of the final ''group practice'' definition and in-office ancillary services exception. Moreover, no mechanism currently exists to administer or monitor that election, and we do not believe most physician groups would favor creation of an election reporting requirement. Given the lack of an election reporting mechanism, any election provision would have to be an alternative to the existing test, making enforcement difficult. In short, an election procedure is impracticable. A single ''bright line'' test is preferable.

The ''substantially all'' and ''75 percent physician-patient encounters'' tests are intended to measure whether a group practice functions as an integrated whole. If a group is unable to take advantage of the benefits afforded group practices under the statute because of the use of independent contractor physicians, it can integrate the physicians into the group as employees or owners or restructure to comply with another exception. As noted above, a substantial number of commenters to the January 1998 proposed rule (as well as commenters to the Phase I rule) asked that independent contractors *not* be considered members of the group to ease compliance with the group practice definition. In response to those original comments, we excluded independent contractors as members of the group, while including them as ''physicians in the group practice'' where that term is relevant.

Comment: Section 411.352(d)(5) establishes a 12-month ''grace period'' for start-up groups to come into compliance with the group practice definition. The grace period does not apply when an existing group adds a new member (for example, a new employed physician) or reorganizes. Several physician professional associations commented that application of this rule could cause group practices that add new physician members to lose their group practice designations for a period of time after the new physician joins, because the new physician could skew the ''substantially all'' test (which requires that at least 75 percent of patient care services provided by group members be provided through the group and billed under a number assigned to the group, with the amounts received treated as revenues of the group). According to the associations, there are frequently delays in obtaining Medicare billing numbers for newly employed physicians. Moreover, the associations believe that the current rule discourages bringing younger physicians into existing practices.

Response: Our intent in excluding existing group practices that add new members from the broad grace period under § 411.352(d)(5) was to ensure that groups would not, in essence, secure perpetual grace periods through the continuing addition of new physicians. In many cases, the addition of new physicians, such as physicians with established medical practices, to an existing group practice will not impair the group's ability to meet the group practice definition. We concur with the commenters, however, that some accommodation should be made for group practices that add new members, as long as the group practice otherwise continues to fit squarely in the definition. We are therefore creating § 411.352(d)(6) to provide that, if the addition of a new member who has relocated his or her practice to an existing group practice would cause the group practice to fall out of compliance with the requirements of the ''substantially all'' test at § 411.352(d)(1), the group practice will have 12 months to come back into full compliance, provided that—

(i) For the 12-month period, the group practice is fully compliant with the ''substantially all'' test if the new member is not counted as a member of the group for purposes of § 411.352; and

(ii) The new physician's employment with, or ownership or investment interest in, the group practice is documented in writing before commencement of the new employment or ownership.

We have limited this rule to new members who have relocated their medical practices (as defined in the revised physician recruitment exception) to prevent abuse by groups that add new members through mergers with other groups. We are retaining the portion of the current rule that precludes group practices that reorganize from taking advantage of the startup or new member grace periods; if a group practice wants to use the exceptions available to group practices, the group should reorganize in accordance with the group practice definition.

Comment: One commenter asked that we clarify whether leased physician employees can be considered employees (that is, members) of a group practice. A commenter noted that the new rules for coverage of ''incident to'' services treat leased employees as employees and suggested that the same treatment should extend to determining whether a leased physician employee is a member of a group practice.

Response: To the extent that a leased employee is a *bona fide* employee of the group under IRS rules, that leased employee physician would be considered an employee of the group practice, and therefore a member of the group. Group practices bear the burden of establishing the necessary criteria for employment. We have clarified the definition of ''member of the group'' accordingly.

Comment: The definition of ''physician in the group practice'' in § 411.351 provides that referrals from an independent contractor who is a physician in the group practice are subject to the prohibition on referrals under section 1877 of the Act and that the group practice is subject to the limitation on billing for referred services. A commenter asked us to clarify that this provision means that independent contractor referrals for DHS within the group implicate section 1877 of the Act to the same extent that the group member's referrals are implicated and not that DHS referrals cannot be made.

Response: The commenter is generally correct. Like group practice members, an independent contractor who is a physician in the group practice can make referrals of DHS to the group practice, as long as an exception applies to those referrals. There is no group practice exception as such. In general, group practices rely on the in-office ancillary services exception for referrals within a group. Referrals from a ''physician in the group practice'' can be covered by this exception if all of the conditions in the exception are met. Alternatively, referrals from an independent contractor to a group practice for DHS could be excepted

under the personal service arrangements or fair market value exceptions.

Comment: A commenter representing free clinics requested modifications to the ''substantially all'' and ''full range of services'' tests to accommodate the special circumstances of volunteer physicians providing free patient care services at free clinics. The commenter suggested that these services be treated comparably to services provided in Health Professional Shortage Areas (HPSAs) under § 411.352(d)(4). The commenter explained that the modifications are necessary to prevent section 1877 of the Act from acting as a disincentive to providing free clinic services. Specifically, the commenter recommended that § 411.352(c) be amended to exclude volunteer patient services provided by physicians in HPSAs from the ''full range of services'' test and that a new subparagraph be added to § 411.352 to create a special rule for volunteer patient services provided at a clinic operated by a governmental entity or agency or by a tax-exempt entity.

Response: We do not believe, nor was it our intent, that donating volunteer services to patients at free clinics or similar facilities should adversely impact a group practice's ability to qualify as a ''group practice'' within the meaning of § 411.352. The ''full range of services'' test at § 411.352(c) measures whether a member of a group practice provides substantially the same scope of patient care services within the group context as he or she provides outside the group context. The test does not require absolute identity of services. To the extent a physician donates the same scope of patient care services at a free clinic (that is, outside the group) as he or she provides as part of the group practice (that is, inside the group), there should be no problem meeting the ''full range of services'' test. To the extent the physician donates patient care services in a free clinic that are different from those he or she provides for the group, we would not expect that the donated patient care services would prevent the group from meeting the ''substantially all'' requirement. To the extent our reference in the Phase I preamble (66 FR 903) to volunteer activities involving treating indigent patients suggested otherwise, we withdraw the reference.

With respect to the ''substantially all'' test at § 411.352(d), a group practice member's donation of volunteer services to a free clinic generally should not impair the group's ability to meet the 75 percent threshold. In those situations where it may, we see no reason that arrangements for the donated services could not be structured such that the services are donated to the free clinic through the group. So structured, we would consider donated patient care services to a free clinic (or comparable charitable enterprise) to be ''billed'' through the group, notwithstanding that no actual bills are sent or collected.

Comment: A commenter representing physicians in group practices with members who provide substantial academic medical services sought relief similar to the preceding comment for time spent by physicians providing academic patient care services. The commenter explained that a medical school physician group would have difficulty meeting the ''substantially all'' test because its members provide substantial academic medical services to clinics and foundations at the medical school. One commenter gave an example of a medical school group in which physicians spend over 25 percent of their time supervising residents and providing care at a university-affiliated clinic, hospital, and foundation, primarily for Medicaid patients. Since these services count as ''patient care'' services under the definition of that term in § 411.351, and the physicians do not bill for these services under their arrangement with the academic medical center, the physician group cannot meet the ''substantially all'' test. The commenter urged that academic patient care services provided by academic physicians to university hospitals, clinics, and foundations as part of the university's faculty practice plan be excluded from the ''substantially all'' test.

Response: As with the donated volunteer services described above, we see no reason that, in situations in which the 75 percent threshold will not otherwise be met, arrangements for the provision of academic patient care services could not be structured such that the services are billed through the group and treated as receipts of the group (66 FR 905).

Comment: A commenter sought clarification that a medical school group practice can use the in-office ancillary services exception, even though it and its physicians are part of a faculty practice plan of an academic medical center.

Response: If the medical school group practice meets the definition of a ''group practice'' in § 411.352, and all of the criteria of the exception are satisfied, it can use the in-office ancillary services exception to protect referrals within the group practice (but not referrals to other components of the academic medical center, such as the teaching hospital).

Comment: A commenter representing several entities described as ''independent practice associations'' (IPAs) expressed concern that physicians in group practices who participate in an IPA representing a significant revenue source for the group practice may forfeit their group practice eligibility because they will not meet the ''substantially all'' test. That test requires that 75 percent of the total patient care services of the group practice members be furnished through the group practice and billed under a billing number assigned to the group practice, and that the amounts received be treated as receipts of the group practice. According to the commenter, IPAs often employ or contract with group practice physicians directly and bill for the provision of their services under managed care contracts. According to the commenter, if a large portion of group members' patient care services are provided and billed under these contracts, they will not meet the 75 percent ''substantially all'' test. The commenter proposed two solutions. First, we could count as ''patient care services'' only ''fee for service'' services, excluding managed care services. Alternatively, we could count only Medicare and Medicaid services.

Response: We are somewhat unclear as to the nature of the particular entities represented by the commenter. They do not appear to be typical IPAs, which generally do not employ physicians. Nevertheless, we understand the commenter to be asking about the treatment of managed care contract services under the ''substantially all'' test. In Phase I, a commenter posed a similar situation: a group member physician contracts with a hospital to provide professional services and reassigns his or her payments for those services to the hospital. Thus, the hospital, not the group, bills Medicare for the services. In response, we affirmed that a group should be able to count professional services provided by the group member under a global payment when calculating the ''75 percent of patient care services'' requirement for purposes of the ''substantially all'' test. As we explained, the ''substantially all'' test is intended to guarantee that group practice members are providing a substantial amount of their services through the group practice (66 FR 905). Thus, ''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'' (66 FR 905). We indicated our intent to interpret the requirement

that ''substantially all'' of a physician's patient care services be provided through the group and billed ''under a billing number assigned to 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.

Applied to the commenter's managed care contracts example, this interpretation means that the group practice could count patient care services provided under managed care contracts that are part of the group practice's business (for example, where the group practice contracts with the IPA to provide the services or where an individual physician member contracts to provide the services, but assigns his or her right to payment to the group). However, services provided by physicians pursuant to outside employment or contractual arrangements that are not tied to the group cannot meaningfully be said to be provided ''through the group practice.'' Accordingly, such services would not be counted as patient care services provided through the group practice. Thus, services provided by physicians during the course of employment with an IPA would count against a group practice under the ''substantially all'' test.

We are not adopting either of the two alternative tests suggested by the commenter. We believe they are too narrow to achieve the purpose of the ''substantially all'' test in measuring the *bona fides* of a group practice.

Comment: Section 411.352(d)(2) requires that data used to calculate compliance with the ''substantially all'' test in § 411.352(d)(1) and supportive documentation must be made available to the Secretary upon request. One commenter asked that we delete this requirement, calling it simply a back-door attestation requirement.

Response: The commenter misapprehends the legal distinction between an attestation, a document created to make mandatory representations, and a documentation requirement, which merely requires that a group retain records of its own activities. The documentation provision, which mandates production of documentation only upon the Secretary's request, enables the government to ascertain whether the ''substantially all'' test has been satisfied. Group practices that choose to take advantage of the special treatment afforded groups under the statute should be prepared to demonstrate compliance with relevant statutory and regulatory standards.

Comment: Section 411.352(f) sets forth a three-part test for determining whether a group practice is a ''unified business.'' Section 411.352(f)(1)(i) requires 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. Section 411.352(f)(1)(ii) requires consolidated billing, accounting, and financial reporting. One commenter asked us to clarify the meaning of these provisions. Specifically, the commenter asked whether the test is met if individual group practice locations devise their own budgets, including salary and compensation, and submit them for approval by the group's governing board.

Response: The ''unified business'' test is intended to be flexible and to accommodate a wide variety of group practice arrangements, while ensuring that a group practice for purposes of section 1877 of the Act is organized and operated on a *bona fide* basis as a single integrated business enterprise with legal and organizational integration. The ''unified business'' test sets general parameters indicative of integration, but does not dictate specific practices. (For further discussion of the ''unified business'' test, see the Phase I preamble (66 FR 905).) With respect to the centralized decision-making aspect, we believe there must be substantial ''group level'' management and operation. While, in the interest of flexibility, we are not prescribing any particular process for managing budgets or determining compensation and salaries, the centralized management of the group practice must exercise substantial control over the process and output of these activities and not simply rubber stamp decisions by the various cost centers or locations.

Comment: The third part of the ''unified business'' test, § 411.352(f)(1)(iii), provides that the group must have ''centralized utilization review.'' Several commenters asked that we delete or modify this requirement because many group practices do not perform utilization review.

Response: We agree and are deleting § 411.352(f)(1)(iii).

Comment: A number of commenters asked that we clarify that physicians in the group practice can be paid a productivity bonus or profit share based directly on services that are ''incident to'' services personally performed by the physician. The commenters stated that while the Phase I preamble plainly contemplated that such bonuses were permitted (66 FR 909), they found the language of the regulatory text in § 411.352(i) to be ambiguous.

Response: The commenters are correct with respect to our intent in Phase I, and we are amending the regulatory text in § 411.352(i)(3) to make our original intent clear. Section 1877(h)(4)(B)(i) of the Act expressly permits a physician in the group practice to receive a profit share or productivity bonus based directly on services that he or she personally performs and services that are ''incident to'' his or her personally performed services. We have revised the regulations to make clear that profit shares or productivity bonuses can be based directly on services that are ''incident to'' the physician's personally performed services.

Comment: Two commenters asked that we apply the group practice bonus and profit sharing rules to employees and independent contractors.

Response: For purposes of section 1877 of the Act, a group practice may pay any employee or independent contractor of the group practice who qualifies as a ''physician in the group practice'' profit shares and productivity bonuses under § 411.352(i). Referrals from a physician in the group practice to the group practice may be protected under the in-office ancillary services exception (provided the conditions of the exception are met). However, if a group practice instead uses the *bona fide* employment, personal service arrangements, or fair market value exceptions to protect referrals from an independent contractor to the group practice, the compensation rules applicable under those exceptions must be satisfied. These rules are discussed in section VIII below.

Comment: Section 411.352(i)(2) provides that ''overall profits'' of the group must be based on any component of the group consisting of at least five physicians. Several commenters asked that we permit groups to distribute profits based on pools of fewer than five physicians. Another commenter asked that we clarify that any grouping of five physicians in the group constitutes an acceptable pool.

Response: As we explained in the Phase I preamble (66 FR 908), we believe a threshold of at least five physicians is broad enough to attenuate the ties between an individual physician's compensation and his or her referrals. We rejected a previous suggestion from a commenter to the January 1998 proposed rule that we use a threshold of three physicians, because we believed that the lesser threshold would result in pooling that would be

too narrow and, therefore, potentially too closely related to DHS referrals. The commenter is correct that any grouping of five physicians is permissible.

Comment: Two commenters asked that we clarify that bonuses based on factors other than the volume or value of referrals of DHS are permitted. Another commenter asked that we clarify that group practices may distribute all their revenue using the approved allocation methodologies in § 411.352(i)(2) and § 411.352(i)(3).

Response: Nothing in the statute or regulations prohibits or restricts group practice bonuses or incentives based on criteria that do not take into account the volume or value of DHS referrals. There is nothing to prevent a group practice from allocating all of its revenue using the ''safe harbored'' allocation methodologies.

Comment: One commenter asked that we clarify that, for purposes of the ''safe harbors'' at § 411.352(i)(2)(iii) and § 411.352(i)(3)(iii), less than five percent of the group practice's revenues and less than five percent of each physician's revenues must be attributable to DHS reimbursable by Medicare or Medicaid.

Response: The commenter is generally correct. The regulations provide that revenues derived from DHS must be less than 5 percent of the group practice's total revenues, and that the amount of those revenues allocated to any individual physician must constitute 5 percent or less of his or her total compensation from the group practice. The regulations define ''DHS'' as Medicare or Medicaid DHS. Thus, an allocation method is acceptable if less than 5 percent of the group practice's and less than 5 percent of each physician's total revenues come from Medicare or Medicaid DHS.

D. Prepaid Plans (Section 1877(b)(3) of the Act; Phase I—66 FR 911; § 411.355(c))

[If you choose to comment on issues in this section, please include the caption ''Prepaid Plans Exception'' at the beginning of your comments.]

Comments related to the prepaid plan exception are discussed in connection with comments to the risk-sharing arrangements exception at section XII.F below.

In addition, in the January 1998 proposed rule, we proposed a prepaid plans exception for certain Medicaid prepaid plans. As explained in Phase I (66 FR 911), a number of commenters urged us to expand the exception to include other Medicaid organizations analogous to the Medicare prepaid plans covered by section 1877(b)(3) of the Act, and we agree with these commenters. While we are deferring final regulations for section 1903(s) of the Act, given the prevalence of managed care in the Medicaid program, we believe it would be useful and appropriate to expand the prepaid plans exception at § 411.355(c) to include referrals of enrollees in Medicaid managed care plans analogous to the Medicare plans previously included in the exception. The modification effectively addresses the application of section 1903(s) of the Act to referrals of items or services provided to Medicaid managed care patients by making clear that such referrals would not result in the denial of payment under section 1877 of the Act and thus would not result in denial of Federal financial participation under section 1903(s) of the Act. In short, instead of creating a separate exception for Medicaid prepaid plans as proposed in 1998, we are achieving the proposed regulatory result through modification of § 411.355(c).

VI. General Exception Related Only to Ownership or Investment in Publicly-Traded Securities and Mutual Funds (Section 1877(c) of the Act; Phase II; § 411.356(a) and § 411.356(b))

[If you choose to comment on issues in this section, please include the caption ''Publicly-Traded Securities Exception'' at the beginning of your comments.]

Existing Law: Section 1877(c) of the Act creates an exception for ownership in certain publicly-traded securities and mutual funds. To qualify for the exception in section 1877(c)(1) of the Act:

(1) The securities must be securities that may be purchased on terms generally available to the public;

(2) The securities must be listed on the New York Stock Exchange, the American Stock Exchange, or any regional exchange in which quotations are published on a daily basis, or be foreign securities listed on comparable exchanges or traded under the National Association of Securities Dealers automated quotation system; and

(3) The ownership must be in a corporation that had shareholder equity exceeding $75 million at the end of the corporation's most recent fiscal year or on average during the previous three fiscal years.

In addition, section 1877(c)(2) of the Act permits ownership of investments in mutual funds with total assets exceeding $75 million at the end of the most recent fiscal year or the average of the last three fiscal years. Investment securities include shares or bonds, debentures, notes, or other debt instruments.

Proposed Rule: The January 1998 proposed rule interpreted the requirement that the investment securities be those that ''may be purchased on terms generally available to the public'' to mean that, at the time the physician (or his or her immediate family member) obtained the ownership interest, the interest could have been purchased on the open market, even if the physician or family member acquired the interest in another manner. For purposes of the $75 million test, the proposed regulation defined stockholder equity as the difference in the value between a corporation's total assets and total liabilities.

Final Rule: For reasons set out in more detail in the responses to comments that follow, we have reconsidered the interpretation of the ''may be purchased on terms generally available to the public'' provision in the January 1998 proposed rule. In this Phase II interim final rule, we are interpreting the provision to mean that the ownership interest must be in securities that are generally available to the public at the time of the DHS referral. In other words, securities acquired by a referring physician or his or her family member prior to a public offering will fit in the exception if they are available to the public at the time of any designated health service referral (and the other conditions in the exception are satisfied). In addition, as explained in this preamble in section II.B, we will not consider stock options received as compensation to be ownership or investment interests until the time that they are exercised. Having received no comments on the definition of stockholder equity, we are adopting the January 1998 proposal.

Comment: Several commenters objected to our interpretation in the January 1998 proposed rule that, in order to qualify for the public securities exception, the securities owned by the referring physician (or his or her immediate family member) must have been generally available to the public at the time the physician or family member acquired their ownership interest. According to the commenters, this interpretation conflicted with the language and history of the statute and the overall statutory scheme, which focuses on DHS referrals. The commenters suggested that the proper interpretation should be that the securities are generally available to the public at the time any DHS referrals are made.

Response: After careful consideration of the proposed rule, the statutory scheme, and the comment letters, we have reconsidered our position and

concur with the commenters. The interim final rule adopts the interpretation proffered by the commenters. We believe this rule strikes an appropriate balance between excepting legitimate investments and precluding abusive ''sweetheart'' deals predicated on referrals.

Comment: Several commenters asserted that the statutory exception's $75 million benchmark is too restrictive and that investments in smaller public companies should be permitted. Two commenters proposed that we except any investment in a publicly-traded company as long as the referring physician's (or immediate family member's) ownership constitutes less than five percent of the total ownership of the company. Another commenter suggested that we except any investment in any publicly-traded corporation or mutual fund. However, one commenter urged us not to expand the publicly-traded securities exception beyond the strict statutory standards.

Response: We find no support in the statutory language for either of the suggested expansions of the exception, nor are we persuaded that either expansion would be without risk of abuse, the standard for promulgating new regulatory exceptions under section 1877(b)(4) of the Act. The commenters urging the five percent ownership test misunderstand the purpose of the statute. The statute is targeted at financial relationships that create financial incentives for physicians to refer to DHS entities. While a five percent test may be probative on the issue of control of an entity, that test would be largely irrelevant to the existence of an incentive to refer. On the other hand, the limitation in the statutory exception to companies with stockholder equity in excess of $75 million is relevant, because it effectively severs any tie between referrals and returns on the investment. In short, the relationship between returns and referrals is sufficiently diffuse. An exception for investments in all publicly-traded companies, including smaller companies, would not preclude abuse.

Comment: One commenter requested that we create a new exception to permit publicly-traded companies that do not meet the statutory thresholds to bill for a *de minimis* amount of Medicare and Medicaid DHS referred by physicians (or immediate family members) if the company does not know that the physicians (or immediate family members) are stockholders of the company.

Response: In Phase I, we added § 411.353(e), which creates an exception for entities that submit claims for DHS if the entity does not have actual knowledge of, and does not act in reckless disregard or deliberate ignorance of, the identity of the referring physician, and the claim otherwise complies with all applicable laws, rules, and regulations. We believe § 411.353(e) adequately addresses the commenter's concerns, and no further exception is needed.

Comment: One commenter requested that we create a new exception to protect investments in privately held companies. According to the commenter, physicians are investing in a variety of risk-bearing, integrated practice structures, such as physician-sponsored organizations (PSOs) and physician practice management companies (PPMCs). The commenter believed that investments in these companies should be protected.

Response: Nothing in the statute or regulations prohibits investments in entities that do not furnish DHS. In Phase I of this rulemaking, we clarified and significantly narrowed the situations in which a managed care entity will be considered an entity providing DHS. (*See* § 411.351 (definition of ''entity''); *see also* 66 FR 943.) We also significantly expanded the statutory exception for referrals to prepaid plans at § 411.355(c) and created a new regulatory exception for risk-sharing arrangements at § 411.357(n). These aspects of the interim final rule largely address the situations raised by the commenter. Of course, if the PSO, PPMC, or other investment entity directly (or indirectly through a subsidiary) furnishes DHS (that is, is an ''entity'' under the definition at § 411.351), there is no reason to treat it differently from any other DHS entity.

Comment: One commenter was concerned that the January 1998 proposed rule imposed an impossible administrative reporting requirement on publicly-traded companies. Under the August 1995 final rule, DHS entities were required to report to the Secretary any ownership, investment, or compensation arrangements, including the names and unique physician identification number (UPIN) of all physicians holding an ownership or investment interest. However, the regulations released entities from reporting any arrangements that qualified for certain exceptions under the Act, including the publicly-traded securities exception. By contrast, the January 1998 proposed rule proposed requiring entities to report all arrangements with physicians, including those that qualify for an exception. According to the commenter, while the proposal makes some effort to accommodate the burden placed on publicly-traded companies, the reporting requirements are unduly burdensome.

Response: As explained in the section on reporting requirements at section IX below, this Phase II interim final rule eliminates the reporting requirement for shareholder information regarding financial relationships that satisfy the exceptions in § 411.356(a) and (b) for ownership and investment interests in publicly-traded securities and mutual funds.

VII. Additional Exceptions Related Only to Ownership or Investment Prohibition (Section 1877(d) of the Act; Phase II; § 411.356)

A. Hospitals in Puerto Rico (Section 1877(d)(1) of the Act; Phase II; § 411.356(c)(2))

Section 1877(d)(1) of the Act provides that an ownership or investment interest in a hospital located in Puerto Rico is not a financial relationship within the meaning of section 1877 of the Act. We received no comments on the January 1998 proposed rule for this exception. The interim final rule adopts the proposed rule without change.

B. Rural Providers (Section 1877(d)(2) of the Act; Phase II; § 411.356(c)(1))

[If you choose to comment on issues in this section, please include the caption ''Rural Providers Exception'' at the beginning of your comments.]

Existing Law: With respect to DHS furnished in a rural area (as defined in section 1886(d)(2)(D) of the Act), section 1877(d)(2) of the Act provides an exception for ownership or investment interests in rural providers that furnish DHS in a rural area, if substantially all of the DHS are furnished to individuals residing in a rural area. Section 507 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), (Pub. L. 108–173), amended section 1877(d)(2) of the Act to specify that, for the 18-month period beginning on December 8, 2003, the rural provider may not be a specialty hospital. Section 507 defined the term ''specialty hospital'' in a new subsection 1877(h)(7).

Proposed Rule: In the January 1998 proposed rule, we defined a ''rural provider'' as an entity that furnishes at least 75 percent of its total DHS to residents of a rural area. Consistent with the statute, we provided that the DHS must be furnished in a rural area, and we defined a ''rural area'' as an area that is not an urban area pursuant to

§ 412.62(f)(1)(ii) of this chapter (that is, an area outside a Metropolitan Statistical Area (MSA)). We proposed eliminating the requirement from the August 1995 final rule that the rural provider be located in a rural area.

Final Rule: Except for codifying the changes made by section 507 of MMA, this interim final rule adopts the January 1998 proposed rule without change. In addition, the Phase II interim final rule creates a limited new exception, § 411.355(j), for certain referrals from a referring physician to a DHS entity with which his or her immediate family member has a financial relationship, if the patient being referred resides in a rural area and there is no DHS entity available in a timely manner in light of the patient's condition to furnish the DHS to the patient in his or her home (for DHS furnished to patients in their homes) or within 25 miles of the patient's home (for DHS furnished outside the patient's home).

We have been asked to ''grandfather'' investments in DHS entities furnishing services in rural areas that are subsequently reclassified as non-rural areas. As we explained in the August 1995 preamble (60 FR 41954), section 1877 of the Act specifically requires that a rural provider provide DHS in a rural area and provide ''substantially all'' of its DHS to residents of a rural area. Accordingly, if an area is reclassified and these requirements cannot be met, a physician investor in a rural provider cannot refer Medicare patients for DHS to that rural provider. As noted in section II.A above, we have established a regulatory exception at § 411.353(f) for certain arrangements that inadvertently and temporarily fall out of compliance with certain exceptions. This new exception would apply to rural providers.

Comment: Two commenters stated that the proposed exception was too broad and would unfairly benefit physician-owned DHS entities in rural areas, especially home health agencies. One commenter suggested that the exception be limited to areas where there is no other provider of the designated health care services.

Response: The statutory exception clearly applies to rural providers of DHS regardless of whether other DHS entities already operate in a particular rural area or serve a particular rural patient population. In this regard, the statute may benefit physician-owned entities to the detriment of competing DHS entities that are not owned by physicians. However, the statutory directive is clear.

Comment: A commenter objected to our proposed interpretation of the term ''substantially all'' in section 1877 of the Act as requiring the DHS entity to furnish at least 75 percent of its DHS to residents of a rural area. The commenter stated that many providers in rural areas are part of larger State-wide or regional health care systems that provide services outside the rural area. The commenter suggested that the ''substantially all'' requirement should be met if the entity provides rural area residents with one or more DHS on a 24-hour basis.

Response: We disagree that a ''24-hour basis'' rule would appropriately or adequately implement the ''substantially all'' requirement. Indeed, the suggested test would create a loophole into which virtually any provider could fit, thereby evading the statutory prohibition. While we understand that many services in rural areas may be provided by entities that are part of larger systems, we are not convinced that fact should permit them to have physician ownership simply because they operate minimally in a rural area. We believe the Congress enacted the rural provider exception to ensure adequate access to DHS for residents in rural areas that might otherwise have difficulty attracting a sufficient number of providers and suppliers. The 75 percent test we are adopting fully implements the statutory requirement that ''substantially all'' of the DHS of an excepted rural provider be furnished to residents of a rural area.

Comment: One commenter urged that physicians be permitted to own DHS entities in ''rural'' areas located inside an urban area (that is, inside a MSA). The commenter gave an example of a radiologist married to a primary care physician, where the nearest alternate radiologist is 15 miles away. In the commenter's view, it would be a hardship for patients if the primary care physician were to send them to the remote radiology facility.

Response: The fundamental premise of section 1877 of the Act is that physicians should not own DHS entities to which they refer. We see no reason to expand the scope of the rural provider exception beyond the bright line rural area definition provided in the statute. Moreover, commenters to the various rulemakings in section 1877 of the Act have consistently urged us to adopt ''bright line'' regulations. The commenter's suggested test would blur an existing clear line and would present a substantial risk of program and patient fraud and abuse.

With respect to the commenter's example of the primary care physician (that is, the referring physician) married to the local radiologist (that is, the DHS entity for purposes of the example), the problem is less with the rural provider exception than with the financial relationship resulting from the family relationship (that is, the radiologist's ownership of the DHS entity is imputed to the referring spouse because of the ''immediate family'' rule). We discussed this problem in some detail in the Phase I preamble at 66 FR 885. There, we responded to a comment asking 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. We responded that the referral should be allowed as long as DHS were not the reason for the original referral and any subsequent referrals by the physician spouse fit within the in-office ancillary services exception. We further recognized that there could be some circumstances, particularly in underserved areas, where a spouse may be the only qualified provider of a particular designated health service. We indicated that we were considering a limited additional exception and invited comments.

Having considered the issue further, and in the interest of ensuring access for patients in remote or sparsely-served areas, we have concluded that a limited exception is warranted for intra-family rural referrals where there are no other available providers or suppliers of the DHS in the area to furnish the designated health service in a timely manner in light of the patient's condition. So as to prevent program abuse and to minimize any unfair competitive effect on non-physician owned DHS entities that may seek to provide services in rural areas, we have crafted a narrow exception under our authority at section 1877(b)(4) of the Act. The new exception, at § 411.355(j), excepts intra-family rural referrals if the patient resides in a rural area and there is no DHS entity available to furnish the referred DHS to the patient in a timely manner in light of the patient's condition (i) at the patient's residence in the case of home health services or other services required to be furnished in the patient's home (for example, certain DME, such as hospital beds), or (ii) within 25 miles of the patient's residence in the case of services furnished outside the patient's home. Although we have considered the 15-mile radius suggested by the commenter, we believe a 25-mile radius will best serve our need to ensure access to care, preclude any potential for program abuse, and minimize the potential for any unfair competitive

effects on non-physician owned entities in rural areas. We note that this standard is consistent with that used elsewhere in this regulation.

This new exception focuses on the location where the services are furnished, not where the DHS entity is located. In other words, if a physician knows that a home health agency located 50 miles away is willing to provide home health services to a patient, the patient may not be referred to a family-owned home health agency under this exception. The referring physician or the immediate family member must make reasonable inquiries as to the availability of other persons or entities to furnish DHS.

However, neither the referring physician nor the immediate family member has any obligation to inquire as to the availability of persons or entities located farther than 25 miles from the patient's residence. Depending on the circumstances, reasonable inquiry might include, for example, consulting telephone directories, professional associations, other providers, or Internet resources. As with all exceptions in section 1877(b)(4) of the Act, the financial arrangement between the immediate family member and the DHS entity must not violate the anti-kickback statute.

We note that while this new exception looks to timely availability of DHS, it does *not* take into account the quality of other available DHS entities. In other words, the exception is not available if a physician makes an intra-family referral because he or she is dissatisfied with the quality of care provided by an otherwise available DHS entity. While quality services for Medicare beneficiaries and others is of the highest priority, it is not feasible to craft an objective, qualitative measure in the new exception. Other Federal, State, and local laws and regulations exist to address quality issues.

C. Hospital Ownership (Section 1877(d)(3) of the Act; Phase II; § 411.356(c)(3))

Existing Law: Section 1877(d)(3) of the Act provides that, with respect to DHS provided by a hospital, an ownership or investment interest in a hospital (and not merely a subdivision of the hospital) is not a financial relationship within the meaning of section 1877 of the Act if the referring physician is authorized to perform services at the hospital. Section 507 of MMA amended section 1877(d)(3) to provide that, effective for the 18-month period beginning on December 8, 2003, the ownership or investment interest must not be a specialty hospital. Section 507 defined the term ''specialty hospital'' in a new subsection 1877(h)(7) of the Act.

Proposed Rule: In the preamble to the January 1998 proposed rule (63 FR 1698), we interpreted the requirement that the DHS be ''provided by the hospital'' to mean that the services had to be furnished by the hospital and not by another hospital-owned entity, such as a skilled nursing facility or a home health agency. We further stated that the exception only protects referred services provided by an entity that is a ''hospital'' under the Medicare conditions of participation and that the referring physician must be authorized to perform services at the hospital to which he or she wishes to refer. We further explained that a physician can have an ownership or investment interest in a hospital by virtue of holding an interest in an organization (such as a health system) that owns a chain of hospitals, because the statute does not require the physician to have a direct interest in the hospital (63 FR 1713). The interest must be in the whole hospital, not in a part or department of the hospital.

Final Rule: The Phase I final rule reincorporated the definition of ''hospital'' that was originally established in the August 1995 final regulations and that was followed by the January 1998 proposed rule (with incidental conforming changes). In this Phase II rulemaking, we are adopting the January 1998 proposed rule for the hospital ownership exception without change, except for conforming amendments to incorporate the provisions of section 507 of MMA.

Comments and responses follow.

Comment: A commenter objected generally to the exception as giving physician-owned hospitals an unfair competitive advantage over not-for-profit community hospitals. The commenter recommended that we limit the exception to situations in which the physician-owned hospital was a sole community provider.

Response: While we recognize that physician-owned hospitals may have a competitive advantage under section 1877 of the Act, the statutory language is clear and applies to physician ownership in any hospital (but not a subdivision, part, or department of a hospital), if the DHS are provided by the hospital and the referring physician is authorized to perform services at the hospital. We believe that the statute requires a *bona fide* authorization to perform services at the hospital (for example, granting privileges to a physician who is not expected to perform services at the hospital is not a *bona fide* authorization to perform services). Notwithstanding, physician ownership of hospitals may implicate the anti-kickback statute, section 1128B(b) of the Act, depending on the circumstances. For example, specialty hospital ventures in which investment opportunities are substantially limited to physicians in a position to refer to the specialty hospital may implicate the anti-kickback statute. Physician ownership interest in specialty hospitals may also implicate section 1877 of the Act, as revised by section 507 of the MMA.

Comment: Several commenters, including several hospital trade associations, objected to our interpretation that the exception only applies to services furnished by the hospital and not to services furnished by other providers owned by the hospital. The commenters believe that the interpretation substantially limits the usefulness of the exception, since many hospitals provide DHS through entities that have separate accreditation or licensure. According to the commenters, the larger the consolidated entity (that is, hospital plus subsidiaries), the greater the attenuation of the financial incentive. A hospital trade association asserted that the proposed interpretation was inconsistent with the statutory language ''in the case of DHS provided by a hospital.'' According to the association, if the statute only protected inpatient and outpatient hospital services provided by the hospital, rather than subsidiaries or affiliates, the use of the broader term ''DHS'' was unnecessary. Another commenter thought the proposed interpretation was inconsistent with the discussion in the January 1998 proposed rule (63 FR 1713) relating to indirect ownership of a hospital through ownership of stock in a hospital chain.

Response: We believe our interpretation is correct and consistent with the statutory language. The commenter's focus on the use of the term ''DHS'' ignores the modifying language ''provided by a hospital'' that immediately follows. The interpretation we are adopting gives meaning to every word in the statutory provision. The interpretation proffered by the commenters would effectively create a blanket exemption for for-profit hospital conglomerates and would create incentives for physicians to refer their patients to such conglomerates for all health services. Instead of attenuating the financial incentive to refer, ownership in a large hospital conglomerate is equally likely to intensify the incentive by increasing the

profit opportunities for the physician. Finally, the commenter's suggested interpretation would give for-profit, hospital-owned DHS entities, including DME suppliers and home health agencies, a significant and unwarranted commercial advantage over their free-standing competitors.

With respect to the comment that our interpretation is inconsistent with the discussion in the preamble to the January 1998 proposed rule addressing ownership interests in hospital chains (63 FR 1713), we disagree. In that discussion, we explained that we would except an indirect ownership interest in a hospital if a direct ownership in the hospital would have been excepted. We explained that the statutory language of the exception was not limited to direct ownership interests and that the exception had to be read in conjunction with section 1877(a)(2) of the Act, which establishes the principle that an ownership interest includes an indirect ownership interest for purposes of section 1877 of the Act. In the case of hospital-owned DHS entities, such as home health agencies, however, direct ownership by physicians would be prohibited (absent some other applicable exception). We see no reason to protect indirect ownership of such entities under the hospital ownership exception, nor do we believe that the Congress intended the exception to be used to circumvent the general prohibition on physician ownership of DHS entities. (We note that, in some cases, another exception-such as the rural provider or in-office ancillary services exception—may apply to referrals from a physician-owner of a hospital to a hospital-owned DHS entity.) Our interpretation conforms conceptually with the language in the exception precluding ownership of a part or subdivision of a hospital.

VIII. Exceptions Relating to Other Compensation Arrangements (Section 1877(e) of the Act; Phase II; § 411.357)

A. Rental of Office Space and Equipment (Sections 1877(e)(1)(A) and (e)(1)(B) of the Act; Phase II; § 411.357(a) and § 411.357(b))

[If you choose to comment on issues in this section, please include the caption ''Space and Equipment Rental Exception'' at the beginning of your comments.]

The Existing Law: Section 1877(e)(1)(A) and section 1877(e)(1)(B) of the Act set forth exceptions for certain lease arrangements for space and equipment that meet six specific criteria: (i) The lease is in writing, signed by the parties, and specifies the space or equipment covered by the lease; (ii) the space or equipment rented or leased does not exceed what is reasonable and necessary for the legitimate business purposes of the lease or rental and is used exclusively by the lessee when being used by the lessee (except that space leases can include appropriately prorated payments for common areas); (iii) the lease or rental term is at least one year; (iv) the rental charges over the term of the lease are set in advance, consistent with fair market value, and not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties; (v) the lease would be commercially reasonable even if there were no referrals between the parties; and (vi) the lease meets other requirements set by the Secretary to protect against program or patient abuse. ''Fair market value'' is defined in section 1877(h)(3) of the Act as the value of rental property for general commercial purposes (not taking into account the property's intended use). For rentals or leases where the lessor is a potential source of patient referrals to the lessee, fair market value means general commercial value not taking into account intended use or the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor. The August 1995 final rule enacted § 411.357(a) and § 411.357(b) (space and equipment rentals, respectively), which tracked the statutory language, including the definition of ''fair market value.''

The Proposed Rule: The preamble to the January 1998 proposed rule set forth several interpretive changes to the lease exceptions. First, we proposed interpreting the requirement that the lease term be for one year as permitting leases to be terminated for cause within the one-year period, provided the parties did not enter into another lease until after the expiration of the original term (63 FR 1713). We also proposed interpreting the one-year term requirement as requiring that any renewal of a lease be for at least one year, thereby precluding holdover month-to-month leases (63 FR 1713). Second, we proposed interpreting the exclusive use provisions to prohibit subleases, unless the sublease itself satisfied the conditions of the exception (63 FR 1714). Third, we proposed interpreting the exceptions as applying to operating leases, but not capital leases (63 FR 1714). Finally, we proposed that ''per click'' (for example, per use or per service) equipment rental payments would qualify for the equipment rental exception, unless the payments were for the use of the equipment on patients referred by the lessor-physician (63 FR 1714).

The Final Rule: The Phase I final rule addressed the definitions of several terms used in the lease exceptions, including: ''fair market value'', ''set in advance,'' ''volume or value of referrals,'' and ''other business generated between the parties.'' Under the final rule, these terms have uniform meanings wherever they appear in the regulations, including the lease exceptions. Additional discussion of the ''volume or value of referrals,'' ''other business generated,'' and ''set in advance'' definitions appear elsewhere in this Phase II preamble in section IV. The final regulations for the lease exceptions at § 411.357(a) and § 411.357(b) adopt the regulatory language of the January 1998 proposed rule, with minor changes noted in the responses to comments below. Specifically:

- Leases or rental agreements may be terminated with or without cause as long as no further agreement is entered into within the first year of the original lease term and any new lease fits on its own terms in an exception.
- Month-to-month holdover leases are allowed for up to six months if they continue on the same terms and conditions as the original lease.
- All leases or rental agreements, whether operating or capital, are eligible for the lease exceptions if they meet the applicable criteria.
- We have revised the ''exclusive use'' provision to allow subleases in many cases. The exclusive use test will be considered met as long as the lessee (or sublessee) does not share the rented space or equipment with the lessor during the time it is rented or used by the lessee (or sublessee). A subleasing arrangement may create a separate indirect compensation arrangement between the lessor and the sublessee that would need to be evaluated under the indirect compensation rules.
- ''Per click'' rental payments are permitted for DHS referred by the referring physician as long as the payments are fair market value and do not take into account the volume or value of referrals or other business generated by the referring physician, as those concepts are defined in § 411.351 and § 411.354.

Our responses to comments on the lease exceptions follow.

Comment: Several commenters requested that we interpret the one-year term rule to include leases or rental agreements that provide for termination without cause, as long as the parties do

not enter into a new agreement during the original term. According to the commenters, parties frequently prefer to use a ''without cause'' provision even if they have sufficient grounds to justify a ''for cause'' termination to avoid the costs of litigation. Several commenters disagreed with our position that upon expiration of a contract's term, holdover month-to-month tenancies would trigger the statutory prohibition. A commenter suggested that as long as the holdover was on the same terms and conditions as the original lease, there was little additional risk of abuse.

Response: We agree that there is little risk from ''without cause'' terminations as long as the parties do not enter into a new lease or rental agreement during the first year of the original term and any new agreement fits on its own terms in an exception. We have modified § 411.357(a)(2) and § 411.357(b)(3) accordingly. We also agree that there is little risk if a holdover month-to-month tenancy or possession proceeds on the same terms and conditions as the original lease or rental agreement for a limited time (that is, no more than six months). We have added § 411.357(a)(7) and § 411.357(b)(6) to reflect these interpretations.

Comment: One commenter sought clarification regarding whether the requirement that an arrangement be commercially reasonable in the absence of referrals only applies to referrals of Medicare DHS. The commenter said that a broader interpretation would prohibit the payment of any amounts for referrals of private pay DHS as part of the acquisition of the practice of a non-retiring physician.

Response: In Phase I, we defined a referral for purposes of section 1877 of the Act to mean a request for, or plan of care that includes, a ''designated health service'' and ''designated health service'' to include only Medicare-covered services. We intend to use uniform definitions in these regulations whenever possible. For purposes of § 411.357(a)(6) and § 411.357(b)(5), we interpret the restriction to mean that the lease or rental agreement must be commercially reasonable even if no referrals of Medicare DHS are made to the DHS entity. We note, however, that, in addition to the commercial reasonableness condition, sections 1877(e)(1)(A)(iv) and (e)(1)(B)(iv) of the Act provide that rental charges may not be determined in a manner that takes into account ''other business generated between the parties.'' As discussed in this preamble in section IV, § 411.354(d)(3) provides that ''other business generated between the parties'' includes private pay health care business (but not personally performed services). Of course, as with all exceptions and consistent with the statutory scheme and purpose, the conduct of the actual financial relationship between the parties must comport with the terms of the written agreement. The written agreement is the documentary evidence of the underlying financial relationship.

Comment: A number of commenters objected to the interpretation in the January 1998 proposed rule that the exclusive use requirement in the lease exceptions prohibits subleases. These commenters recommended that we permit subleases if they meet the other requirements of the exception.

Response: We concur with the commenters that the Congress did not intend for the lease exceptions to preclude lessees from subletting leased space or equipment. The statutory lease exceptions provide that the lessee must use the leased space or equipment ''exclusively'' when the lessee is using the space or equipment. Upon further consideration of the statutory scheme and purpose, we believe a fair reading of the exclusive use provision in the context of the lease exceptions is that the rented space or equipment cannot be shared with the lessor when it is being used or rented by the lessee (or any subsequent sublessee). In other words, a lessee (or sublessee) cannot ''rent'' space or equipment that the lessor will be using concurrently with, or in lieu of, the lessee (or sublessee). (The statute and these regulations do allow shared common space when the rent is appropriately prorated.) Thus, for example, if a DHS entity rents examination rooms from a physician practice, the physician practice may not use those same examination rooms while the lessee (or a sublessee) is using or renting them.

To preclude referring physicians or group practices from circumventing this rule by setting up separate real estate holding companies or subsidiaries to act as the ''lessor'', we are modifying the regulations to preclude sharing of rented space with the lessor or any person or entity related to the lessor, including, but not limited to, group practices, group practice physicians, or other providers owned or operated by the lessor. We believe our interpretation effectuates congressional intent to curb abusive rental arrangements, gives meaning to the exclusive use requirement in the statutory exceptions, and, in conjunction with other conditions in the exceptions (such as the fair market value and ''reasonable and necessary for legitimate business purposes'' requirements) adequately protects against abuses, while allowing legitimate subletting arrangements.

Persons or entities should be aware that, depending on the circumstances, a sublease may create an indirect compensation arrangement between the original lessor and the sublessee through a chain of leases (that is, compensation arrangements). The indirect compensation arrangement thus created would have to fit in the indirect compensation arrangements exception in § 411.357(p).

Finally, we note that, depending on the circumstances, equipment leases may be eligible alternatively under the new fair market value exception in § 411.357(l) (66 FR 917). However, that exception, which is limited to items and services provided by physicians, does not apply to space leases.

Comment: Several commenters disagreed with our interpretation that the lease exceptions apply only to operating leases and not capital leases.

Response: We agree with the commenters. Any kind of *bona fide* lease arrangement that in form and substance satisfies the regulatory conditions can fit in the exceptions.

B. Bona Fide Employment Relationships (Section 1877(e)(2) of the Act; Phase II; § 411.357(c))

[If you choose to comment on issues in this section, please include the caption ''Employment Relationships Exception'' at the beginning of your comments.]

Existing Law: Section 1877(e)(2) of the Act establishes an exception for payments made by an employer to a physician (or immediate family member) with whom the employer has a *bona fide* employment relationship for the provision of services, if certain conditions are met. These conditions require that—

(1) The employment is for identifiable services;

(2) The amount of the payment is fair market value for the services and is not determined in a manner that takes into account (directly or indirectly) the volume or value of referrals by the referring physician;

(3) The employment agreement would be commercially reasonable even if no referrals were made to the employer; and

(4) The employment meets such other requirements as the Secretary may impose to protect against program or patient abuse.

The statute expressly provides that employers may pay employees productivity bonuses based on services the employee personally performs. The statute defines an ''employee'' as an individual who would be considered an

employee under the usual common law rules applicable in determining the employer-employee relationship, as applied for purposes of section 3121(d)(2) of the Internal Revenue Code of 1986. (*See* section 1877(h)(2) of the Act.) We note that there is no presumption of employment under section 1877 of the Act.

The August 1995 final rule incorporated the provisions of sections 1877(e)(2) and 1877(h)(2) of the Act into the regulations in § 411.357(c) and § 411.351, respectively, without imposing any additional requirements.

Proposed Rule: The January 1998 proposed rule retained the employee exception in § 411.357(c), with certain additional requirements. The preamble to the January 1998 proposed rule took the position that the productivity bonus provision created an improper financial incentive for physicians to generate referrals of DHS that the physician would personally perform. Thus, under the authority in section 1877(e)(2)(C) of the Act to add additional requirements in the interest of protecting against abuse, we proposed excluding any productivity bonus based on a physician's own referrals of DHS, even where personally performed. We pointed out that this restriction would not limit a physician's ability to receive productivity bonuses for generating referrals of non-DHS or non-covered services. The proposed rule also added a restriction on compensation related to other business generated between the parties that is not present in the statute. The proposed rule made no changes to the August 1995 final rule definition of ''employee.''

Final Rule: We are adopting the January 1998 proposed rule without the proposed limitation on productivity bonuses or the addition of the ''other business generated'' language. The limitation is no longer relevant given our determination in the Phase I rulemaking that personally performed DHS are not referrals for purposes of section 1877 of the Act. Moreover, as we explained in the Phase I preamble, the statute contemplates that employed physicians can be paid in a manner that directly correlates to their own personal labor, including labor in the provision of DHS. What the statute does not permit are payments for an employee's productivity in generating referrals of DHS performed by others (66 FR 876). Except as permitted under the group practice definition for employees of group practices, ''incident to'' DHS may not be the basis for productivity bonuses paid to employed physicians. We are adopting without change the January 1998 proposed rule definition of ''employee'', which follows the statutory language.

Comments to the ''employee'' exception and our responses follow.

Comment: Several commenters asked us to expand the statutory definition of ''employee'' in § 411.351 beyond the common law definition established in the statute to include leased employees as defined by State law.

Response: We believe that the statutory definition is clear and that incorporation of State law definitions of employment would be inconsistent with the statute. As noted above in the discussion of group practices, to the extent that a leased employee is a *bona fide* employee of the DHS entity under IRS rules, remuneration paid to that employee would be eligible under the exception. As with all exceptions, the DHS entity would bear the burden of establishing the necessary indicia of employment. There is no presumption of employment.

Comment: A commenter expressed concern that physicians employed by health care systems are pressured into referring to DHS entities within the same health system, sometimes without regard to a patient's best interests. Other commenters, however, urged that employers should be allowed to control their employees and should be able to require referrals to the employer or an entity affiliated with the employer. These commenters believed that the proper focus is on whether the referral requirement interferes with a physician's medical judgement. A commenter representing emergency room physicians explained that emergency room physicians are often constrained when making referrals because of hospital policies and rules, on-call policies, contractual arrangements, patient's prior contact with primary care doctors or specialists, common practice, or professional courtesy.

Response: We agree that health care referrals should always take a patient's best interests into account and that referral requirements should not interfere with a physician's medical judgement. However, we believe that section 1877 of the Act was not intended to interfere unduly with legitimate employment and health system structures. As discussed above, we have narrowed the rule for directed referrals in § 411.354(d)(4) to employers, managed care organizations, and certain contractual arrangements (including many emergency room physician contracts). We have concluded that a referral restriction will not violate the volume and value of referrals standard in section 1877 of the Act if—

- The referring physician is compensated at fair market value for services performed in an arrangement that otherwise fits within the employment (or another) exception;
- The referral restriction relates solely to the physician's services covered by the scope of the employment or contract and is reasonably necessary to effectuate the legitimate purposes of the compensation relationship; and
- Referrals are not required (directly or indirectly)—

A. When the patient expresses a different choice,

I. When the patient's insurer determines the provider, or when the referral is not in the best medical interest of the patient in the physician's judgment.

We believe this narrower rule strikes a reasonable balance between the legitimate business needs of employers and health systems, and protection of patient choice and physician judgment.

Our determination here is limited to the effect of directed referrals under section 1877 of the Act. Other laws and regulations exist to address medically inappropriate referrals.

Comment: A number of commenters objected to the January 1998 proposal to prohibit productivity bonuses based on personally performed DHS. Some commenters suggested that the limitation should apply only to referrals of DHS performed by others. Some commenters urged, however, that employers be permitted to base productivity bonuses on DHS rendered under the supervision of an employee or, in the case of physicians employed by a group practice, under the supervision of another member of the group practice. A commenter urged that productivity bonuses be permitted for supervision of ''incident to'' services that are not DHS.

Response: We are not adopting the 1998 proposed prohibition. In Phase I, we concluded that personally performed DHS are not referrals within the meaning of section 1877 of the Act. Accordingly, physicians may be paid productivity bonuses based on personally performed services, including personally performed DHS. In addition, nothing in the exception precludes a productivity bonus based solely on personally performed supervision of services that are not DHS, since that bonus would not take into account the volume or value of DHS referrals.

Productivity bonuses based on supervising DHS raise a different issue. We are concerned that, in some cases, a payment for supervision services may

merely be a proxy payment for having generated the DHS being supervised. In many cases, especially in hospitals, the supervision required under Medicare rules is minimal, and the supervisor need do nothing more than be present in the facility while conducting other work. Accordingly, we are concerned that such payments could mask improper cross-referral or circumvention schemes. We note that any payment for supervision services must meet the fair market value standard in the exception.

As for productivity bonuses for employees of group practices, we expect that most group practices will rely on the in-office ancillary services exception, rather than the employment exception, to protect referrals by employed physicians. In that case, the group practice may compensate the employed physicians under the productivity bonus provisions of the ''group practice'' definition in § 411.352 (discussed above at section V.C). If a group practice chooses to rely on the employment exception, it must restrict productivity bonuses to personally performed services and comply with the overall fair market value requirement.

Comment: Two commenters asked whether the employment exception would be satisfied if an employer paid an employed physician a flat fee for each mid-level provider he or she supervises in order to compensate the physician for the time spent on supervision.

Response: We see nothing in the exception that would bar flat fee compensation based on the number of mid-level providers under the physician's supervision, as long as the compensation is fair market value for actual time dedicated to supervision services and is not determined in any manner that takes into account, directly or indirectly, the volume or value of DHS referrals generated by the physician. The burden of proving the time will be on the DHS entity.

Comment: A number of commenters raised questions regarding physician compensation that is stable and unvarying, but could still be viewed as predicated on the volume or value of referrals. For example, some commenters inquired regarding exclusivity provisions in employment contracts (for example, contracts for hospital-based physicians). The commenters noted that the exclusivity provision could be viewed as taking into account the volume or value of referrals, even if the dollar compensation paid to the exclusively employed physician is unvarying. One commenter observed that exclusivity in a hospital-based physician contract may be important for liability and insurance purposes. Similarly, some commenters asked for clarification regarding inclusion of covenants not to compete in employment contracts.

Response: We agree that exclusive contracting arrangements between hospitals and traditional hospital-based physicians (radiologists, pathologists, anesthesiologists, and emergency room physicians) can, in certain circumstances, serve legitimate business purposes. To the extent that these payments are for personally performed services, we do not believe they raise any substantial concerns under the statute or regulations. If the payments reflect or take into account non-personally performed services, they may raise concerns under the statute and would merit case-by-case determination, regardless of the apparent fixed payment. In the circumstances described by the commenters, non-compete covenants in employment contracts generally do not take into account the volume or value of referrals. However, the payment for the non-compete covenant must be at fair market value. (We note that, in some contexts, these covenants in conjunction with a lease arrangement may not be able to satisfy the special fair market value rules for leases of space and equipment.)

Comment: Several commenters urged that the exception permit hospitals to pay incentives to employed physicians based on meeting hospital or drug utilization targets. The commenters believe that these payments should not be construed as based on the volume or value of referrals for purposes of section 1877 of the Act.

Response: There is no exception in the statute or in these regulations that would permit payments to physicians based on their utilization of DHS, except as specifically permitted by the risk-sharing arrangements, prepaid plans, and personal service arrangements exceptions. None of those exceptions permit those payments other than in the context of services provided to enrollees of certain health plans. We believe that the Congress intended to limit these kinds of incentives consistent with the civil monetary penalty provision at section 1128A(b)(1) of the Act that prohibits a hospital from paying physicians to reduce or limit care to hospital patients. Given that prohibition, we cannot say that payments based on lowering utilization present no risk of fraud or abuse. Our specific authority in section 1877(e)(2)(D) of the Act to add additional requirements to the employment exception is limited to requirements needed to protect against program or patient abuse. Since section 1128A(b)(1) of the Act represents a legislative determination of potential abuse, we cannot create an exception for those activities.

Comment: According to a commenter representing an integrated delivery system, employers should be able to reward employees based on appropriateness of referrals as measured by quality-oriented medical records review and compliance with clinical protocols and guidelines. In addition, the commenter supported allowing employers to pay employed physicians in part based on volume data in relationship to industry norms. The commenter believed that the statutory language, unencumbered by the 1998 proposed addition, would achieve this result.

Response: We agree that nothing in the statutory exception bars payments based on quality measures, as long as the overall compensation is fair market value and not based directly or indirectly on the volume or value of DHS referrals, and the other conditions of the exception are satisfied. For example, nothing in the statute or regulations would prohibit payments based on achieving certain benchmarks related to the provision of appropriate preventive health care services or patient satisfaction. To the extent that a payment gives a physician an incentive to reduce the volume or value of DHS, it must be a qualified physician incentive plan payment under the personal service arrangements exception or fit in the prepaid plans or risk-sharing arrangements exceptions. Moreover, hospitals should be aware that payments to reduce or limit services—which could include certain payments based on ''appropriateness'' of referrals—may violate the civil money penalty provision at section 1128A(b)(1) of the Act.

Comment: A commenter presented the following scenario. A hospital employs a physician at an outpatient clinic and pays the physician for each patient seen at the clinic. The physician reassigns his or her right to payment to the hospital, and the hospital bills for the Part B physician service (with a site of service reduction). The hospital also bills for the hospital outpatient services, which may include some procedures furnished as ''incident to'' services in a hospital setting. The commenter's concern is that the payment to the physician is inevitably linked to a facility fee, which is a designated health service (that is, a hospital service). Accordingly, the commenter wondered whether the payment to the physician

would be considered an improper productivity bonus based on a DHS referral (that is, the facility fee).

Response: The fact that corresponding hospital services are billed would not invalidate an employed physician's personally performed work, for which the physician may be paid a productivity bonus (subject to the fair market value requirement).

Comment: A commenter described the following scenario. A DME supplier leases a supply closet in a physician's office. The DME supplier and the physician share a non-physician employee who measures braces and fits other supplies. If the physician does not see the patient, the DME supplier bills Medicare. If the physician does see the patient, the physician bills Medicare for a level 1 service. The DME supplier and the physician each pay for the employee's services for which each bills. The commenter inquired whether the shared employee creates a financial relationship.

Response: The scenario presented by the commenter suggests several possible financial relationships. First, the ''shared'' employee raises significant issues. If the salary paid by the DME supplier covers any portion of the employee's work that benefits the physician (for example, work for which the physician would otherwise have incurred costs), that portion of the employee's salary could be remunerated to the physician that would create a financial relationship between the physician and the DME company. Second, if the shared employee is a family member of a referring physician, the employee's salary payments from the DME supplier would also create a compensation arrangement with the referring physician. Third, the rental of the supply closet creates a direct financial relationship between the physician and the DME supplier.

Comment: A commenter inquired whether a physician employed by a hospital-owned management services organization (''MSO'') could refer to the hospital if his or her compensation from the management services company fits in the employment exception.

Response: The arrangement described by the commenter is a potential indirect compensation arrangement (hospital—MSO—physician) that would need to be analyzed under the indirect compensation rules (discussed above in section II.B). Under the indirect compensation analysis, the physician's compensation would be excepted if it is fair market value for services and does not reflect the volume or value of referrals to the hospital (that is, the DHS entity). The employment exception is not applicable in the commenter's example, because the exception applies to direct employment arrangements between a referring physician and an employer that is an entity furnishing DHS (for example, section 1877(e)(2)(C) of the Act: ''even if no referrals were made *to the employer*'') (emphasis added). In the example, the hospital—not the employer MSO—is the entity furnishing DHS. Thus, the referring physician's financial relationship with the hospital is indirect.

Comment: A commenter urged that a physician employed by a hospital should be allowed to refer to a home health agency owned by the hospital.

Response: As in the preceding comment, the commenter's scenario potentially involves an indirect compensation arrangement between the employed physician and the home health agency (the DHS entity) that would have to fit in the indirect compensation arrangements exception. Under that exception, the compensation paid by the hospital to the physician could not vary or otherwise take into account referrals to the home health agency. However, the hospital can require its employees to refer to its home health agency without running afoul of the restriction on compensation that reflects referrals if the requirements of § 411.354(d)(4) are satisfied.

C. Personal Service Arrangements (Section 1877(e)(3) of the Act; Phase II; § 411.357(d))

[If you choose to comment on issues in this section, please include the caption ''Personal Services Exception'' at the beginning of your comments.]

Existing Law: Section 1877(e)(3) of the Act establishes an exception for personal service arrangements if—

(1) The arrangement is set out in writing, signed by the parties, and specifies the services covered by the arrangement;

(2) The arrangement covers all of the services to be provided by the physician (or immediate family member) to the entity;

(3) The aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement;

(4) The term of the arrangement is for at least one year;

(5) The compensation paid over the term is set in advance, does not exceed fair market value, and, except for certain physician incentive plans, is not determined in a manner that takes into account the volume or value of referrals or other business generated between the parties;

(6) The services do not involve the counseling or promotion of an unlawful business arrangement or other activity; and

(7) The arrangement meets the other requirements that the Secretary may impose by regulation to protect against program or patient abuse.

For purposes of the exception, a physician incentive plan (PIP) is defined in section 1877(e)(3)(B)(ii) of the Act as ''any compensation arrangement between an entity and a physician or physician group that may directly or indirectly have the effect of reducing or limiting services provided with respect to individuals enrolled with the entity.'' Under a PIP, compensation may be determined in a manner that takes into account (through a withhold, capitation, bonus or otherwise) directly or indirectly the volume or value of referrals or other business generated between the parties, provided that the PIP meets the following requirements—

(1) No specific payment is made as an inducement to reduce or limit medically necessary services provided with respect to a specific enrolled individual;

(2) If the PIP places the physician at substantial financial risk, the PIP complies with the requirements in section 1876(i)(8)(A)(ii) of the Act; and

(3) Upon the Secretary's request, the entity provides the Secretary with access to descriptive information regarding the PIP to enable the Secretary to determine whether the PIP is in compliance with applicable requirements under the personal services exception.

The August 1995 final rule incorporated section 1877(e)(3) of the Act into regulations in § 411.357(d) and the definition of ''physician incentive plan'' in § 411.351, without imposing any additional requirements.

Proposed Rule: The January 1998 proposed rule contained several technical changes and some additional proposed interpretations. The technical changes would conform the PIP requirements to the regulations governing PIPs issued on March 27, 1996 (61 FR 13430) established in § 417.479; delete § 411.357(d)(3), a time-sensitive provision that is now obsolete; and reorder certain paragraphs for clarity.

We proposed interpreting the exception as covering services furnished by a physician or his or her immediate family member (63 FR 1701). We proposed interpreting the requirement that the proposed arrangement cover all services to be provided by the physician (or immediate family member) to permit multiple agreements between the

physician and the entity if each individual agreement fits in an exception and all of the agreements incorporate one another by reference (63 FR 1701). With respect to covered ''services'' under the exception, we concluded that the exception is limited to ''personal services'', that is, services of any kind performed personally by an individual for an entity, but not including any items or equipment. Thus, ''personal services'' would not be limited to generic Medicare services (defined in § 400.202). We further interpreted the exception to permit the contracting physician (or immediate family member) to perform the services personally or to provide the services through technicians or others whom they employ (63 FR 1701). We interpreted the exception to apply to situations in which an entity has an arrangement with either an individual physician (or immediate family member) or a group practice to provide personal services. Thus, a hospital could use the exception if it contracted with a group practice for purposes of having group members serve as the hospital's staff (63 FR 1702).

With respect to PIPs, we concluded that the exception applies only when the entity paying the physician or physician group is the kind of entity that enrolls its patients, such as a health maintenance organization (63 FR 1701).

Final Rule: As described in more detail in the responses to comments, we are adopting the January 1998 proposed rule, with some modifications. These modifications include clarifying the treatment of the termination provisions, clarifying that payments from downstream subcontractors are included in the physician incentive plan exception, and easing the incorporation by reference rule. These changes are discussed in greater detail in the following comments and responses. In addition, we are making a technical change to § 411.357(d)(2)(iii) (the physician incentive plan (PIP) exception) by updating the citations to reflect that, since January 1, 1999, the PIP requirements that apply to Medicare risk contracts have been set forth at § 422.208 and § 422.210.

As indicated in the Phase I preamble (66 FR 897) and above in this preamble, we believe that the personal service arrangements exception is the applicable exception for most foundation-model physician practices. The fair market value exception may also be available, depending on the circumstances. Changes we have made to the regulations, particularly in the definitions of ''referral'' and ''set in advance,'' should enable foundation-model practices to use the personal service arrangements exception to engage freely in common foundation-model structures and compensation arrangements. In particular, the regulations make clear that independent contractor physicians—including most, if not all, foundation-model physicians—can receive compensation that takes into account the volume or value of personally performed services (that is, services that are not referrals for purposes of section 1877 of the Act) and can be compensated using a percentage-based compensation methodology as long as the methodology is set in advance. We also discuss, in the following responses to comments, new ''safe harbors'' for determining fair market value for physician services.

Comment: Several commenters suggested that the exception not be limited to contracts between entities and physicians or group practices. For example, the commenters suggested that contracts with hospitals, universities, or corporations for the services of employed physicians should be included.

Response: In light of the new exceptions for fair market value compensation arrangements in § 411.357(l), indirect compensation arrangements in § 411.357(p), and risk-sharing arrangements in § 411.357(n), we do not believe any further change is necessary to accommodate the types of arrangements described by the commenter under section 1877 of the Act.

Comment: Several commenters sought clarification concerning whether the aggregate compensation paid under a personal services arrangement needed to be set in advance.

Response: The aggregate compensation need not be set in advance under the personal service arrangements exception. The requirements under the ''set in advance'' standard are set forth in § 411.354(d)(1) and discussed in this Phase II preamble at section IV above.

Comment: Many commenters stated that the proposed regulations would not permit any termination of a personal service arrangement without cause before the end of the one-year term. These commenters believed that termination should be permitted for any reason as long as the parties do not enter into the same or substantially the same arrangement within the original term.

Response: As with leases, we agree that there is little risk as long as the parties do not enter into the same or substantially the same arrangement during the first year of the original term and any subsequent agreement fits on its own terms in an exception. This provision includes, but is not limited to, arrangements for the same or substantially same services to the same or substantially same patients or entities. We have modified § 411.357(d)(1)(iv) to reflect this interpretation.

Comment: A number of commenters urged that we expand the PIP exception to include incentive plans with entities other than HMOs. Commenters also advocated for expansion of the PIP exception to include arrangements involving subcontractors of the HMO.

Response: The PIP exception in the final rule has been modified to clarify that it applies to downstream subcontractor arrangements related to health plan enrollees. We addressed the issue of incentive plans with other entities in Phase I in connection with the new risk-sharing arrangements exception, discussed in the Phase I preamble (66 FR 912–914).

Comment: Several commenters recommended that the exception be modified to allow physicians to hire independent contractors or use wholly owned companies to perform services they have contracted to provide.

Response: The commenter's proposal would present a potential for abuse. The personal service arrangements exception is not limited to professional services, and physicians may be hired to provide non-physician services as well. Allowing physicians to use independent contractors to provide services would allow a physician to enter into brokering arrangements for virtually any kind of service and take a fee as a middle person, without actually performing any services. This is contrary to the intent and purpose of the statute. Using *bona fide* employees to provide contract services is different. The employment relationship ties the employee to the physician in a manner evidencing a *bona fide* business operated by the physician to provide the services. Along these same lines, we agree that a physician should be able to use a wholly owned company to provide contracted services under the exception.

Comment: One commenter inquired about the relationship between supervision requirements and services provided by a physician's employees.

Response: Nothing in these regulations affects the supervision necessary for Medicare payment and coverage purposes. A physician may only provide services through his or her employees if he or she provides the requisite level of supervision under the applicable payment and coverage rules.

Comment: Several commenters objected to our proposed interpretation

that items and equipment cannot be included in an arrangement under the personal service arrangements exception (63 FR 1701). These commenters urged that equipment or items incidental or peripheral to the provision of personal services should be covered by the exception, if the equipment or items comprise only a minor component of the overall arrangement. These commenters urged that providers not be required to parse an arrangement through several exceptions. One commenter noted that there is a difference between a lease, in which exclusive possession of the leased equipment is transferred, and a services contract in which the services provider uses his or her own equipment to provide a service. One commenter inquired, for example, whether parties contracting for personal services and an equipment lease would have to have two separate contracts.

Response: We have reconsidered our position on items or equipment under the personal service arrangements exception. It is a common practice for many independent contractors to provide the tools of their trade in connection with their services contracts. As a practical matter, given the similarities between the personal service arrangements and equipment rental exceptions, the proposed exclusivity rule would be unnecessarily formalistic. Both exceptions require fair market value compensation that does not take into account the volume or value of DHS referrals or other business generated by the referring physician. For purposes of determining fair market value, however, we will separate services and equipment contained in a single arrangement. As previously noted, in all cases the conduct of the actual financial relationship between the parties must comport with the terms of the written agreement.

Comment: Several commenters inquired about various forms of remuneration to ''voluntary'' or ''affiliated'' physicians. For example, one commenter wanted the exception to cover ''voluntary leadership'' arrangements in which physicians volunteer several hours per week to enhance patient care or further an organization's health care mission, receiving only incidental out-of-pocket expenses or training. According to the commenter, the time volunteered by the physician almost always exceeds the value of the training and costs incurred.

Response: Nothing in the statute precludes a physician from ''donating'' time spent in excess of the fair market value of the compensation received in the circumstances described by the commenter.

Comment: A commenter explained that many integrated delivery systems rely on affiliation agreements to encourage integration in managed care endeavors. The commenter believed that integrated delivery systems should be able to structure compensation under affiliation agreements that reflects the volume or value of appropriate referrals. The commenter suggested that the PIP exception in § 411.355(d)(2) be expanded to apply equally to compensation ''intended to improve the quality of patient care.''

Response: As discussed earlier in the context of employment arrangements, we do not believe an expansion of the physician incentive plans exception is appropriate. Compensation arrangements that reward physicians for reducing or limiting care to patients under their clinical care are subject to abuse. (*See,* for example, section 1128A(b)(1) of the Act.) The only permitted arrangements are those that will fit in an existing exception. We note that physician incentive payments under existing exceptions are limited to enrollees of a health plan. Section 1877 of the Act is not a *per se* prohibition on other forms of incentive payments that are not based on the volume or value of referrals or other business generated between the parties and that do not directly or indirectly reduce or limit medically necessary patient care. For example, a bonus paid to a physician for ensuring that his or her patients received preventive care services would not be considered to be a payment to reduce or limit medically necessary services.

Comment: Several commenters stated that requiring multiple agreements to incorporate one another by reference imposes an undue administrative burden on providers, particularly large providers with high volumes of physician contracts, all subject to various commencement and termination dates. In addition, one commenter was concerned that the incorporation requirement potentially created a situation in which an agreement could be technically breached due to a default under a marginally related contract. The commenter offered the following example: if the wife of a physician were to breach her contract as a fitness instructor at a hospital, that breach could taint the hospital's contract with her spouse's group practice for the provision of medical services to hospital patients. Some commenters recommended that the incorporation requirement be deleted or that it be changed to require a cross-reference to a master list of contracts that would be maintained and updated centrally.

Response: We agree that the incorporation requirement may impose a significant burden on entities. We included the incorporation requirement to fulfill the statutory directive in section 1877(e)(3)(A)(ii) of the Act that arrangements cover all of the services to be provided. To alleviate the burden on entities, we are adopting the commenters' suggestion and changing the regulations to require either incorporation of other agreements or cross-referencing to a master list of contracts that is maintained and updated centrally. We understand that some providers may organize their contracting functions by department or otherwise have more than one central repository for contracting data. The master list alternative will be satisfied if more than one master list is maintained and cross-referenced, so long as the several master lists, taken together, cover all of the contracts with the referring physician or immediate family member. Moreover, annual or other regular financial statements (such as quarterly statements) that clearly show parties, dates, payments, and purposes of payments separately for each personal service contract can qualify as a master list if the statements are appropriately cross-referenced in the agreement. We are adding a requirement that the master list or lists be made available for inspection by the Secretary upon request and that the list or lists be maintained in a manner that preserves the historical record (that is, updating should not be done in a manner that erases records of past contracts). We believe this solution adequately fulfills the statutory ''covers all'' requirement while minimizing the burden on entities.

Comment: A commenter expressed concern that the personal service arrangements exception does not contain an exception for productivity bonuses, noting that this is a particular issue for contractors of group practices, who under the January 1998 proposed rule were not considered members of the group. The commenter asked whether independent contractors can be paid a percentage of collections related to work personally performed by the contractor if the percentage is fair market value and not based on DHS referred to the group by the independent contractor.

Response: Changes made in the Phase I rulemaking largely address the commenter's concern. First, under Phase I, independent contractors are considered ''physicians in the group'' and may be paid productivity bonuses

in accordance with the group practice rules set forth in § 411.352. However, if the independent contractor generates DHS referrals for the group practice, and the group practice relies on the personal service arrangements exception rather than the in-office ancillary services exception to protect those referrals, then the compensation rules of the personal service arrangements exception would apply. Second, under the Phase I rules, the definition of ''referral'' no longer includes personally performed DHS, so compensation paid for personally performed services does not vary based on the volume or value of referrals. Thus, all physicians, whether group practice physicians, employed physicians, or independent contractor physicians, can be compensated for personally performed DHS, whether self-referred or referred by someone else. (We note that, under the statute, productivity bonuses for services ''incident to'' personally performed services are only permitted for physicians in group practices.) The personal service arrangements exception requires that a physician's compensation be ''set in advance.'' Under changes we are making in this Phase II rule to the ''set in advance'' requirement in § 411.354(d)(1), certain percentage compensation arrangements will be considered ''set in advance.'' Assuming that the new ''set in advance'' requirements are met, the scenario described by the commenter would be permitted, since the compensation is fair market value and none of the compensation relates to referrals of DHS.

Comment: Two commenters representing independent dialysis laboratories urged us to issue additional regulations prohibiting referrals between dialysis centers and laboratories owned by a common parent company. These commenters believed that the two major corporations that own dialysis facilities should be subject to the same referral prohibition as physicians. In addition, these commenters raised concerns about medical director contracts or other employment or services contracts entered into in connection with a physician's sale of his or her dialysis facility to a corporate owner. The commenters believe that these contracts—which often are long-term and include non-compete clauses—are part of the overall purchase price of the facility and should be considered when determining whether the sale is at fair market value. They also believe that these contracts serve to lock the physician into referring to the corporation's laboratories, thus competitively disadvantaging independent laboratories.

Response: Section 1877 of the Act is limited to referrals by physicians and does not cover referrals among commonly held entities, absent involvement of a referring physician. With respect to medical director contracts or other contracts between corporate dialysis facilities and physicians, these arrangements may create indirect compensation arrangements between the medical director and the corporate laboratory that would need to fit in the indirect compensation exception. In other words, the medical director contract creates a link between the physician and the dialysis facility, which is linked through ownership to the parent corporation, which is linked by ownership to the corporation's laboratory (the DHS entity). If the physician's compensation takes laboratory referrals into account, the arrangement would not fit in the exception. (See discussion of indirect arrangements in section II.B)

Comment: One commenter recommended that we establish a benchmark for evaluating whether end-stage renal disease (ESRD) facility medical director compensation is fair market value by establishing a presumed appropriate fair market value hourly rate.

Response: With respect to the commenters' suggestion that we fix a fair market value benchmark for medical directors, we are not in a position—nor would it be appropriate—to set a fixed, industry-wide fair market value rate for ESRD medical directors. However, we are creating a ''safe harbor'' provision under the definition of ''fair market value'' in § 411.351 for hourly payments to physicians for their personal services. The ''safe harbor'' provision applies to payments for services provided personally by the physician, but not to services provided by the physician's employees or other persons or entities. The safe harbor is not limited to medical director services for ESRD facilities, but may be used for other hourly physician compensation paid by any DHS entity.

The safe harbor consists of two methodologies for calculating hourly rates that will be deemed to be ''fair market value'' for purposes of section 1877 of the Act. The first methodology requires that the hourly payment be less than or equal to the average hourly rate for emergency room physician services in the relevant physician market, provided there are at least three hospitals providing emergency room services in the market. The second methodology requires averaging the fiftieth percentile salary for the physician's specialty of four national salary surveys and dividing the resulting figure by 2000 hours to establish an hourly rate. The ''safe harbor'' provides a choice of six recognized, readily-available surveys. If the relevant specialty does not appear on the survey, the safe harbor looks to the salary for general practice.

Compliance with these safe harbor methodologies is entirely voluntary; DHS entities may continue to establish fair market value through other methods. DHS entities that choose to use either of the two ''safe harbor'' methodologies will be assured that their compensation rates will be deemed fair market value for purposes of section 1877 of the Act. (Their arrangements will still need to meet all other conditions of an applicable exception.) For example, we believe that nephrology salary data from four surveys could be used to calculate an hourly payment for medical directors of ESRD facilities (that is, the average fiftieth percentile nephrologist salary from four surveys divided by 2000 hours). DHS entities using other methodologies to determine fair market value will continue to bear the risk that their rates may not be considered fair market value.

For purposes of section 1877 of the Act, we would treat a sale of a dialysis facility and an accompanying employment contract as separate arrangements to be evaluated under the isolated transactions exception and the employment exception, respectively. Both exceptions require fair market value compensation.

Finally, we note that the arrangements described by the commenters may be problematic under the anti-kickback statute.

Comment: Commenters representing independent dialysis laboratories stated that dialysis corporations sell dialysis supplies at a discount to physicians who agree to refer to the corporation laboratories and enter into management contracts with independent dialysis facilities that steer the facility business to the corporation laboratories.

Response: If the dialysis corporations sell items or services to physicians at a price below fair market value (including any discount), the arrangement will not fit in the exception for payments by a physician for items or services at § 411.357(i). Similarly, cut-rate management contracts in exchange for the ability to steer business will not fit in an exception. Again, these arrangement may raise concerns under the anti-kickback statute.

Comment: Two commenters recommended that the personal service arrangements exception allow the substitution of *bona fide locum tenens* physicians, consistent with the Medicare reassignment rules.

Response: A physician may use a *locum tenens* physician to provide contracted services under this exception. To determine whether a physician is a *bona fide locum tenens* physician for purposes of this rule, we will look to the definition of ''locum tenens'' in § 411.351, except that the requirement in the definition that the regular physician must be a member of a group practice will not apply (for example, the regular physician could be a sole practitioner). We will apply this standard, even if the contracted services are not reimbursable by Medicare. Also in this regard, in Phase I we expanded the group practice definition to include independent contractors and *locum tenens* physicians.

Comment: In the preamble of the January 1998 proposed rule (63 FR 1700), we indicated our intent to interpret the ''commercially reasonable'' requirement for purposes of all exceptions that require commercial reasonableness to mean that an arrangement was a sensible, prudent business arrangement from the perspective of the particular parties involved, even in the absence of potential referrals. In the commenter's view, this interpretation injected an unwarranted subjective element into the test.

Response: An arrangement will be considered ''commercially reasonable'' in the absence of referrals if the arrangement would make commercial sense if entered into by a reasonable entity of similar type and size and a reasonable physician (or family member or group practice) of similar scope and specialty, even if there were no potential DHS referrals.

D. Remuneration Unrelated to the Provision of Designated Health Services (DHS) (Section 1877(e)(4) of the Act; Phase II; § 411.357(g))

[If you choose to comment on issues in this section, please include the caption ''Remuneration Unrelated to DHS Exception'' at the beginning of your comments.]

Existing Law: Under section 1877(e)(4) of the Act, remuneration provided by a hospital to a physician that does not relate to the furnishing of DHS does not constitute a prohibited compensation arrangement. The exception does not apply to remuneration from a hospital to a member of a physician's immediate family. (Until January 1, 1995, the payments to immediate family members were included.) Nor does it apply to remuneration from entities other than hospitals.

Proposed Rule: To conform to various statutory changes, the January 1998 proposed rule proposed to revise § 411.357(g) by removing that portion that was based on the predecessor provision of section 1877(b)(4) of the Act, since that provision had expired, and by changing the reference to remuneration not related to the furnishing of clinical laboratory services to remuneration not related to the furnishing of DHS.

In addition, the January 1998 proposed rule discussed proposed interpretations of the exception. First, in order to come within the exception, the remuneration would have to be completely unrelated to the provision of DHS. Where a hospital made payments that were inordinately high for apparently unrelated services to a physician who referred DHS to the hospital, we would presume the excess payment was, in fact, related to the DHS. Second, we gave several examples to illustrate potentially ''unrelated'' services. These examples included fair market value payments by a teaching hospital to a physician to rent a house for use by visiting fellows, as well as payments for teaching, general administrative services, or utilization review. By contrast, payments to a physician for a medical device used in the provision of DHS (for example, inpatient procedures) or for malpractice insurance would be considered related to the provision of DHS. We stated that the test would be whether there was any link between the remuneration and the referral or provision of DHS. We noted that some of these arrangements might fit in another statutory or regulatory exception.

Final Rule: We have incorporated the technical changes described in the January 1998 proposed rule. In light of the statutory history, we are interpreting the exception to be narrow and available only if remuneration is wholly unrelated to the provision of DHS. In general, for purposes of the exception, we will treat any item, service, or cost that could be allocated in whole or in part to Medicare or Medicaid under applicable cost reporting principles to be related directly or indirectly to the provision of DHS. In addition, other remuneration will be considered related to DHS for purposes of this exception if it is furnished, directly or indirectly, explicitly or implicitly, in a selective, targeted, preferential, or conditional manner to medical staff or other physicians in a position to make or influence referrals. The exception will not apply to any other remuneration that is related in any manner to the provision of DHS. Given the other exceptions, especially the personal services arrangements and fair market value exceptions, any *bona fide* compensation relationships related in any way to DHS could be structured to satisfy another exception.

Section 411.357(g) has been modified to reflect these interpretations, which are explained further in the responses to comments.

Comment: Several commenters objected to our statement that any link to the provision of DHS would make the exception unavailable. One commenter stated that our position appeared to mean that if either party would use the items or services provided under the arrangement to furnish DHS, the exception would not apply. Another commenter stated that the broad statements in the preamble to the January 1998 proposed rule were not consistent with the statutory language. Another commenter objected to the example in the preamble suggesting that payments to a physician for a medical device used for an inpatient procedure would be considered related to the provision of a designated health service. The same commenter stated that payment for malpractice insurance should not be considered related to the provision of DHS and that under the proposed interpretation, even granting staff privileges would trigger the prohibition.

Response: We believe that the exception for services unrelated to DHS in section 1877(e)(4) of the Act is intended to be very limited and available only if the remuneration is wholly unrelated to the provision of DHS, such as the rental of residential property. We believe this narrow reading is consistent with the statutory history. Initially, under the original statute, the exception was necessary to insulate a hospital's relationships with physicians that were unrelated to the provision of clinical laboratory services, a very small element of a hospital's practice. Since 1995, however, *all* hospital services are DHS and a narrower interpretation of the exception is required to prevent abuse. Given this breadth of DHS, the statute's purpose, and the industry's desire for bright line rules in connection with section 1877 of the Act, we will treat any item, service, or cost that could be allocated in whole or in part to Medicare or Medicaid under applicable cost reporting principles as related to the provision of DHS. To the extent that the preamble to

the January 1998 proposed rule suggested that general administrative or utilization review services were not related to DHS, we are withdrawing that interpretation. Even if not covered by cost reporting principles, remuneration that is otherwise related to the provision of DHS will not come within the protection of the exception. We will consider remuneration to relate to DHS if it is furnished, directly or indirectly, explicitly or implicitly, to medical staff or other physicians in a position to make or influence referrals in any manner that is selective, targeted, preferential, or conditional. For example, a loan from a hospital to a physician to finance the physician's purchase of an interest in a limited partnership that owns the hospital would be related to the provision of DHS. Likewise, for example, a hospital's lease of office space in a nearby medical building to physicians in a position to refer to the hospital would be related to the provision of DHS. Any such arrangements must comply with another exception. Elsewhere in this rulemaking, we have promulgated sufficient exceptions that any legitimate arrangement between a hospital and a referring physician should be able to qualify for protection under another exception. Finally, the provision of malpractice insurance or other support services to physicians who would otherwise have to pay for them clearly creates a compensation arrangement within the language and intent of the statute.

Comment: One commenter objected that the exception is limited to remuneration paid to physicians and does not extend to payments to immediate family members.

Response: When the Congress amended the exception in 1993, it limited the provision solely to remuneration paid by a hospital to a physician. Accordingly, the regulation tracks the current statute. Legitimate arrangements with immediate family members should be able to qualify for one of the other available exceptions, such as the personal service arrangements or fair market value exceptions.

Comment: A commenter objected to the statement in the preamble that we would presume that an above fair market value payment for services unrelated to the provision of DHS was actually related to those services. The commenter stated that we had no authority to add an additional requirement (that is, that payments for unrelated services be fair market value) to the statutory exception.

Response: The commenter misunderstood our position. We agree that a payment that is wholly unrelated to the provision of DHS does not have to be fair market value for the exception to apply. However, as an enforcement matter, we will carefully scrutinize any payments that are above fair market value to ensure that they are not disguised payments related to DHS.

Comment: One commenter concluded that our broad reading of ''related'' meant that payments to physicians for covenants not to compete could not fit in the exception, since those covenants were related to the furnishing of DHS. The commenter observed that there is a distinction between a reasonable geographic restriction on providing medical services and an affirmative obligation to make referrals.

Response: We agree with the commenter that a covenant not to compete is not necessarily equivalent to an obligation to make referrals. The statutory exception in section 1877(e)(4) of the Act, however, only protects payments unrelated to the provision of DHS, and a payment by a hospital to a physician for a covenant not to compete is plainly related to the provision of DHS. Nevertheless, transactions involving non-compete covenants can be structured to fit within other exceptions.

Comment: One commenter asked whether the unrelated services exception would be available if the payment were from an entity related to a hospital, but not the hospital itself.

Response: The exception is only available for payments from the hospital itself. Depending on the circumstances, payments from a legal entity related to the hospital would be analyzed as a direct compensation arrangement subject to the direct compensation exceptions or as an indirect compensation arrangement to which the indirect compensation exception may apply.

E. Physician Recruitment (Section 1877(e)(5) of the Act; Phase II; § 411.357(e))

[If you choose to comment on issues in this section, please include the caption ''Physician Recruitment Exception'' at the beginning of your comments.]

Existing Law: Section 1877(e)(5) of the Act excepts remuneration provided by a hospital to a physician to induce the physician to relocate to the geographic area served by the hospital in order to be a member of the hospital's medical staff. To qualify, the following conditions must be met—

(i) The physician is not required to refer patients to the hospital;

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

(iii) The arrangement meets any other requirements imposed by the Secretary to protect against program or patient abuse.

The August 1995 final rule incorporated the provisions of section 1877(e)(5) of the Act into our regulations at § 411.357(e), with the additional requirements that the arrangement and its terms be in writing and signed by both parties and that the physician not be precluded from establishing staff privileges at another hospital or referring to another entity.

Proposed Rule: The January 1998 proposed rule retained § 411.357(e), with minor editorial changes. In the preamble, we interpreted the rule to require that the recruited physician reside outside the hospital's geographic area and actually relocate into the area. We specifically solicited comments on how to define a hospital's ''geographic area.'' We suggested that recruitment payments to physicians already residing in the hospital's geographic area, for example, community physicians or hospital residents, might be excepted under the proposed new ''fair market value'' compensation exception (§ 411.537(l)).

Final Rule: The final rule substantially modifies the January 1998 proposed rule in the following respects:

- The final rule looks to the relocation of the recruited physician's medical practice, rather than the physician's residence. A physician will be deemed to have relocated to the hospital's geographic area (defined as the lowest number of contiguous postal zip codes from which the hospital draws at least 75 percent of its inpatients) if: (i) The physician has relocated the site of his or her practice a minimum of 25 miles; or (ii) at least 75 percent of the physician's revenues from services provided by the physician to patients (including services to hospital inpatients) are derived from services provided to new patients.
- Residents and physicians who have been in medical practice less than one year will not be considered to have an established practice and will therefore be eligible under the physician recruitment exception regardless of whether or not the physician actually moves his or her practice location.
- We have created a regulatory exception for federally qualified health

centers (FQHCs) that make recruitment payments to physicians on the same basis as hospitals.

• Recruitment payments made through existing medical groups (rather than directly to the recruited physician) in connection with the recruitment of a new physician are covered under certain conditions elaborated below.

• We have added a limited new exception at § 411.357(t) for some retention payments made to physicians with practices in HPSAs.

• We have modified the proposed language requiring recruited physicians to establish staff privileges at other hospitals and to refer to other entities to make clear our original intent that recruitment payments not be used to lock physicians into using the recruiting hospital, except insofar as there may be a separate, excepted employment or contractual arrangement under which required referrals may be permitted in accordance with § 411.354(d)(4). The revised language makes clear that recruited physicians must be allowed to establish staff privileges at other hospitals and, except as noted in the preceding sentence, to refer to other entities (even if the other hospital or entity is a competitor). For purposes of section 1877 of the Act, reasonable credentialing restrictions on physicians becoming competitors of a hospital would not violate this condition.

The reasons for these changes are discussed in the responses to comments that follow.

Comment: A number of commenters objected to the proposed requirement that the recruited physician had to relocate his or her residence to qualify for the exception. The commenters suggested that the relevant inquiry should be where the physician practices medicine, not where the physician lives. One commenter urged abandonment of the relocation requirement entirely on the grounds that other conditions in the proposed regulation were sufficient to prevent abuse. Another commenter proposed that the exception apply as long as the recruited physician is new to the hospital's medical staff and either relocates his or her practice at least ten miles or derives 75 percent of his or her patient revenue from patients new to the physician. A hospital trade association proposed that the test be that the recruited physician either relocates to the hospital's service area (to be defined as the lowest number of contiguous zip codes of 51 percent of its inpatients) or relocates 15 miles.

Response: In general, we agree with the commenters that our proposed regulation was unnecessarily restrictive. The relocation requirement is statutory, and even if it were not, we believe a relocation requirement is an important safeguard against abusive financial incentives disguised as ''recruitment'' payments. We are persuaded, however, that the recruited physician's practice location, not his or her residence, should be the relevant consideration. As to the test for ''relocation to the geographic area served by the hospital,'' we believe the regulations should set bright line rules, but also incorporate some flexibility to accommodate variations in legitimate recruitment arrangements. We have revised § 411.357(e) by combining and modifying several of the commenters' suggestions. Specifically, the hospital's geographic service area is defined for purposes of the exception as the area composed of the lowest number of contiguous zip codes from which the recruiting hospital draws 75 percent of its inpatients. Given the significant easing of the ''relocation'' test described below, we believe using a 75 percent criteria is more appropriate than the 51 percent suggested by the commenter. In particular, it is less likely to lead to abusive recruiting payments to established physicians from nearby hospitals.

The relocation test may be met by moving one's medical practice a minimum distance of 25 miles *or* by establishing a practice with a substantial base of new patients (75 percent of the physician's revenues from professional services provided to patients in the relocated practice (including services provided to hospital inpatients)). For the 75 percent revenues test, the regulations measure practice revenue annually on a fiscal or calendar year basis (at the physician's option). For the initial ''start up'' year of the recruited physician's relocated practice, the test is whether it is reasonable to expect that the recruited physician will meet the 75 percent test. New patients are those patients who have not been seen by the physician in his or her previous practice for at least three years. We believe these tests provide clear rules with sufficient flexibility to permit legitimate recruitment arrangements, while protecting against potentially abusive arrangements (for example, cross-town recruitment of an established physician's practice from a competitor hospital). Recruitment payments to community or other local physicians who do not meet the relocation requirement will not fit in the fair market value exception in § 411.357(1), which requires fair market value payments for services rendered.

Comment: Many commenters objected to treating residents and new physicians as residing in the hospital's service area. These commenters argued that these physicians have not yet established a medical practice, so hospitals should be permitted to recruit them. Other commenters pointed out that for many hospitals with residency programs, the residents were the most likely physicians to stay in the community.

Response: We agree and have modified the regulation to provide that hospital residents, as well as physicians who have been in practice one year or less, will not be subject to the relocation requirement. In our view, these physicians do not have an established practice to relocate. However, the recruited physician must establish his or her medical practice in the geographic area served by the hospital to be eligible for recruitment payments under the exception.

Comment: Two commenters wanted the exception to protect recruitment payments from DHS entities other than hospitals.

Response: The statutory exception is expressly limited to recruitment payments made by hospitals, and we are not persuaded that a wholesale extension to other DHS entities is warranted. Under our authority in section 1877(b)(4) of the Act to create additional exceptions, we are extending the exception to cover federally qualified health centers (FQHCs) that recruit physicians to join their medical staffs. We believe that FQHCs should be able to recruit physicians to join their medical staffs under the same terms and conditions applicable to hospitals. This extension is consistent with the statutory intent and scheme and will help ensure that the statute does not impede efforts by FQHCs, which provide substantial services to underserved populations, to recruit adequate staffs. We are not persuaded that the exception should similarly be extended to other DHS entities, such as nursing homes or home health agencies, that may want to recruit physicians into their service areas. These kinds of recruitment arrangements could pose a risk of abuse. We are not extending the recruitment exception to cover recruitment payments made by physician practices. In the first place, physician practices do not have medical staffs comparable to hospitals under the terms of the exception. Moreover, the in-office ancillary services exception is available to cover referrals from recruited physicians. Because the FQHC expansion falls under our authority in section 1877(b)(4) of the Act, FQHCs will be subject to the additional general conditions that their arrangements not violate the anti-kickback statute and that

claims submissions comply with all program rules. Since these are pre-existing obligations, they are not unduly burdensome.

Comment: Several commenters observed that, contrary to statements in the January 1998 proposed rule (63 FR 1702), payments to recruit residents and payments to existing group practices to recruit physicians would not fit in the new fair market value exception. Two commenters noted that the proposed fair market value exception required compliance with the anti-kickback statute or an anti-kickback safe harbor and that the only available safe harbor was limited to physician recruitment in rural areas. Another commenter questioned whether recruitment would be an ''item or service'' for purposes of the fair market value exception. The commenter considered that a physician's relocation to a community benefits the community, not the recruiting hospital. Another commenter claimed that the commercial reasonableness and fair market value criteria in the fair market value exception would require hospitals to incur costs for expensive valuations and stated that comparative data was kept confidential and difficult to obtain. Finally, a commenter pointed out that the proposed fair market value exception included none of the additional safeguards contained in the physician recruitment exception.

Response: In the preamble to the Phase I rule, we stated that physician recruitment arrangements might fit in the new fair market value exception, depending on the specific facts. Nevertheless, we recognized that many recruitment arrangements that offer ''extra'' payments to induce physicians to relocate would not be covered because the compensation would exceed the fair market value of the physician's services (66 FR 919). We concluded that we would consider the issue further in Phase II of the rulemaking.

Upon further consideration, we do not believe that recruitment incentives can fit in the fair market value exception in § 411.357(l). We agree that the physician's relocation is not properly viewed as a benefit to the hospital, except as a potential source of DHS referrals—a consideration that is antithetical to the premise of the statute. As discussed above, we have modified the recruitment exception to make clear that payments to hospital residents can be covered. Payments by a hospital to a physician practice to assist the physician practice in recruiting physicians to the community who will join the existing practice are discussed in the following comment and response. On the issue of anti-kickback compliance, we refer to the discussion in the Phase I rulemaking (66 FR 918).

Comment: Many commenters believed the exception should be expanded to include hospital payments to medical groups in connection with the recruitment of a new physician to join the group. One commenter pointed out that the proposed rule protected any ''remuneration provided by a hospital to recruit a physician,'' but did not specify to whom the payment had to be made (63 FR 1725). The commenters stated that many new physicians prefer to join existing groups and that such arrangements save the costs and labor of setting up a new practice and provide cross-coverage and peer review. Another commenter stated that under the existing Internal Revenue Service (IRS) rules, recruited physicians must report forgivable recruitment loan amounts in the years the debt is forgiven. According to the commenter, this rule discourages recruited physicians from staying in a community; allowing the payments to be made to a group practice might ease the tax burden. One commenter suggested that payments to a medical group be permitted if the group—

- Agrees to participate in Medicare and Medicaid;
- Agrees to participate in the hospital's on-call program;
- Provides professional services to all hospital patients; and
- Enters into an agreement with the recruited physician that does not contain a covenant not to compete or a liquidated damages provision if the physician leaves the group. According to the commenter, these conditions are consistent with IRS Revenue Ruling 97–21. Another commenter thought that payments could be made to groups to recruit physicians as long as the terms of the arrangement are set out in writing and signed by all the parties, and the group agrees to pass substantially all of the remuneration to the recruited physician.

Response: Section 1877(e)(5) of the Act expressly excepts payments made by a hospital ''to a physician.'' We recognize that many new or relocating physicians prefer to join existing practices rather than set up a new practice for legitimate reasons, such as cost, cross-coverage, and professional expertise. We also recognize that hospitals may want to provide financial support through existing medical groups to aid in recruiting new physicians to the community. We are concerned that a recruitment arrangement involving direct or indirect payments to an existing physician practice might be used improperly to pay for referrals from the existing physician practice, in essence creating an improper financial relationship between the hospital and the existing physician practice. However, we have concluded that some narrowly tailored accommodation for recruitment into existing groups would be appropriate under the recruitment exception and have sought to create criteria that would preclude abuse of the exception. Accordingly, the regulations provide that the exception will apply to remuneration provided by a hospital (or FQHC) to a physician indirectly through payments to another physician or physician practice, as long as the following conditions are met:

- The arrangement between the hospital and the physician practice is set out in writing and signed by the parties.
- Except for actual costs incurred by the physician or physician practice in recruiting the new physician, the remuneration is passed directly through to or remains with the recruited physician. Records of the actual costs and the passed-through amounts must be maintained for a period of at least 5 years and made available to the Secretary upon request.
- In the case of an income guarantee made by the hospital to a physician who joins a local physician practice, costs allocated by the physician practice to the recruited physician may not exceed the actual additional incremental costs to the practice attributable to the recruited physician.
- The new physician must establish a medical practice in the hospital's geographic service area and join the hospital's medical staff.
- The physician practice's arrangement with the recruited physician is set out in writing and signed by the parties.
- The new physician is not required to refer patients to the hospital and is allowed to establish staff privileges at any other hospital(s) and to refer business to other entities (except insofar as required referrals are permitted under § 411.354(d)(4)).
- The remuneration from the hospital under the arrangement is not determined in any manner that takes into account (directly or indirectly) the volume or value of any referrals (actual or anticipated) by the recruited physician or by the physician practice receiving the direct payments from the hospital (or any physician affiliated with that physician practice).
- The physician practice receiving the hospital payments may not impose additional practice restrictions on the recruited physician (for example, a non-

compete agreement), but may impose conditions related solely to quality considerations.

The regulations similarly apply to payments made directly to a physician who joins a physician practice.

Because we are expanding this exception under our authority in section 1877(b)(4) of the Act, which authorizes the creation of new exceptions only if the excepted arrangement presents no risk of program or patient abuse, the arrangement must not violate the anti-kickback statute and must comply with all relevant claims submission and billing laws and regulations. In this context, if there is any intent unlawfully to reward or induce referrals from the physician practice whose recruitment the hospital chose to underwrite, the anti-kickback statute would be violated and the exception would not apply.

This rule for pass-through hospital recruitment payments establishes an exception applicable to the compensation arrangement created between the hospital and the recruited physician (and between the hospital and the existing physician practice). We note that if the physician practice receiving the payments from the hospital is a DHS entity to which the recruited physician will refer (that is, the practice submits claims to Medicare for DHS), any separate or additional financial relationship it has with the recruited physician will have to fit in an exception (for example, the in-office ancillary services exception).

Comment: Several commenters suggested that the regulatory exception should be expanded to permit hospitals to provide incentives to retain physicians already on the medical staff. Several commenters pointed out that these incentives are particularly useful for hospitals in rural or inner city areas where there is a shortage of health professionals and constant turnover is a significant problem and expense. One commenter suggested that retention payments could be limited to situations where the hospital had a *bona fide*, reasonable, and documented belief that a physician may terminate his or her staff privileges and join another hospital staff.

Response: We are sympathetic to the problems faced by hospitals and other entities in certain rural and inner city areas in retaining sufficient numbers of qualified physicians in the community. On the other hand, we are concerned about, among other things, protecting payments to physicians in bidding wars between hospitals. The commenter's suggested standard of a reasonable and documented belief that a physician may terminate his staff privileges would not adequately address this potential abuse. We are persuaded that a narrow retention exception for some remuneration paid to physicians with practices in HPSAs to retain them in the community is appropriate and consistent with the statutory scheme. Therefore, in accordance with our authority under section 1877(b)(4) of the Act, we have added a new exception for retention payments made to a physician with a practice located in a HPSA (regardless of whether the HPSA is specifically designated for the physician's particular specialty) who has a firm written recruitment offer from an unrelated hospital or FQHC that specifies the remuneration being offered and that would require the physician to move the location of his or her practice at least 25 miles *and* outside of the geographic area served by the hospital or FQHC making the retention payment. The retention payment must be limited to the lower of (i) the difference between the physician's current income from physician and related services and the income the physician would receive from physician and related services in the recruitment offer (over no more than a 24-month period) or (ii) the reasonable costs the hospital or FQHC would otherwise have to expend to recruit a new physician to the geographic area served by the hospital or federally qualified health center in order to join the medical staff of the hospital or federally qualified health center to replace the retained physician. Parties must use a reasonable methodology to calculate the physician's current and anticipated incomes for purposes of this test. Moreover, parties must use the same methodology when calculating the physician's income from his or her current job and the anticipated income from the recruitment offer. Any retention payment must be subject to the same restrictions, if any, on repayment or forgiveness of indebtedness as the recruitment offer. A hospital may enter into a retention arrangement with a physician no more frequently than once every five years and the amount and terms of the retention payment may not be altered during the term of the arrangement in any manner that takes into account the volume or value of referrals or other business generated by the physician. Except in these limited circumstances, we are unable to devise a sufficiently clear and flexible exception for retention payments that would be without risk of program or patient abuse. If a hospital or federally qualified health center wishes to retain an employed physician by matching a salary offer from another facility, the hospital or federally qualified health center may structure an arrangement to fit in this exception. Alternatively, the arrangement may be structured to fit in the employee exception at § 411.357(c) (as discussed in this preamble at section VIII.B), provided the compensation to be paid to the employed physician will be fair market value and the other conditions of the exception are satisfied. The new exception for retention payments in underserved areas does not protect payments made indirectly to a retained physician via another person or entity, including a physician practice.

Apart from physicians practicing in HPSAs or employed physicians, we think the best approach is to make decisions on retention arrangements on a case-by-case basis through advisory opinions. Thus, the final rule provides for approval of retention payments to physicians in other underserved areas (or serving underserved patient populations) on a case-by-case basis through an advisory opinion. We are not further defining underserved areas or underserved patient populations for purposes of this regulation in order to give the Secretary maximum flexibility in evaluating the special circumstances attendant on retention payments. We expect to approve retention payments in advisory opinions only in unusual and compelling circumstances. We caution that retention arrangements can implicate the anti-kickback statute, and parties should take care to scrutinize their arrangements for compliance with that statute.

Comment: A trade association representing academic medical centers requested a special exception for teaching hospitals.

According to the commenter, teaching hospitals often need to recruit local community physicians to teach. The commenter noted that many academic medical centers have closed medical staffs and would not be able to satisfy the condition that the recruited physician not be required to refer to the hospital.

Response: We are not persuaded that a special exception is needed in light of the academic medical center exception created in the Phase I rulemaking and codified in § 411.355(e) (*see* discussion in section XII.A below). In addition, arrangements with local faculty may fit in the personal service arrangements exception in § 411.357(e)(3) or the employment exception in § 411.357(e)(2).

F. Isolated Transactions (Section 1877(e)(6) of the Act; Phase II; § 411.357(f))

[If you choose to comment on issues in this section, please include the caption ''Isolated Transactions Exception'' at the beginning of your comments.]

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

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

The August 1995 final rule incorporated the provisions of section 1877(e)(6) of the Act into our regulations in § 411.357(f), with an additional requirement that there be no additional transactions between the parties for 6 months after the isolated transaction, except for transactions that are specifically excepted under another exception. The August 1995 final rule also established definitions of ''transaction'' and ''isolated transaction'' in § 411.351. The rule defined a ''transaction'' as an instance or process of two or more persons doing business and an ''isolated transaction'' as a transaction involving a single payment between two or more persons. The definition specifies that a transaction involving long-term or installment payments is not considered an isolated transaction.

Proposed Rule: The January 1998 proposed rule proposed retaining § 411.357(f) and the definitions in § 411.351, with a clarification that ''transactions'' can involve persons or entities.

Final Rule: The final rule retains the existing exception and definitions with the following modifications (as well as the clarification that transactions can involve persons or entities).

First, we are modifying the definition of ''isolated transaction'' to permit installment payments, provided the total aggregate payment is: (i) Set before the first payment is made; and (ii) does not take into account, directly or indirectly, referrals or other business generated by the referring physician. Additionally, the outstanding balance must be guaranteed by a third party, secured by a negotiable promissory note, or subject to a similar mechanism to assure payment even in the event of default by the purchaser or obligated party. *Second*, post-closing adjustments that are commercially reasonable and not dependent on referrals or other business generated by the referring physician will be permitted if made within 6 months of the date of a purchase or sale transaction.

Comments and our responses follow.

Comment: Two commenters found the single payment requirement—in conjunction with the six-month prohibition on other transactions—impractical since it precluded common post-closing adjustments in connection with sales of practices and other transactions. According to the commenters, escrows or post-closing adjustments occur shortly after the initial closing and are designed to remedy unknown conditions, shortfalls in accounts receivable, or similar contingencies. One commenter suggested that commercially reasonable post-closing adjustments be permitted within six months, while another commenter requested a one-year grace period.

Response: We have adopted the commenters' suggestion to modify the rule to permit post-closing adjustments within six months of the date of sale if they are commercially reasonable, even if there are no referrals or other business generated by the referring physician.

Comment: Several commenters questioned the necessity for the single payment rule. Several pointed out that the safe harbor under the anti-kickback statute for the sale of a physician's practice (§ 1001.952(e)) does not contain a similar requirement. According to these commenters, as long as the purchase price is set at the time of closing, consistent with fair market value, and not dependent on referrals, it should not matter if the funds are paid out over time. Two commenters observed that a seller would have a breach of contract claim for any unpaid amounts. One commenter pointed out that any risk that a selling physician would have an ongoing incentive to refer to a sold entity to assure payment by the purchaser could be addressed by requiring the purchase obligation to be secured in the event of the purchaser's default or bankruptcy.

Response: The Congress clearly intended that an isolated transaction, whether through a single payment or installment payments, creates a financial relationship between the parties on a prospective basis. We have reconsidered the single payment requirement in light of the comments and have modified the final rule to also permit installment sales under certain conditions. We are concerned, however, that many installment transactions provide continuing incentives to refer. Resort to costly and uncertain litigation to enforce a contractual right is insufficient protection against the pressure to continue referrals. To address that concern, the installment payments rule requires that payments must be either immediately negotiable or otherwise secured so that the seller is guaranteed payment in the event of the purchaser's default or bankruptcy.

Comment: A publicly-held company suggested that we create a special exception for installment payments by companies that are eligible for the publicly-held entity exception in § 411.356(a).

Response: As discussed above, the final rule permits installment sales that meet certain conditions. There is no reason to distinguish between large publicly-held companies and other purchasers.

Comment: A physician association objected to the prohibition on other unexcepted transactions within six months of the transaction qualifying under the isolated transaction exception. According to the association, a better rule would be a maximum number of transactions within a calendar year.

Response: We decline to adopt the suggestion. We think that the concept of an isolated transaction is incompatible with the suggestion that parties can routinely engage in multiple transactions each year or more than one transaction during a short period of time.

Comment: One commenter asked us to clarify that only transactions related to DHS are subject to the prohibition on other transactions within six months of an isolated transaction.

Response: The prohibition applies to all transactions. A financial relationship between a DHS entity and a referring physician can be created by any financial relationship, whether or not the financial relationship involves DHS and whether or not the financial relationship involves Medicare or private pay business. Unless the financial relationship—whatever it may be—can fit in one of the statutory or regulatory exceptions, the physician may not refer any Medicare DHS to the DHS entity and the entity may not

submit claims to Medicare for DHS provided in the event that such patients are nevertheless referred.

G. Certain Group Practice Arrangements with Hospitals (Section 1877(e)(7) of the Act; Phase II; § 411.357(h))

Existing Law: Section 1877(e)(7) of the Act provides that an arrangement between a hospital and group under which DHS are furnished by the group but are billed by the hospital does not constitute a compensation arrangement for purposes of the prohibition on referrals if the following conditions are met:

- With respect to the services furnished to a hospital inpatient, the arrangement is for the provision of inpatient hospital services under section 1861(b)(3) of the Act. The arrangement began before December 19, 1989, and has continued in effect without interruption since that date.
- With respect to the DHS covered by the arrangement, substantially all of those services furnished to patients of the hospital are furnished by the group under the arrangement.
- The arrangement is set out in a written agreement that specifies the services to be furnished by the parties and the amount of compensation.
- The compensation paid over the term of the agreement is consistent with fair market value, and the compensation per unit of services is fixed in advance and is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.
- The compensation is provided under an agreement that would be commercially reasonable even if no referrals were made to the entity.
- The arrangement between the parties meets any other requirements the Secretary may impose by regulation as needed to protect against patient or Medicare program abuse.

The 1995 final rule incorporated the provisions of section 1877(e)(7) of the Act, as they relate to clinical laboratory services, into the regulations in § 411.357(h), without imposing any additional requirements.

Proposed Rule: The January 1998 proposed rule proposed to revise § 411.357(h) to apply the provisions to all DHS, not just clinical laboratory services, and to make certain minor changes. In particular, the proposed rule proposed modifying the regulation to make clear that the arrangement for which the protection of the exception was sought had to have begun prior to December 19, 1989, and have continued in effect, without interruption, since that time. We also proposed interpreting the regulatory language to permit changes to the arrangement over time with respect to the services covered by the arrangement or the physicians providing those services. We also clarified that the ''substantially all'' test in section 1877(e)(7)(A)(iii) of the Act required that at least 75 percent of the DHS covered under the arrangement furnished to patients of the hospital be furnished by the group under the arrangement.

Final Rule: We received no comments to this provision. This interim final rule adopts the proposed rule.

H. Payments Made by a Physician for Items and Services (Section 1877(e)(8) of the Act; Phase II; § 411.357(i))

Existing Law: Section 1877(e)(8) of the Act creates an exception for certain payments that a physician makes to a laboratory in exchange for clinical laboratory services or to an entity as compensation for other items or services, if the items or services are furnished at a price that is consistent with fair market value. The August 1995 final rule incorporated the provisions of section 1877(e)(8) of the Act into the regulations in § 411.357(i).

Proposed Rule: The January 1998 proposed rule proposed to interpret ''other items or services'' to mean any kind of items or services that a physician might purchase, but not including clinical laboratory services, or any items or services specifically listed under other compensation exceptions (63 FR 1703). In other words, under the proposed rule, exceptions would be mutually exclusive. In the August 1995 final rule, we had defined remuneration to include discounts and explained that the exception in section 1877(e)(8) of the Act would not be available if the remuneration included a discount that did not reflect fair market value. In the preamble to the January 1998 proposed rule (63 FR 1694), we clarified that a discount would meet the fair market value standard if it were made pursuant to an arm's-length transaction; were offered to all similarly situated individuals regardless of whether they make referrals; did not reflect the volume or value of past or future referrals; and were passed on to Medicare and other insurers. In addition, the January 1998 proposed rule proposed a new exception in § 411.357(j) for discounts to physicians based on the volume of referrals, provided the discount is passed on in full to the patients or their insurers and does not benefit the physicians in any way. The proposed exception would not contain a fair market value standard.

Final Rule: The final rule adopts the January 1998 proposed rule, without the proposed exception for discounts. Upon further consideration, we believe that legitimate discounts will fall within the range of values that is ''fair market value.'' In addition, pursuant to our authority under section 1877(b)(4) of the Act, we are extending the exception to cover payments by a referring physician's immediate family member. We believe the Congress did not intend that the fair market value purchase by immediate family members of items and services from health care entities would create a prohibited financial relationship such that the physician could not refer to the entity.

Comment: Several commenters questioned the statutory authority for our determination that items or services that were potentially covered under another exception, such as a lease or personal service agreement, could not also be excepted under this provision. One commenter noted that in some instances, some payers will not pay separate physician and facility charges for certain hospital-based physician clinics because the physician payment includes practice expenses. In those situations, it is common for the hospital to charge the physician some amount for office space and equipment. However, those kinds of transactions cannot fit in the lease or services exceptions.

Response: In the case of this particular exception, the determination that items and services addressed by another exception should not be covered in this exception is consistent with the overall statutory scheme and purpose and is necessary to prevent the ''payments by a physician'' exception from negating the statute. However, we are modifying the regulatory text to make clear that parties can use the fair market value exception, where applicable, which should address some of the issues raised by commenters.

XI. Definitions (Section 1877(h) of the Act; Phase I—66 FR 922–49; § 411.351)

[If you choose to comment on issues in this section, please include the caption ''Definitions'' at the beginning of your comments.]

A. Designated Health Services—General Principles (Section 1877(h)(6) of the Act; Phase I—66 FR 922)

Section 1877(h)(6) of the Act lists eleven broad categories of DHS, but does not further define those categories. In response to requests for clear definitions of the various DHS, Phase I defined the entire scope of the following categories of DHS by reference to specific CPT and HCPCS codes: Clinical

laboratory services; physical therapy, occupational therapy, and speech-language pathology services; radiology and certain other imaging services; and radiation therapy services and supplies. The list of codes used to define these DHS categories appeared in an Attachment to Phase I and is updated on an annual basis in the physician fee schedule final rule and on the CMS Web site. For the convenience of the reader, we are also including this list of codes as an Attachment to this Phase II rule. Commenters generally responded favorably to our use of codes in defining DHS. Phase I defined the remaining DHS categories in regulatory descriptions that did not refer to a service-by-service list of CPT or HCPCS codes.

In Phase I, we also published separate lists of CPT and HCPCS codes to identify DHS that may qualify for the new regulatory exceptions in § 411.355(g) (regarding EPO and other dialysis-related outpatient prescription drugs furnished in or by an ESRD facility) and § 411.355(h) (regarding preventive screening tests, immunizations and vaccines). Services that qualify for one of these exceptions remain DHS for purposes of section 1877 of the Act; however, referrals may be made and claims may be submitted for these DHS if all of the conditions of the applicable exception are satisfied.

As noted below in the comments and responses section, we received a number of comments from various providers advocating that we either exclude certain services from the definition of a particular DHS category or create an exception for financial arrangements involving those services because, in the commenters' view, the items or services pose a low risk of overutilization or abuse. For the reasons stated in Phase I (66 FR 922–923) and our responses below, we continue to decline to make service-by-service determinations of the risk of abuse. Accordingly, we are not adding any new regulatory exceptions for additional DHS in this Phase II rulemaking.

Our responses to comments on the various DHS definitions follow in the order set forth in Phase I.

Comment: Some commenters found it confusing to have a service included on both the list of codes used to define certain DHS and the list of codes that identifies certain services as ''excluded'' under either § 411.355(g) or § 411.355(h). These commenters suggested that such services be omitted from the DHS list.

Response: If a particular service is a DHS, the fact that it potentially qualifies for an exception under § 411.355 does not negate the fact that it is a DHS. The various exceptions serve to permit referrals and claims submission for DHS when certain enumerated conditions are satisfied. The exceptions do not convert DHS into services that are not DHS. Thus, we cannot omit from the DHS code lists those services that may be covered by a regulatory exception, such as the exception in § 411.355(h) for certain preventive screening tests, immunizations and vaccines. However, with respect to certain definitions in the Attachment to Phase I regarding the codes that would be ''excluded'' under the exceptions in § 411.355(g) and § 411.355(h), we are making a number of technical revisions to the definitions of DHS in § 411.351 to more clearly reflect the regulatory scheme. In addition, in the December 31, 2002 physician fee schedule final rule (67 FR 79966), we have clarified that the codes listed under ''Drugs Used by Patients Undergoing Dialysis'' and ''Preventive Screening Tests, Immunizations and Vaccines'' constitute items or services to which the physician self-referral prohibition does not apply if the items or services are furnished in compliance with all of the conditions listed in the exceptions at § 411.355(g) and § 411.355(h), respectively.

Comment: One commenter urged us to define all categories of DHS by reference to specific CPT, HCPCS, or other relevant codes. In particular, the commenter was concerned about potential confusion regarding whether a supply is considered a DME, orthotic or prosthetic supply versus an ordinary supply.

Response: As explained in the Phase I preamble (66 FR 923), some DHS are not amenable to definition through codes. For those services, we believe the definitions provided in Phase I are sufficiently clear to permit entities and physicians to identify them readily.

With respect to the commenter's particular concern, we are unclear as to how or why the Phase I definitions of ''durable medical equipment'' and ''prosthetics, orthotics, and prosthetic devices and supplies'' generate any significant confusion. Phase I did not change any existing definitions for those terms. As discussed in the Phase I preamble (66 FR 932), the simplest way to determine the proper classification of these items is to consult the Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) fee schedule, which identifies such items by HCPCS code and is available on the CMS Web site at: *http://cms.hhs.gov/providers/pufdownload/default.asp#dme.* Most supplies paid under the DMEPOS benefit (as opposed to ordinary supplies used in physician offices) are listed on this Web site. In general, a supply is categorized as a DME supply or a prosthetic, prosthetic device, or orthotic supply if it is disposable in nature and necessary for the effective use of DME, a prosthetic, a prosthetic device, or orthotic equipment by the patient outside of the physician's office.

B. Professional Services as Designated Health Services (Phase I—66 FR 924)

Comment: Our DHS definitions, including the definition of ''radiology and certain other imaging services'' at § 411.351, encompass both the professional and technical components of a service. A commenter stated that including the professional component is contrary to the statute and creates a significant obstacle to the delivery of ultrasound services provided anywhere except in a physician's office. For example, according to the commenter, if a physician refers a hospital inpatient for an ultrasound, and a member of the referring physician's group practice interprets the ultrasound (that is, provides the professional component), the in-office ancillary services exception is not applicable and the group cannot bill for the professional service.

Response: First, we do not find any evidence that the Congress intended to exclude all professional physician services from the list of DHS, for the reasons explained in the Phase I preamble (66 FR 924). Second, under the physician services exception (section 1877(b)(1) of the Act; § 411.355(a)), the self-referral prohibition does not apply to physician services that are personally performed by, or under the supervision of, another physician who is in the same group practice as the referring physician. Unlike the in-office ancillary services exception, the physician services exception does not impose any ''same or centralized building'' requirement. Thus, a physician may refer a hospital inpatient for ultrasound services when the professional component is furnished in a hospital by, or under the supervision of, another physician in his or her group practice. In many other cases, physician services that are DHS will fall under one of the other exceptions or will be personally performed by the referring physician and therefore not constitute a ''referral'' for purposes of section 1877 of the Act.

C. Clinical Laboratory Services (Phase I—66 FR 924)

In Phase I, we defined the entire scope of ''clinical laboratory services'' by reference to codes ''as specifically

identified by the CPT and HCPCS codes posted on the HCFA Web site * * * and in annual updates * * *, except as specifically excluded on the HCFA Web site and in annual updates.'' We are deleting the phrase ''except as specifically excluded on the HCFA Web site and in annual updates'' in response to comments discussed in section XI.A addressing the distinction between items and services that do not constitute a DHS and items and services that are DHS but may qualify for an exception under § 411.355. We are not making any other changes to the definition of ''clinical laboratory services.''

Comment: One commenter urged us to exclude from the definition of ''clinical laboratory services'' all laboratory tests for which the requirements of CLIA have been waived. The commenter stated that CLIA-waived tests should not be considered DHS because they are an integral part of patient care furnished in the physician office setting.

Response: We see no reason to exclude CLIA-waived tests from the definition of ''clinical laboratory services'' under § 411.351. Under CLIA regulations, clinical laboratory tests are categorized based on complexity. The three categories are: waived tests, tests of moderate complexity, and tests of high complexity. The commenter is addressing the set of relatively simple tests that the CLIA rules categorize as waived tests. Under § 493.15, waived tests must: (1) Be cleared by the Food and Drug Administration (FDA) for home use; (2) employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible; or (3) pose no reasonable risk of harm to the patient if the test is performed incorrectly. None of these factors reduces the risk of overutilization or other abuse for purposes of section 1877 of the Act. To the extent waived tests are an integral part of patient care and are furnished during an office visit, they will likely fit in the in-office ancillary services exception at § 411.355(b).

D. Physical Therapy Services (Phase I—66 FR 924–927)

In Phase I (66 FR 924–27, 955), we defined ''physical therapy, occupational therapy, and speech-language pathology services'' as those particular services identified by the CPT and HCPCS codes on our Web site (and in annual updates published in the **Federal Register**), regardless of who provides them. We listed the codes for each of these services under a single category because they overlap (for example, a particular service that is associated with a single CPT or HCPCS code may be within the scope of practice of both physical therapists and occupational therapists). We believe that the list of CPT and HCPCS codes for these services represents what most clinicians would define as physical therapy/occupational therapy/speech-language pathology services. However, we are removing CPT code 94762 (measure blood oxygen level) from the list of physical therapy/occupational therapy/speech-language pathology services because it is not a physical therapy service.

We received the following comments.

Comment: One commenter was concerned that our use of the phrase ''regardless of who provides them'' might imply that people other than licensed physical therapists and physical therapist assistants could provide physical therapy services in a physician's office. The commenter believed that we should develop policies to avoid unlicensed or unqualified individuals from providing physical therapy services.

Response: We do not intend for the description of ''Physical therapy, occupational therapy, and speech-language pathology services'' in § 411.351 to have any effect on who is allowed to furnish physical therapy services to Medicare patients. Section 411.351 merely defines the scope of services included in the definition; it does not address the qualifications required to perform them. As noted in the preamble to Phase I final rule (66 FR 926), some physical therapy services can be performed by physicians, and we defer in this rule to existing Medicare policy concerning which professionals may provide a given service.

Comment: A commenter stated that we should add two CPT codes to the list of physical therapy codes: 97601 for removal of devitalized tissue from wound without anesthesia and 97602 for non-selective debridement, without anesthesia.

Response: We agree. In Phase I, we defined physical therapy services, as described in section 1861(p) of the Act, to include the following: (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; and (iii) the establishment of a maintenance therapy program for an individual whose restoration potential has been reached. Removing devitalized tissue and non-selective debridement without anesthesia are physical medicine modalities, and the CPT places the codes for these services within a series of codes for other physical therapy services. We are therefore including CPT codes 97601 and 97602 on the list of codes used to define physical therapy services.

Comment: One commenter asserted that we should not interpret the term ''physical therapy services'' to include speech-language pathology. According to the commenter, neither section 1877 of the Act nor its legislative history indicates that the term ''physical therapy'' encompasses speech-language pathology. Another commenter asserted that the Congress intended speech-language pathology services and physical therapy services to be separate benefits. The commenter asserts that although speech therapy services are referenced in section 1861(p) of the Act, the definition of these services is included in a separate statutory provision, section 1861(ll)(l) of the Act. The commenter noted that we also recognize speech-language pathology services as distinct from physical therapy.

Response: As previously noted in Phase I (66 FR 926), the definition of ''outpatient physical therapy services'' in section 1861(p) of the Act specifically states that ''[t]he 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 under an arrangement with, and under the supervision of, such provider, clinic, rehabilitation agency, or public health agency * * *.'' Thus, by definition, speech-language pathology services are a subset of outpatient physical therapy services under the Medicare statute. Although the term ''speech-language pathology services'' is defined elsewhere in the Act, and there may be different regulatory guidelines applicable to physical therapy services and speech-language pathology services, the statute clearly includes the latter within the definition of ''outpatient physical therapy services.''

Comment: One commenter asserted that the Phase I preamble incorrectly stated that device mapping (the fine tuning of cochlear implants) is performed by speech-language pathologists (66 FR 935). According to the commenter, device mapping is not within the speech-language pathology scope of practice. The commenter also asserted that CPT code 92507 (speech/hearing therapy) is not a designated health service and should be deleted from the code list.

Response: In Phase I (§ 411.351; 66 FR 955), we described ''speech-language

pathology services'' as services performed ''for the diagnosis and treatment of speech, language, and cognitive disorders that include swallowing and other oral-motor dysfunctions.'' We noted in the Phase I preamble (66 FR 935) that, although cochlear implants are considered prosthetic devices, cochlear rehabilitation services (billed under CPT code 92510) are considered speech-language pathology services for purposes of Medicare coverage and payment. The Phase I Attachment also included CPT codes 92506 (speech/hearing evaluation) and 92507–92508 (speech/hearing therapy) as physical therapy/occupational therapy/speech-language pathology services.

We have removed CPT code 92506 (speech/hearing evaluation) from the list of codes used to define physical therapy, occupational therapy, and speech-language pathology services. CPT code 92506 is a diagnostic audiology service. Contrary to the commenter's request, we are not removing CPT code 92507 (speech/hearing therapy) because it is a speech-language pathology service. In addition, we note that we removed CPT 92510 (rehab for ear implant) from the code list in the December 31, 2002 physician fee schedule final rule (67 FR 80017) because we no longer recognize this code as valid for payment purposes. The services formerly billed under this code may be billed under 92507–92508, which remain on the list of codes used to define physical therapy, occupational therapy, and speech-language pathology services.

We did not intend to include audiology services within the scope of our description of speech-language pathology services. Accordingly, we are removing the following four codes, which were erroneously added to the DHS code list in the CY 2003 physician fee schedule update (67 FR 79966, 80016, effective for services furnished on or after March 1, 2003): CPT 92601 (cochlear implant f/up exam <7); 92602 (reprogram cochlear implant <7); 92603 (cochlear implant f/up exam 7>); and 92604 (reprogram cochlear implant 7>). All of these codes represent diagnostic audiology services.

Comment: A commenter stated that there are two additional CPT codes that should be considered speech-language pathology services: CPT 92520 (laryngeal function studies) and CPT 92511 (nasopharyngoscopy). According to the commenter, these services are clearly within the scope of practice of speech-language pathologists.

Response: As we stated in Phase I (66 FR 925), we are defining this category of DHS using specific codes that correspond to services that we consider to be speech-language pathology services. The Medicare program does not currently recognize nasopharyngoscopy (CPT 92511) and laryngeal function studies (CPT 92520) as therapy services. We intend that the list of CPT/HCPCS codes will reflect existing Medicare coverage and payment policies for each DHS category on the list. To include the codes suggested by the commenter would be contrary to existing policy; therefore, we are not including these codes as DHS under the physician self-referral prohibition.

E. Occupational Therapy Services (Phase I—66 FR 926)

We received no comments on this subject. Accordingly, we are not making any changes to the relevant portion of the definition of ''physical therapy, occupational therapy, and speech-language pathology services.''

F. Radiology and Certain Other Imaging Services (Phase I–66 FR 931)

Under section 1877(h)(6)(D) of the Act, ''radiology services, including magnetic resonance imaging, computerized axial tomography, and ultrasound services'' are DHS. Radiation therapy services and supplies are DHS under section 1877(h)(6)(E) of the Act. In the January 1998 proposed rule, we proposed a single definition for both of these DHS categories. In Phase I, we took the following steps, among others, to define this category with greater clarity:

- We separately defined the DHS identified in section 1877(h)(6)(D) and section 1877(h)(6)(E) of the Act.
- We defined the category of services covered by section 1877(h)(6)(D) of the Act under the name ''radiology and certain other imaging services'' to make clear the Congress's intent to include some imaging services other than radiology.
- We defined the entire scope of DHS under section 1877(h)(6)(D) of the Act in a list of CPT and HCPCS codes.
- We excluded the following services from the definition of ''radiology and other imaging services'': (i) X-ray, fluoroscopy, and ultrasound services that require the insertion of a needle, catheter, tube or probe; (ii) radiology procedures that are integral to the performance of, and are performed during, nonradiological medical procedures; and (iii) nuclear medicine procedures.

We received a number of comments concerning radiology services, particularly with respect to nuclear medicine. We are deleting the parenthetical ''(except as otherwise specifically excluded on the CMS Web site and in annual updates)'' in response to comments discussed in section XI.A addressing the distinction between items and services that do not constitute a DHS and items and services that are DHS but may qualify for an exception under § 411.355. In response to comments, we are modifying the definition to exclude certain radiology procedures performed immediately after a nonradiological medical procedure.

Comment: Several commenters asked us to confirm their belief that the only services that constitute ''radiology and certain other imaging services'' for purposes of section 1877 of the Act are those represented by the codes listed in the Attachment to Phase I (66 FR 963) and its subsequent updates.

Response: The commenters are correct.

Comment: One commenter asserted that echocardiograms should not be considered DHS because section 1877 does not include cardiology services as DHS. In addition, an association of cardiologists stated that the Congress's choice of language indicates that it intended to include only ultrasound services that are appropriately considered radiology services. That is, the commenter asserted that, although echocardiography is a diagnostic procedure using ultrasound technology, it should not be considered a radiology service because echocardiography is a service performed primarily by cardiologists, billed under cardiology CPT codes, and furnished to cardiology patients. In addition, the commenter asserted that echocardiography has not been identified as a service that poses a high risk of improper referrals, unlike other services appropriately included in the radiology services category. Another association of cardiologists asserted that we should exclude any ultrasound service not generally performed by radiologists, but instead performed by other specialists as part of their own specialties (such as cardiac, ophthalmic, and gynecologic ultrasound), just as we excluded nuclear medicine in Phase I.

Response: In Phase I, we responded to public comments that questioned why cardiac, vascular, and obstetric ultrasound procedures should be considered radiology services. As we explained then, ''these services are subject to the physician self-referral provisions because section 1877(h)(6)(D) of the Act specifically includes ultrasound as a DHS, not because they are ordinarily considered to be 'radiology services.' '' (66 FR 928). We see no reason to reconsider this

determination. As explained in Phase I, we do not believe the Congress intended for us to make service-by-service determinations with respect to the risk of overutilization or other abuse. In many cases, these services may qualify for the in-office ancillary services exception or another exception.

Comment: The Phase I definition of ''radiology and other imaging services'' specifically states that the list of codes used to define these services excludes ''[r]adiology procedures that are integral to the performance of, and performed during, nonradiological medical procedures.'' One commenter preferred the language we used in the preamble to the January 1998 proposed rule to indicate our intention to exclude radiology services that are ''incidental'' or ''secondary'' to another procedure (63 FR 1676).

Response: We decline to adopt the standard advocated by the commenter. Many of the comments we received on the January 1998 proposed rule indicated that the ''incidental or secondary'' standard was confusing or ambiguous. As noted in Phase I (66 FR 928), ''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 procedure being an adjunct procedure) or whether the primary purpose was to take a picture with an imaging modality.'' Those who commented on the ''integral'' standard generally favored the new language.

Comment: One commenter asserted that radiology services may be needed before a procedure to plan the manner in which a needle, catheter, or probe will be guided, and that radiology services may be performed after a procedure to assess whether the procedure was effective. Another commenter asserted that we should exclude all interventional radiology services, since in almost all cases, the physician making the referral performs part or all of the procedure.

Response: We interpret the commenter to request that such pre- and post-procedure radiology services be considered ''integral to and performed during'' a procedure so as to qualify under the standard set forth at § 411.351 (Radiology and other imaging services, subpara. (2)). We agree, in part, with the commenter. We have modified the definition of radiology and other imaging services at § 411.351 to make clear that radiology services performed immediately after a procedure in order to confirm the placement of an item during the procedure are not DHS. Otherwise, we decline to change the regulations for the reasons set forth in Phase I (66 FR 928–929). In addition, depending on the circumstances, existing exceptions in the statute and regulations, such as the in-office ancillary services exception or the rural provider exception, may apply to radiology procedures furnished pre- or post-surgery.

Comment: Two commenters addressed ophthalmic A-scans, and one of the commenters also addressed B-scans. According to the commenters, because A-scans (particularly CPT 76519) must be performed before cataract surgery to determine the appropriate power of the intraocular lens (IOL) to be implanted, these procedures are integral to cataract surgery even though they are not performed during the surgery. One commenter asserted that B-scans are performed only in support of another service or procedure. For example, the commenter stated that B-scans may be used in certain cataract surgery cases to view the posterior segment or retina of the eye to determine if a structural pathology is present. Both commenters argued that the ''integral to and performed during'' standard should be changed to accommodate A-scans and B-scans. Alternatively, the commenters advocated that we create a special exception for A-scans on the grounds that they are sufficiently integral to another procedure and are subject to little or no overutilization or abuse. One of the commenters alleged that such an exception would be based on the same rationale as that which led us to create the exception in § 411.355(g) regarding EPO and other dialysis-related drugs furnished in or by an ESRD.

Response: We do not see a meaningful distinction between the A-scans and B-scans described by the commenters and other radiology services ordered by surgeons in connection with surgeries; nor do we think that A-scans and B-scans pose no risk of abuse. Moreover, we do not believe that our rationale for creating the exception in § 411.355(g) pertains here. Unlike ESRD services, A-scans and B-scans are not necessarily performed in conjunction with services that are paid for under a composite rate, nor are they subject to strict utilization and coverage criteria. Nevertheless, we would expect that in many cases, the in-office ancillary services exception may apply to A-scans and B-scans.

Comment: Commenters expressed concern that, in many cases, ASCs will not be able to provide radiology and ultrasound services that are not performed during surgery. These commenters urged that, if CMS continues to consider radiology and ultrasound services performed before or after surgery to be DHS, then the same reasons that support a special exception for prosthetic devices implanted in an ASC should also support a specific exception for these radiology services.

Response: We are not persuaded that a special exception is warranted. The exception for implants in ASCs applies to the implantation of a device during a surgical procedure, rather than before or after it. In those circumstances, the implant is clearly integral (indeed, inseparable) from the surgery itself. Similarly, radiology included in the ASC composite rate for an ASC procedure is not a DHS for the reasons set forth in Phase I at 66 FR 923. We see no reason to treat radiology services that are furnished in an ASC, but are not paid for in the ASC composite rate, differently from radiology services provided by any other entity.

Comment: One commenter advocated that we create an exception to permit interventional radiologists to order diagnostic, non-interventional radiology or other imaging procedures from an entity with which they have a financial relationship prior to performing interventional radiology and related surgical procedures. The commenter noted that the professional component of the diagnostic procedure may be performed at a hospital or an ASC by another physician in the radiologist's group practice. According to the commenter, a limited exception would enable beneficiaries to benefit from interventional radiology.

Response: We see no need for a new exception. The self-referral prohibition does not apply to a radiologist's request for diagnostic radiology tests pursuant to a consultation because the request is not a ''referral'' for purposes of section 1877 of the Act. Our expansion of the definition of ''referral'' would permit a radiologist to order diagnostic radiology services that are supervised by another radiologist in the same group practice.

If the request is not made pursuant to a consultation, the referral of the professional component may nevertheless qualify for another exception (such as the physician services exception). With respect to any technical component billed by a hospital or ASC, there are sufficient exceptions available in the statute and regulations to address legitimate financial relationships between physicians and these entities.

Comment: A commenter urged us to amend the final rule to clarify that not only the ordering physician, but also other ''physicians in the group practice,'' may provide the professional component of a radiology service if all

the following conditions apply: (1) A physician in the group has ordered the technical component; (2) the professional component is provided at an institutional provider; and (3) the patient is either an outpatient or inpatient of the institution where the professional component is provided.

Response: As explained in section II.D, above, we have expanded the consultation exception in the definition of ''referral'' in § 411.351 to permit supervision by another physician in the same group practice as the radiologist, as long as the request results from a consultation initiated by another physician and the other conditions of the exception are satisfied. Moreover, the physician services exception may apply in the circumstances described by the commenter.

Comment: One commenter expressed concern that the exclusion of some interventional radiology codes for services such as angiographies, angiograms, cardiac catheterizations, and endoscopies might afford some physicians more incentive to refer for costly interventional tests that may not be medically necessary. Although these studies would be DHS under 1877(h)(6)(K) when performed as inpatient or outpatient hospital services, some will be performed at freestanding facilities and therefore not constitute a DHS. The commenter asked that we reassess our decision, or, in the alternative, instruct contractors to monitor utilization patterns for excluded interventional radiology services.

Response: As explained in Phase I (66 FR 929), the services referenced by the commenter are not fundamentally radiological in nature because they do not involve an imaging service that is described in 1877(h)(6)(D) of the Act. These services are DHS when performed in a hospital inpatient or outpatient setting. Other statutes, including the Federal anti-kickback statute, are available even in instances where a particular item or service is not DHS under section 1877 of the Act.

Comment: An association representing radiologists urged us to consider nuclear medicine a DHS because excluding nuclear medicine, as was done in Phase I, increases the risk of program abuse. The commenter asserted that nuclear medicine is a subspecialty of radiology and that radiologists perform and interpret the vast majority of nuclear medicine studies performed in the United States. The commenter also asserted that the exclusion of nuclear medicine has encouraged potentially abusive business arrangements involving physician financial relationships with entities to which they refer patients for positron emission tomography (PET) scans. Another commenter expressed concern that echocardiography is a DHS, while nuclear medicine procedures (some of which are commonly performed as a clinical alternative for stress echocardiography) are not. The comment suggested that a physician's financial interest in nuclear medicine modalities could influence the physician to select nuclear medicine procedures over echocardiography.

Response: We are making no changes to the treatment of nuclear medicine procedures under the DHS definitions at this time. However, we are mindful of the issue raised by the commenter and are continuing to consider the application of section 1877 of the Act to nuclear medicine procedures. Moreover, parties should be mindful that arrangements involving nuclear medicine may violate the anti-kickback statute, depending on the circumstances.

G. Radiation Therapy Services and Supplies (Phase I—66 FR 931)

Phase I indicated that the list of codes for radiation therapy services and supplies identified on our Web site and in annual updates is based on section 1861(s)(4) of the Act (42 U.S.C. § 1395(x)(s)(4)) and § 410.35, but does not include nuclear medicine procedures. As explained above in the immediately preceding section concerning radiology services, we are continuing to consider the application of section 1877 of the Act to nuclear medicine procedures, but we are not changing the treatment of nuclear medicine procedures under the DHS definitions at this time.

Comment: One commenter opposed our use of CPT and HCPCS codes to define the scope of ''radiation therapy services and supplies'' because Medicare has never used these codes to define such services.

Response: As explained above, we used codes in Phase I to define various categories of DHS in response to public comments urging us to create ''bright line'' definitions for DHS. In general, commenters were pleased with this approach. The list of codes applies only to section 1877 of the Act and the corresponding regulations. The list is updated annually, and we look to commenters to identify any specific codes that we have listed that should not be considered ''radiation therapy services and supplies.''

Comment: One commenter stated that services that are furnished before or after radiation treatment (such as a consultation to plan the placement of radioactive elements or post-surgical dosimetry services) should not be considered radiation therapy services for physician self-referral purposes. According to the commenter, these services are neither radiation therapy services nor inpatient or outpatient hospital services; they are physician services performed in a physician's office.

Response: Pre-planning placement services (CPT codes 77300 and 77305 through 77331) and normal follow-up post-surgical dosimetry services are professional physician services, as are many other radiation therapy services. To the extent that those services are billed as an outpatient hospital service, they would constitute a designated health service under section 1877(h)(6)(K) of the Act. We think that, in many cases, these services will be performed or supervised by a radiation oncologist pursuant to a consultation and therefore will not constitute a ''referral'' under § 411.351. To the extent that a request for these services constitutes a referral, it would appear that the in-office ancillary services exception and the physician services exception could apply in many cases. However, these exceptions are not available for any technical component that is billed as an outpatient hospital service.

Comment: One commenter asked us to reconsider our statement in the January 2001 final rule preamble (66 FR 931) that there is no logical or empirical evidence that physician ownership of brachytherapy centers improves quality of care.

Response: The commenter offered no evidence or support for the proposition that physician ownership of brachytherapy centers improves quality of care. Our position remains the same.

Comment: One commenter asked that we exclude from the list of codes that defines ''radiation therapy services and supplies'' the CPT codes for brachytherapy (CPT codes 77781 through 77784). The commenter stated that excluding brachytherapy from the list of DHS codes would be appropriate because the Congress did not intend to include as DHS invasive forms of radiation therapy. According to the commenter, when the Congress expanded section 1877 to apply to radiation therapy services and supplies, radiation therapy typically encompassed only the use of an external electron beam through the body without any invasive procedure. The commenter also noted that the definitions of ''radiation'' and ''radiation therapy'' found in Stedman's Medical Dictionary

do not include treatments (such as brachytherapy) in which surgical means are necessary to insert radioactive isotopes into the body. *See The American Heritage Stedman's Medical Dictionary,* Houghton Mifflin Company, Boston, Massachusetts, October 1995 (defining ''radiation'' as the emission and propagation of energy in the form of rays or waves, and ''radiation therapy'' as the treatment of disease with radiation, especially selective irradiation with X-rays or other ionizing radiation and by ingestion of a radioisotope). The commenter asserted that the same logic that caused us to exclude certain invasive radiology procedures from the definition of ''radiology and certain other imaging services'' should persuade us to exclude brachytherapy from the definition of ''radiation therapy services and supplies.''

Response: As noted in § 411.351, the list of codes defining ''radiation therapy services and supplies'' is based on section 1861(s)(4) of the Act (authorizing Medicare payment for ''x-ray, radium and radioactive isotope therapy''). Brachytherapy involves the placement of radioactive isotopes under the skin for therapeutic purposes, and therefore is clearly within the scope of services identified in section 1861(s)(4) of the Act. Accordingly, brachytherapy is also within the scope of the DHS category of ''radiation therapy services and supplies.'' We find nothing in the statutory scheme or language to suggest that the Congress intended to exclude radiation therapy involving surgical or invasive procedures. We do not believe the Congress intended the definitions of DHS under the statute to be frozen in time, as this would eventually defeat the purpose of the statute. Just as new clinical laboratory tests are, and will continue to be, included in the definition of ''clinical laboratory tests,'' so, too should new radiation therapy services and supplies be included in the definition of ''radiation therapy and supplies.'' Moreover, in 1993, when section 1877 of the Act was made applicable to radiation therapy services and supplies, the Congress would have understood that this category included brachytherapy services. AMA-approved brachytherapy codes have been in existence since 1983: One brachytherapy service (CPT code 77776) received a CPT code in 1983; ten brachytherapy services (CPT codes 77761–63; 77777–78; 77789; 77326–28; and 77799) received CPT codes in 1984; and four brachytherapy services (CPT codes 77781–84) received CPT codes in 1991. Finally, the AMA chose to place the codes for these brachytherapy items and services in the 77000 section, a section for radiation therapy services.

Comment: The same commenter argued in the alternative that we should use our authority pursuant to section 1877(b)(4) of the Act to create an exception for financial relationships involving brachytherapy services. According to the commenter, such financial relationships do not pose a risk of program or patient abuse because brachytherapy is not a diagnostic procedure; it is used only after a diagnosis of cancer has been made by the treating physician. In addition, the commenter asserted that, since brachytherapy can be performed only once on a patient, any abuse in the form of repetitive billing would be obvious. Finally, the commenter asserted that abuse is more likely to occur with other competing and more expensive procedures that have higher profit margins, such as radical prostatectomy or external beam radiation.

Response: We are not persuaded that an additional exception is warranted. To the extent brachytherapy services and supplies are furnished by a radiation oncologist pursuant to a consultation, the consultation exception could apply. To the extent that a urologist provides the services, there are a number of exceptions that could be available, depending on the circumstances. We recognize that there would be no exception available for a facility fee billed by an entity owned by a urologist, unless the entity were located in a rural area or the DHS qualified under the in-office ancillary services exception. However, we continue to believe that brachytherapy may be subject to abuse. For example, a urologist who owns a brachytherapy facility may be more inclined to order brachytherapy rather than another radiation therapy treatment in which he or she may not have a financial interest. The statuory language and structure reflects the Congress' intent to curb physician ownership in DHS entities to which they refer because such ownership creates an inappropriate financial incentive to make referrals. With respect to the commenter's assertions regarding the nature of brachytherapy, all radiation therapy services and supplies are furnished only after a diagnosis of cancer is made; thus, we see no reason to differentiate among radiation therapy treatments on that basis. The fact that other treatments may be more expensive or have higher profit margins—and therefore may be more likely to be abused—is not a basis for concluding that brachytherapy poses no risk of abuse.

Comment: A commenter stated that brachytherapy is less invasive than other procedures for removing a tumor in the prostate gland and that including it as a designated health service will prohibit physicians in multiple specialties from collaborating to provide the service.

Response: We are unclear from the comment as to why including brachytherapy as a DHS will prohibit collaboration on such services. While certain financial interests in brachytherapy services may be prohibited, nothing in the statute or regulations prohibits physicians' professional collaboration on patient care. A physician's personally performed service is not considered a referral for purposes of section 1877 of the Act. Futhermore, physicians are free to refer to one another as long as they do not have a prohibited financial arrangement. Finally, we are not aware of a brachytherapy access problem in the United States.

H. Durable Medical Equipment (DME) and Supplies (Phase I—66 FR 931)

We received only one comment regarding our definition of DME, in which we defined DME with reference to section 1861(n) of the Act and § 414.202. We are not making any changes to this definition.

Comment: The January 1998 proposed rule explicitly stated that home dialysis equipment and supplies do not constitute DME for the purposes of section 1877 of the Act. A commenter sought clarification that the ESRD benefit under section 1861(s)(2)(F) of the Act (providing coverage for home dialysis supplies and equipment) is distinct from the DME benefit in section 1861(s)(6) of the Act, and that home dialysis equipment and supplies are not covered as DME under Medicare.

Response: The commenter is correct. Our position regarding home dialysis equipment and supplies remains the same: The DME and ESRD benefits are distinct, and home dialysis equipment and supplies are not DME, as defined in section 1861(n) of the Act and § 414.202 of the regulations.

I. Parenteral and Enteral Nutrients, Equipment and Supplies (Phase I—66 FR 932)

We received only one comment on this subject and are making no change to the definition set forth in Phase I.

Comment: A commenter stated that the Phase I preamble (66 FR 933) asserts incorrectly that enteral nutrition is widely available in grocery stores, drug stores, and other retail outlets. The statement was made in response to a

comment advocating that we exclude from the definition or create an exception for parenteral nutrition furnished by a physician group practice to its own patients.

Response: We have received conflicting reports about the routine availability of enteral nutrition in grocery stores and drug stores. The commenter may be correct with respect to patients who are completely dependent on enteral formulas for nutrition. Regardless, the Congress specifically excluded the provision of parenteral and enteral nutrients from the in-office ancillary services exception in section 1877(b)(2) of the Act. Accordingly, to the extent that the commenter would like us to reconsider our overall response to the original comment, we cannot do so.

J. Prosthetics, Orthotics, and Prosthetic Devices and Supplies (Phase I—66 FR 933)

We received no comments on this subject and are making no substantive changes to the definition.

K. Home Health Services (Phase I—66 FR 936)

We received no comments on this subject and are making no changes to the definition.

L. Outpatient Prescription Drugs (Phase I—66 FR 937)

Phase I defined outpatient prescription drugs as ''all prescription drugs covered by Medicare Part B.'' We note that, effective January 1, 2006, many additional outpatient prescription drugs will be covered under Medicare Part D, which was added to the Social Security Act by section 101 of MMA. In light of the expanded coverage, we will revisit the definition of ''outpatient prescription drugs'' in a future rulemaking. The MMA amended Title XVIII to include a definition for ''covered Part D drug'' in section 1860D–2(e) of the Act. While we have no specific proposal at this time, we are interested in receiving comments regarding approaches to expanding the definition of ''outpatient prescription drugs'' to reflect the definition of ''covered Part D drug'' in the MMA. We received the following comments regarding outpatient prescription drugs.

Comment: A commenter asked us to clarify that antigens are not ''outpatient prescription drugs'' or, in the alternative, to clarify that a referral by a physician for antigens which he or she personally provides is not a ''referral'' within the meaning of section 1877 of the Act.

Response: We responded to this comment in section V.A, noting that the provision of antigens may be protected under the physician services or in-office ancillary services exceptions. We also noted that when antigens are personally furnished by the referring physician, there is no ''referral'' for purposes of section 1877 of the Act.

Comment: One commenter urged that any drug administered in a physician's office not be considered an ''outpatient prescription drug'' because the physician may not be required to write a prescription for that item. According to the commenter, section 1877 of the Act was intended to govern only the in-office dispensing (as opposed to administration) of drugs. In the alternative, the commenter believed that we should exclude all injectables from the definition of ''outpatient prescription drugs,'' whether or not they would qualify as immunizations or vaccines. According to the commenter, the administration of injectable drugs is so integral to a physician service that physicians should be permitted to furnish injectables without complying with the in-office ancillary services exception.

Response: We responded to similar comments in Phase I (66 FR 938). We continue to find no meaningful distinction between prescription drugs dispensed by pharmacies and those mixed and administered in a physician's office. Drugs administered in the physician office setting are outpatient prescription drugs; they are available only upon a physician's order and are provided in an outpatient setting. Phase I made clear that drugs administered in a physician's office may, and typically will, fit in the in-office ancillary services exception. If administered personally by the referring physician, there is no ''referral'' for purposes of section 1877 of the Act. We are not convinced that creating an additional exception for all drugs administered in the physician office is either necessary or without any risk of fraud or patient abuse.

M. Inpatient and Outpatient Hospital Services (Phase I—66 FR 940)

In the January 1998 proposed rule, we solicited comments on whether we should exclude lithotripsy from the DHS category of ''inpatient and outpatient hospital services.'' We received hundreds of comments urging us to exclude lithotripsy as a designated health service. We addressed these comments in the Phase I preamble (66 FR 940 through 941) and declined to exclude the service as an inpatient or outpatient hospital service. After the publication of Phase I, we received similar comments from two associations representing physicians with ownership interests in lithotriptors.

Given the statutory language, we are not revising the regulatory definition. However, in light of the unique legislative history regarding the application of section 1877 of the Act to lithotripsy, we will not consider lithotripsy an ''inpatient or outpatient service'' for purposes of section 1877 of the Act. Contractual arrangements between hospitals and physicians or physician practices regarding lithotripsy nevertheless constitute a ''financial relationship'' under section 1877 of the Act. Accordingly, such contractual arrangements must comply with an exception if the physician will refer Medicare patients to the hospital for services that otherwise constitute an ''inpatient or outpatient hospital service'' or another designated health service.

N. Other Definitions (Phase I—66 FR 942)

1. Consultation

The definition of ''consultation'' is addressed in section III.B.2 of the Phase I preamble (66 FR 873), in section II.D of this Phase II preamble (including comments and responses), and in the regulations in § 411.351.

2. Entity

The definition of ''entity'' is addressed in section VIII.N.2 of the Phase I preamble (66 FR 943) and in the regulations in § 411.351. Comments and our responses on the Phase I definition follow.

Comment: Several commenters claimed that the definition of ''entity'' was confusing. In particular, the commenters urged that the definition be restructured to be more clear and that the statement that certain organizations that employ a supplier or operate a facility that ''could'' accept reassignment be changed to clarify whether such entities would, in fact, be deemed to provide DHS.

Response: We have rewritten the language in an effort to provide greater clarity. The substance of the definition remains unchanged.

Comment: A commenter representing independent practice associations urged that we exclude IPAs from the definition of ''entity'' when they furnish DHS directly, through employees or entities that they own.

Response: We discern no reasonable basis to treat IPAs that furnish DHS differently from other entities that furnish the same services. If an IPA

furnishes DHS through employees or owned entities, then it is a DHS ''entity'' for purposes of section 1877 of the Act.

3. Fair Market Value

The definition of ''fair market value'' is addressed in section VIII.N.3 of the Phase I preamble (66 FR 944) and in the regulations in § 411.351. The following are our responses to comments to the Phase I definition.

Comment: A commenter expressed concern that the discussion of ''fair market value'' in the Phase I preamble does not provide sufficiently clear guidance for determining ''fair market value.'' That commenter recommended that the regulations include a rebuttable presumption of reasonableness and ''fair market value'' when entities benchmark their arrangements to objective measures or when they obtain the opinion of independent third parties as to ''fair market value'' in a particular arrangement. The commenter suggested that the presumption be similar to that contained in the IRS's intermediate sanctions provisions.

Response: We appreciate the commenter's desire for clear ''bright line'' guidance. However, the statute covers such a wide range of potential transactions that it is not possible to verify and list appropriate benchmarks or objective measures for each. Moreover, the definition of ''fair market value'' in the statute and regulation is qualified in ways that do not necessarily comport with the usage of the term in standard valuation techniques and methodologies. For example, the methodology must exclude valuations where the parties to the transactions are at arm's length but in a position to refer to one another. In addition, the definition itself differs depending on the type of transaction: leases or rentals of space and equipment cannot take into account the intended use of the rented item; and in cases where the lessor is in a position to refer to the lessee, the valuation cannot be adjusted or reflect the value of proximity or convenience to the lessor. Our Phase I discussion made clear that we will consider a range of methods of determining fair market value and that the appropriate method will depend on the nature of the transaction, its location, and other factors. While good faith reliance on a proper valuation may be relevant to a party's intent, it does not establish the ultimate issue of the accuracy of the valuation figure itself. With respect to valuing physician services, however, we are establishing several ''safe harbored'' methodologies discussed in more detail in section VIII.C.

Comment: A commenter sought clarification that determinations of ''fair market value'' could involve comparisons of national or regional data where appropriate. By way of example, the commenter suggested that the market for physician recruitment has become national.

Response: Whether resort to national or regional data is appropriate will depend on the facts and circumstances of each case. The regulations necessarily cover a wide variety of arrangements, services, and markets, and no single means for determining ''fair market value'' will apply to all. For hourly physician compensation, we have added ''safe harbored'' methodologies for establishing fair market value that take into account national and regional data (section VIII.C of this preamble). If parties are using comparables to establish fair market value, they should take reasonable steps to ensure that the comparables are not distorted.

4. Group Practice

The definition of ''group practice'' is addressed in section VI.C of the Phase I preamble (66 FR 894), in section V.C of this Phase II preamble, and in the regulations in § 411.352.

5. Health Professional Shortage Area

The definition of ''health professional shortage area'' is addressed in section VIII.N.5 of the Phase I preamble (66 FR 945) and in the regulations in § 411.351. We received no comments on this definition and are making no changes to it.

6. Employee

The definition of ''employee'' is addressed in section VIII.N.6 of the Phase I preamble (66 FR 946), in section VIII.B of this Phase II preamble, and in the regulations in § 411.351.

7. Immediate Family Member

The definition of ''immediate family member'' is addressed in section VIII.N.7 of the Phase I preamble (66 FR 946) and in the regulations in § 411.351. We received no comments on this definition and are making no changes to it.

8. Referral

The definition of ''referral'' is addressed in section III.B of the Phase I preamble (66 FR 871), section II.C of this Phase II preamble, and in the regulations in § 411.351.

9. Remuneration and the Exceptions in Section 1877(h)(1)(C) of the Act

The definition of ''remuneration'' (along with the exceptions) is addressed in section VIII.N.9 of the Phase I preamble (66 FR 946) and in the regulations in § 411.351.

The statute expressly excludes from the definition of ''remuneration'' payments made by an insurer or 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 that insurer or by that self-insured plan. This might occur, for example, if a plan enrollee receives out-of-network care in an emergency room. In practice, the application of this rule may not have the intended effect of excluding those payments from the definition of ''remuneration.'' This is because, in many cases, payments are made by downstream subcontractors of insurers or self-insured plans (for example, providers who have assumed risk under a plan), rather than the insurer or plan itself. Accordingly, we have revised the regulations to cover payments made by downstream subcontractors.

In addition, we received the following comment:

Comment: A commenter recommended that the items and services enumerated by the new exceptions for non-monetary compensation, medical staff incidental benefits, and compliance training be excluded from the definition of ''remuneration'' rather than included in various new exceptions.

Response: We disagree. Most, if not all, of the items and services covered by the new exceptions fit squarely in the broad statutory definition of ''remuneration.'' The Congress included in the definition of ''remuneration'' a short list of specific items and services that it intended to exclude. The items and services covered by the new exceptions are not among them. Treating them as remuneration (that is, as creating compensation arrangements) and then excepting them is consistent with the statutory scheme and structure.

We note that among the items specifically excluded from the definition of remuneration are items used to collect, transport, process, or store specimens. In the Phase I preamble, we indicated that sterile gloves do *not* fit in this category of items excluded from the definition of remuneration (66 FR 948). Our use of the term ''sterile gloves'' was intended to be illustrative, not exclusive, and other gloves similarly are *not* excluded from the definition of remuneration. As stated in the Phase I preamble, the provision of any free gloves would be remuneration and would need to fit in an exception.

10. Transaction and Isolated Transaction (Phase II—§ 411.357(f))

The definitions of ''transaction'' and ''isolated transaction'' are addressed in section VIII.F of this Phase II preamble and in the regulations in § 411.351.

XII. Regulatory Exceptions

In Phase I, we created a number of new exceptions using the authority granted to the Secretary in section 1877(b)(4) of the Act. We are creating some additional exceptions under section 1877(b)(4) of the Act in Phase II.

Several commenters to Phase I objected to the condition in these new regulatory exceptions that the arrangement in question not violate the anti-kickback statute. The commenters felt that this condition injected an unnecessary facts and circumstances test in what is intended to be a bright line area of law. If the requirement is retained, a commenter urged that the language used in all references to violation of the anti-kickback statute in the regulations be made consistent. One commenter claimed to be confused by the requirement in new exceptions that compensation arrangements comply with all billing and claims submission laws or regulations. The commenter pointed out that, in some cases, it is difficult to see how compensation arrangements implicate billing or claims filing.

We have endeavored to craft bright line rules under these regulations wherever possible. However, our authority under section 1877(b)(4) of the Act is expressly limited to arrangements that pose no risk of program or patient abuse. Thus, if an arrangement poses even a low risk, we cannot create a new exception. The statutory ''no risk'' standard is not limited to a determination of ''no risk'' under section 1877 of the Act. Given this broad ''no risk'' standard, it would be impossible to create new exceptions for many arrangements without the anti-kickback statute condition. Many arrangements that might otherwise warrant an exception under section 1877 of the Act—a strict liability statute—pose some degree of risk under the anti-kickback statute; these arrangements cannot, therefore, be said to pose *no* risk. We are rectifying the lack of consistency in the language used in these regulations when referring to the anti-kickback statute by making technical changes to several provisions. We are also clarifying through a new definition at § 411.351 that a party will be considered to have received a favorable advisory opinion from the OIG with respect to the anti-kickback statute if the opinion indicates that the OIG will not subject the party's arrangement to sanctions arising under the anti-kickback statute.

The billing and claims submission condition was also included to satisfy the absolute *no* risk standard under section 1877(b)(4) of the Act. We agree that many compensation arrangements will not implicate billing or claims filing. However, some arrangements may, and the exceptions are designed to cover a wide scope of arrangements. Moreover, most referrals will implicate billing and claims submission for the referred item or service. If a particular arrangement does not implicate billing or claims submission in any way, then the parties need not be concerned with that condition. We have also revised the regulations to rectify the lack of consistency of the language used in this regard. Specifically, technical changes have been made to several provisions.

We received one comment proposing a new exception that we are not promulgating. The request was for an exception for referrals in areas with a demonstrated community need (for example, areas lacking adequate health care facilities or providers, particularly inner city areas). The proposed exception would be comparable to the rural area exception and permit physician ownership of inner city DHS entities. We are unable to adopt the suggestion. The Congress clearly limited ownership of DHS entities in underserved areas to rural providers (section 1877(d)(2) of the Act). We cannot conclude that ownership in inner city areas—which are proximate to more affluent urban areas from which to draw additional business—would be without risk. We are mindful of the difficulties some inner city areas experience in providing adequate health care to community residents. However, given the numerous statutory and regulatory exceptions—including the fair market value exception—we are not persuaded that section 1877 of the Act is a significant impediment.

Comments and responses to new regulatory exceptions not already discussed in this preamble are set forth below.

A. Academic Medical Centers (Phase I—66 FR 915; § 411.355(e))

[If you choose to comment on issues in this section, please include the caption ''Academic Medical Centers Exception'' at the beginning of your comments.]

In Phase I, we added a new regulatory exception for academic medical center arrangements, using the authority granted the Secretary under section 1877(b)(4) of the Act. While most commenters praised the new exception in § 411.355(e), many suggested ways to improve it. The most significant comments addressed the requirements in § 411.355(e)(1)(ii) relating to the referring physician's compensation. In particular, commenters observed that the requirement that a physician's compensation be ''set in advance'' precluded calculating any component of the compensation using a percentage-based methodology. In addition, the requirement that compensation not take into account ''other business generated by the referring physician within the academic medical center'' potentially affected compensation based on a physician's professional services. Commenters viewed these provisions as more strict than the requirements for physician compensation paid by group practices under § 411.352 or for other physician compensation arrangements.

Other commenters requested modifications to various elements of the definition of an ''academic medical center'' in § 411.355(e)(2). These commenters wanted greater flexibility as to the number and organization of affiliated practice plans, and they objected to the requirements that a majority of the affiliated hospital's medical staff be faculty members and a majority of the hospital's admissions come from faculty members.

Our modification of the ''set in advance'' and the ''other business generated'' provisions (see section IV above) should address the concerns of many commenters. We are revising the rule to make it easier to qualify as an academic medical center or a component of an academic medical center, and we have clarified some of the exception's terminology. The particular changes are discussed in the responses to comments that follow.

Comment: One commenter asked that we broaden the definition of an academic medical center in § 411.355(e)(2) to eliminate the requirement that an academic medical center include an accredited medical school. According to the commenter, if a hospital has an approved medical education program, it should be enough to ensure that the hospital is part of an academic medical center. One commenter suggested including any hospital or health system that sponsors five or more medical education programs.

Response: We agree that the definition is overly restrictive. We have modified the definition of an academic medical center in § 411.355(e)(2)(i) to permit hospitals or health systems that sponsor four or more approved medical education programs (for purposes of the

exception, an ''accredited academic hospital'') to qualify, provided they meet the other criteria in the exception. We think a requirement for four programs will adequately ensure that the hospital or health system has a substantial teaching mission. A hospital or health system meeting the requirement in § 411.355(e)(2)(i) may be the same hospital that meets the ''affiliated hospital'' requirement of § 411.355(e)(2)(iii), and we have modified the regulation to reflect this. Finally, to reflect this broader reading of an ''academic medical center,'' we have revised the regulations to clarify that the referring physician may be on the faculty of the affiliated medical school or the accredited academic hospital.

Comment: We received many comments related to various aspects of the affiliated faculty practice plan requirement in § 411.355(e)(2)(ii). A number of commenters objected to the requirement that the practice plan be a tax exempt organization under either section 501(c)(3) or 501(c)(4) of the Internal Revenue Service (IRS) Code. These commenters noted that many bona fide plans are organized as professional corporations or not-for-profit organizations under State law or are not separate legal entities. Other commenters sought clarification as to whether an academic medical center could have more than one affiliated faculty practice plan. Finally, several commenters asked whether the faculty practice plan could be affiliated with the teaching hospital, rather than the medical school.

Response: We recognize that there are many variants of the basic academic medical center arrangement. We are eliminating the requirement that the faculty practice plan or plans be organized in any particular manner. As long as the other criteria of the exception can be met, there is sufficient assurance that the faculty practice plan is part of a *bona fide* academic medical center and that the practice plan supports the core teaching mission. We are also clarifying § 411.355(e)(2)(ii) to reflect that an academic medical center may have more than one affiliated faculty practice plan and that the faculty practice plans can be affiliated with the teaching hospital, the medical school, or the accredited academic hospital.

Comment: A number of commenters questioned aspects of § 411.355(e)(2)(iii), especially the requirements that a majority of the affiliated hospital's medical staff be faculty members and that a majority of the hospital's admissions be made by faculty members. A number of commenters suggested that these requirements are unnecessary in light of § 411.355(e)(1)(i), which contains the requirements for referring physicians. Some commenters sought clarification that residents and non-physician practitioners need not be counted when calculating the percentage of medical staff that are faculty members. Other commenters suggested that courtesy and volunteer faculty should count as faculty members for purposes of the tests in § 411.355(e)(2)(iii), even if they do not qualify as referring physicians under § 411.355(e)(1)(i). One commenter on behalf of a children's hospital stated that children's hospitals frequently affiliate with several medical schools in their geographic area. The commenter suggested that we permit children's hospitals to aggregate the faculty members from all affiliated medical schools. Another commenter on behalf of children's hospitals asked that the tests be restructured to be alternatives, so that satisfying either test would be sufficient. One commenter asked that we include in the exception arrangements between a medical college and a hospital other than an affiliated teaching hospital by broadening the definition of an affiliated hospital; this commenter suggested that we include unaffiliated hospitals where otherwise *bona fide* faculty members of the academic medical center may be assigned by the medical school to perform services as part of their continued employment or appointment with the academic medical center. The commenter noted that these kinds of arrangements occur for a variety of practical reasons, ranging from availability of sophisticated specialty equipment to accommodating the needs of communities located near unaffiliated hospitals.

Response: Given the breadth of the academic medical center exception, it is important to ensure that the relationship between the components is sufficiently focused on the academic medical center's core mission. We believe the tests for affiliated hospital faculty and admissions set forth in § 411.355(e)(2)(iii) are strong indicators of that core relationship. A teaching hospital can include any faculty, including courtesy and volunteer faculty, in determining whether it qualifies under these tests. We are, however, revising the regulatory text to clarify (i) that the majority of physicians on the medical staff must be on the faculty, and (ii) that the aggregation of faculty from any affiliated medical school is permitted. We agree with the commenters that residents and non-physician professionals do not need to be included as medical staff for purposes of § 411.355(e)(2)(iii).

Comment: Several commenters raised issues about the requirement in § 411.355(e)(1)(i) that the referring physician must be an employee of a component of the academic medical center. Other commenters asked that volunteer faculty be included in the requirement. One commenter representing a State institution wanted primary care physicians included, even though they do not have substantial teaching responsibilities. One commenter asked that we clarify that the physician can be an employee of the hospital, as well as the medical school.

Response: The purpose of the academic medical center exception is to provide protection under section 1877 of the Act for academic medical centers because they often have complex compensation arrangements with their faculty. If a physician is not an employee of any of the components of the academic medical center, we believe the relationship between the physician and the party paying the remuneration should not be sufficiently different from the usual arrangements of entities or organizations that are not academic medical centers, and one of the other exceptions under section 1877 of the Act should apply. For the same reasons, we are not including primary care physicians who do not perform substantial academic services or clinical teaching services. While we recognize that primary care services may be part of a State institution's mission, the primary care physicians are essentially in the same circumstances as employed physicians of any health system. Arrangements with those physicians can be structured to fit in other exceptions, including the fair market value exception or the personal services exception.

The referring physician need not be an employee of the medical school, however. Section 411.355(e)(1)(i) requires only that the referring physician be a *bona fide* employee of a component of the academic medical center. A referring physician could be an employee of the teaching hospital and a volunteer faculty member, for example, as long as his or her employment encompasses substantial academic services or clinical teaching services.

Comment: Several commenters also asked that we clarify what constitutes ''substantial academic or substantial clinical teaching services'' under § 411.355(e)(1)(i)(D).

Response: In the Phase I rule, we did not specify what constitutes ''substantial academic services or

clinical teaching services'' because we believe it will vary with the precise duties of a given faculty member, and we wanted to provide academic medical centers with flexibility. Nevertheless, to provide added clarity, we are adding a ''safe harbor'' provision to § 411.355(e)(1)(i)(D) that will deem any referring physician who spends at least 20 percent of his or her professional time or, in the alternative, 8 hours per week providing academic services or clinical teaching services (or a combination of academic services and clinical teaching services) as fulfilling the requirement. This test is intended to be a ''safe harbor'', not an absolute requirement, and the regulation is being modified to make clear that physicians who do not qualify under this ''safe harbor'' may still be providing substantial academic services or clinical teaching services, depending on the circumstances. Academic medical centers should use a reasonable and consistent method for calculating a physician's academic services and clinical teaching services. We are also modifying the regulation text to clarify that the substantial services test can be met through either academic services (which would include, without limitation, both classroom and academic research services) or clinical teaching services, or a combination of both.

Comment: One commenter asked that we clarify in which State the referring physician must be licensed.

Response: The referring physician must be licensed in the States in which he or she practices.

Comment: Many commenters objected to the requirements of § 411.355(e)(1)(ii) that the total compensation paid to the referring physician by all components of the academic medical center be ''set in advance'' and not take into account ''other business generated by the referring physician within the academic medical center.'' The commenters stated that many faculty practice plans, like many group practices, base some part of the physician's compensation on a percentage of collections or revenues attributable to the physician's personally performed services. Moreover, commenters were unclear as to what effect the requirement that the compensation not take into account ''other business generated'' by the referring physician would have on a physician's personally performed services. The commenters generally thought that academic medical centers should be allowed to compensate referring physicians in the same manner as group practices or entities that employ physicians.

Response: We believe the changes made to the definitions of ''set in advance'' and ''other business generated'' described in section IV above largely address the commenters' concerns. We are not persuaded that further changes are needed. Nor are we persuaded that academic medical center arrangements are more similar to group practices than to other contractual arrangements.

Comment: Section 411.355(e)(l)(ii) (and the corresponding preamble discussion) refers to the referring physician's total compensation for the ''previous 12-month period (or fiscal year or calendar year).'' A commenter found this reference unclear insofar as compensation is generally set for a future period. Moreover, the commenter wondered how the ''set in advance'' requirement would be applied to compensation in a prior time period. The commenter suggested that the phrase ''previous 12-month period'' be deleted and that the exception instead require that the compensation be fixed for a specified time period.

Response: We are revising § 411.355(e)(l)(ii) to delete ''the previous 12-month period (or fiscal year or calendar year)'' language. Upon further consideration, we do not believe that a time period requirement is necessary in light of the remaining conditions in § 411.355(e)(l)(ii) and the exception as a whole.

Comment: One commenter asked us to clarify that in establishing a referring physician's compensation, an academic medical center is not limited to the fair market value at other academic medical centers if the fair market value for comparable private practice physicians in its area is higher.

Response: The commenter is correct. An academic medical center can use either measure of fair market value.

Comment: One commenter asked that the regulation except all transfers of funds between the components of an academic medical center and any other supporting organization, such as a foundation, as long as the supporting organization's primary purpose is supporting the nonprofit mission of the academic medical center, including health care services, education, research, and disease prevention.

Response: We agree in part with the commenter, although we consider the commenter's proposed change to be overly broad in the context of this exception. We have revised the rule to include, in the list of possible components of an academic medical center, not-for-profit supporting organizations whose primary purpose is supporting the teaching mission of the academic medical center.

Comment: A commenter asked that we clarify that the components of the academic medical center need not be separate legal entities.

Response: We have made a clarifying change to § 411.355(e)(1)(i)(A).

Comment: A number of commenters asked that we modify the requirement in § 411.355(e)(1)(iii)(B) that the relationship among the components be set out in a written agreement. Some commenters asked that we permit the relationship to be set out in several separate documents. Others suggested that a course of conduct should be sufficient. A commenter representing an academic medical center with components all owned by a single legal entity noted that the relationship of its components is not reflected in written agreements among the components. This commenter suggested that transfers of funds documented in routine financial reports covering the components should suffice in lieu of written agreements.

Response: We did not intend to restrict the written agreement to a single document. We have modified the regulatory text of § 411.355(e)(1)(iii)(B) to permit the relationship to be memorialized in multiple writings. In order to permit the government to verify an academic medical center's compliance with the exception, it is necessary that the relationship of the components be memorialized in writing or that there be a clearly established course of conduct that is appropriately documented. In the case of a single legal entity academic medical center, we agree that financial reports documenting the transfers of funds between components would be sufficient.

Comment: One commenter asked us to revise the language in § 411.355(e)(1)(iii)(C) to permit use of research money for bona fide research, teaching, indigent care, and community service, the same missions listed in § 411.357(e)(1)(iii)(A), as long as use of the funds is consistent with the terms and conditions of the research grant. The commenter explained that in many instances compensation paid to a physician under a research grant may properly be used for these purposes.

Response: We agree that some additional flexibility in this area is warranted. We have modified the regulations to cover research money used for teaching, a core academic medical center function. However, while we recognize the importance of indigent care and community service, the commenter's proposal is overly broad in the context of research grants,

which can be an area subject to potential abuse. Payments to referring physicians for indigent care or community service may be structured to fit in other exceptions.

B. Services Furnished Under Certain Payment Rates (§ 411.355(d); Phase I—66 FR 924)

Existing Law: In the August 1995 final rule, we took the position that clinical laboratory services furnished as part of a larger service paid by Medicare on a composite basis, such as surgery in an ambulatory surgical center (ASC) or treatment in an end-stage renal dialysis (ESRD) facility, was a referral to an entity providing clinical laboratory services. Accordingly, if the DHS entity and the referring physician had a prohibited financial relationship, any referral and corresponding claim would be tainted. However, under the authority granted in section 1877(b)(4) of the Act, the Secretary determined that referrals for certain clinical laboratory services furnished in ASCs or ESRD facilities or by a hospice do not pose a risk of Medicare program or patient abuse when payments for these services are included in the composite rates for those services. An exception for the services was included in the August 1995 final regulation at § 411.355(d).

Proposed Rule: The January 1998 proposed rule would have retained the exception for certain composite rate services, extending it to all DHS, with an amendment to allow the Secretary to except services furnished under other payment rates that the Secretary determines provide no financial incentive for either underutilization or overutilization or other risk of program or patient abuse. We specifically solicited comment on whether there are analogous composite rates under the Medicaid program.

Final Rule: In the Phase I final rule, we defined designated health services'' to exclude services that are reimbursed by Medicare as part of a composite rate (for example, ASC services, skilled nursing facility (SNF) Part A services, or ESRD composite rate services), except to the extent the specifically enumerated DHS in section 1877(h)(6) of the Act are themselves payable through a composite rate (that is, all services provided as home health services or inpatient or outpatient hospital services remain DHS.) (See § 411.351.)

Further, we created several exceptions for specific DHS often performed in association with services reimbursed on a composite rate, such as implants furnished in an ASC and certain drugs administered in or by an ESRD facility. Accordingly, we declined to extend § 411.355(d) beyond clinical laboratory services. Further, we indicated that we were reconsidering the need for § 411.355(d) in light of the new DHS definition and additional regulatory exceptions, and specifically solicited comments on this issue (66 FR 924).

Two commenters believe that the new composite rate exception rendered the prior exception unnecessary and potentially confusing insofar as it would suggest that a separate exception is needed or that clinical laboratory and other DHS would be subject to disparate treatment. One commenter conceded that the prior exception is redundant given the new composite rate rule, but asked that we nonetheless retain it and extend it to all DHS. The commenter stated that a clear, separate rule has been helpful for providers. On balance, we concur with the first two commenters. We are deleting the ASC/ESRD/Hospice exception, formerly in § 411.355(d). We are persuaded that the risk of undue confusion outweighs any utility in having a repetitive exception.

We note that services separately listed in section 1877(h) of the Act that are paid on a composite basis now or in the future (for example, home health and hospital services) are DHS, notwithstanding that they are paid on a composite basis. This concept was incorporated in the Phase I regulations at § 411.351 (definition of ''designated health services'').

C. Implants in an ASC (Phase I—66 FR 934; § 411.355(f))

In Phase I, we established a new exception for implants furnished by an ASC as a DHS entity. The new exception was necessary because many implantable items are DHS, but are not bundled in the ASC composite rate. Accordingly, the ASC becomes a DHS entity when it furnishes the implants.

Comment: A commenter sought clarification that the new exception for ASC implants applies whether the ASC bills the insurer or the physician bills.

Response: The exception applies to a financial relationship between the physician and the ASC (as the DHS entity) and to a referral for an implant used during an ASC procedure. Accordingly, the exception applies when the implant is billed by the ASC. When a physician bills for an implant, the physician is the DHS entity (as defined in § 411.351), rather than the ASC. In other words, not all implants qualify for this exception; implants implanted in an ASC qualify only if the ASC is the entity furnishing the implant. When a physician bills for the implant, another exception would need to be satisfied, such as the in-office ancillary services exception.

Comment: A commenter also sought confirmation that the exception applies to the implantation of radioactive seeds in the course of brachytherapy.

Response: The exception in § 411.355(f) applies only to ''implanted prosthetics, implanted prosthetic devices, and implanted DME.'' Accordingly, the implantation of radioactive brachytherapy seeds cannot qualify for this exception.

D. Fair Market Value Exception (Phase I—66 FR 917; § 411.357(l))

In Phase I, we finalized an exception for fair market value arrangements originally proposed in the January 1998 proposed rule, with several modifications in response to comments. The fair market value exception applies to arrangements, in writing, for the provision of items and services *by* physicians (provided directly or through employees). Several commenters to the Phase I rule advocated expanding the exception to include remunerative relationships other than the provision of items or services. The commenters urged us to expand the exception to cover the transfer, lease or license of real property, intangible property, property rights, or a covenant not to compete. Moreover, in the commenters' view, the exception should apply equally when the entity provides the items, services, property rights, and so forth to the physician. A commenter pointed out that the fair market value exception does not apply to leases of space *by* entities *to* physicians, contrary to statements in the preamble suggesting that the exception could apply in such circumstances. According to one commenter, as long as the arrangement is commercially reasonable, serves a legitimate business purpose, and provides for fair market value compensation that is set in advance and does not take into account the volume or value of referrals, the arrangement would be free of the potential abuse addressed by section 1877 of the Act. In addition, some commenters asserted that a written agreement should not be necessary if there is equally effective alternative evidence that the arrangement meets all of the requirements of the exception.

We are not persuaded to make substantive changes to the fair market value exception. We believe the other exceptions in the statute and regulations adequately address the various arrangements noted by the commenters, including arrangements in which physicians pay for items or services, such as office space. Moreover, we

believe that it would be difficult to expand the exception to be as comprehensive as the commenters advocate without posing a risk of fraud or abuse.

E. Non-Monetary Compensation up to $300 and Medical Staff Incidental Benefits (Phase I—66 FR 920; § 411.357(k) and § 411.357(m))

In Phase I, we finalized the proposed exception for non-monetary compensation up to $300 and added a new exception for incidental benefits provided by a hospital to its medical staff. Our responses to comments to the Phase I regulations on this subject follow.

Comment: A commenter suggested that we raise the $300 threshold in the non-monetary compensation exception to $600 to conform to IRS Code section 6041A(a), which requires businesses to report remuneration paid to service providers in excess of $600 per year. This change would enable providers to have a single tracking system for both purposes.

Response: We decline to adopt the suggestion. We believe $600 is too high for purposes of section 1877 of the Act and would create a risk of abuse. We do not think it should be unduly burdensome for providers to track when they have met the $300 threshold.

Comment: A commenter stated that the non-monetary compensation and medical staff incidental benefits exceptions imposed an undue burden on DHS entities by requiring them to keep track of the value of all items they provide to each physician in a given year. In addition, the commenter wondered whether an entity would risk having claims denied under section 1877 of the Act if it sends a $25 dollar holiday basket at the end of the year that inadvertently puts the total value of goods provided to the physician over the $300 limit.

Response: Section 1877 of the Act is clearly intended to make DHS entities responsible for monitoring their compensation arrangements with physicians. DHS entities that are not providing a high volume of free items to referring physicians are unlikely to be much affected by the requirement that they not provide more than $300 worth of items a year, nor should tracking be problematic.

Comment: Several commenters suggested that the $300 and $25 thresholds in § 411.357(k) and § 411.357(m) be indexed for inflation, because otherwise the usefulness of the exceptions will diminish over time.

Response: We agree that indexing is appropriate and have revised the regulations to reflect this change. The $300 limit for non-monetary compensation in § 411.357(k) and the $25 limit in § 411.357(m) will be adjusted annually for inflation to the nearest whole dollar effective January 1 of each year using the increase in the Consumer Price Index–Urban All Items (CPI–U) for the 12-month period that ends the previous September 30. As soon as possible after September 30 each year, we intend to display both the increase in the CPI-U for that 12-month period and the new limits on the physician self-referral Web site at *http://cms.hhs.gov/medlearn/refphys.asp.*

Comment: A commenter questioned the restriction in the non-monetary compensation exception on gifts conferred on group practices, rather than individual physicians, such as office parties, equipment, or supplies. The commenter thought that these gifts should be allowed as long as the value apportioned over each physician in the practice is less than $300. By precluding any compensation requested by a physician, the strict anti-solicitation provision reduces the risk that compensation might be solicited in exchange for referrals. Because this is an exception under section 1877(b)(4) of the Act, the exception must be drafted so that covered arrangements pose no risk of patient or program abuse. Consistent with the statutory scheme and structure, as well as the industry's expressed preference for bright line rules, the anti-solicitation provision applies to all physician requests for compensation, regardless of the purpose of the request.

Response: We are retaining the restrictions. Our intent with respect to group gifts is to preclude high value gifts to group practices that may control referrals to the benefactor. The anti-solicitation provision reduces the risk of abuse.

Comment: Several commenters sought clarification of the ''on-campus'' rule under the new regulatory exception for incidental benefits provided to a hospital's medical staff in § 411.357(m). In particular, the commenters viewed the ''on campus'' rule as unduly restrictive with respect to electronic communications, internet access (for access to records and patient-related communications), and pagers or two-way radios offered by hospitals to their medical staff. A commenter also explained that many hospitals are developing integrated information systems that electronically link various components of a health care system, including physicians. As part of these programs, physicians may be provided with dedicated computers to allow remote access to a hospital's system in connection with hospital services provided to hospital patients. These systems allow physicians to order tests and medications for hospital patients, check test results, schedule surgery, and access treatment protocols and other decision support references from their own offices.

A commenter also expressed concern about hospital Web sites that identify or list hospital-affiliated physicians. According to the commenter, these listings primarily benefit the hospital or health system and patients, but they may confer an incidental benefit on physicians that would be difficult to value and administratively difficult to track. The commenter urged that these listings be clearly excepted under the incidental benefits exception.

Response: The ''on-campus'' requirement in the exception was intended to make clear that the new exception for medical staff incidental benefits was limited to benefits, such as parking, cafeteria meals, and the like, that are customarily provided by hospitals to their medical staff and that are incidental to services being provided by the medical staff at the hospital. The exception was not intended to cover the provision of tangential, off-site benefits, such as restaurant dinners or theater tickets, which must comply with the exception for nonmonetary compensation up to $300. As indicated in the Phase I preamble, it was clearly our intent to cover benefits in the form of computer and internet access that ''facilitates the maintenance of up-to-date medical records and the availability of cutting edge medical information'' (66 FR 921).

Accordingly, we have modified § 411.357(m) to make our intent clear. We are also modifying § 411.357(m)(1) and § 411.357(m)(2) of the regulation by changing the word ''offered'' to ''provided'' to be consistent with other paragraphs of the exception and by making clear that § 411.357(m)(1) will be satisfied if the benefits are offered to all members of the medical staff practicing in the same specialty, even if some members do not accept them. Moreover, in the interest of clarity, we are changing the phrase ''performing other duties'' to ''are engaged in other services or activities.'' These changes will help clarify that dedicated electronic or Internet items or services can meet the requirement in § 411.357(m)(2), since those items or services would be provided ''only during periods when the medical staff members are * * * engaged in other services or activities that benefit the

hospital or its patients.'' Similarly, the revised exception will cover dedicated pagers or two-way radios used to facilitate instant communication with physicians in emergency or other urgent patient care situations when they are away from the hospital campus.

We also agree that the simple listing or identification of the medical staff on a hospital's Web site is an incidental benefit that should be excepted. We are revising the regulation to include listings of affiliated physicians in hospital advertising. However, advertising or promoting a physician's private practice on a hospital Web site is not covered; those arrangements would have to fit in the exception for non-monetary compensation under $300 or the hospital would have to charge the physician or practice a fair market value rate for the advertising. In light of all of the conditions contained in the exception, we do not believe that the arrangements that fit in the exception will pose a risk of program or patient abuse.

A hospital's provision of a computer or other technology that is wholly dedicated to use in connection with hospital services provided to the hospital's patients would be for the hospital's benefit and convenience and would not constitute remuneration to a physician for purposes of section 1877 of the Act. Moreover, while we believe that the provision of valuable information technology, such as computer hardware or software, to physicians may be subject to abuse, using our authority under section 1877(b)(4) of the Act, we are creating a new regulatory exception at § 411.357(u) for the provision of information technology items and services (including both hardware and software) by a DHS entity to a physician to participate in a community-wide health information system designed to enhance the overall health of the community, so long as certain conditions are met. The health information system must be community-wide, that is, available to all providers, practitioners, and residents of the community who desire to participate. The health care system must be one that allows community providers and practitioners to access and share electronic health care records. In addition to health care records, the system may permit access to, and sharing of, complementary drug information systems, general health information, medical alerts, and related information for patients served by community providers and practitioners. The DHS entity may only provide information technology items and services that are necessary to enable the physician to participate in the health information system. Thus, for example, if a physician already owns a computer, it may only be necessary to provide software or training specific to the health information system. Likewise, it would not be considered necessary to provide Internet access to a physician who already has Internet service. In all cases, the information technology items or services furnished under the exception must principally be used by the physician as part of the community-wide health information system. The items and services may not be provided in any manner that takes into account the volume or value of referrals or other business generated by the physicians. Thus, the exception would not apply to the selective provision of items and services to referral sources. Finally, as with all exceptions under section 1877(b)(4) of the Act, the arrangement must not violate the anti-kickback statute and all claims and billing must comply with applicable Federal and State laws and regulations. Under these circumstances, we do not believe that an exception for the provision of community-wide information technology items and services poses a risk of program or patient abuse; however, we will revisit the terms of the exception if we become aware of abusive arrangements.

Comment: A physician professional association asked that § 411.357(m)(5) be deleted from the exception for medical staff incidental benefits. Section 411.357(m)(5) requires that the incidental benefits be of a type offered to medical staff members at other local hospitals or by comparable hospitals in comparable regions. The commenter stated that this requirement imposed an unnecessary burden of inquiry on hospitals. The commenter believes that the $25 per occurrence limit was a sufficient safeguard.

Response: Section 411.357(m)(5) was not intended to, and did not, impose any duty of inquiry on hospitals. We believe that most hospital administrators are familiar with customary medical staff benefits offered by other hospitals locally and farther afield. The provision was included to help limit the exception to the provision of customary and usual staff benefits, such as meals, lab coats, and parking. We are concerned that the exception not be misused to protect an ever-increasing array of new ''incidental benefits'' that collectively are of considerable value to physicians. Nevertheless, we are persuaded that the other conditions in the exception sufficiently protect against such abuse. Accordingly, we are deleting § 411.357(m)(5).

Comment: One commenter considered the $25 per occurrence limit in the medical staff incidental benefits exception to be too low. The commenter suggested that the limit be deleted, or, in the alternative, raised to $100.

Response: We are not persuaded that the limit is unnecessary or too low. Benefits of higher value may still be protected under the exception for non-monetary compensation up to $300. However, as with the exception for non-monetary compensation, we have revised the regulations to provide for annual inflation indexing.

Comment: A commenter sought clarification regarding our statement in the Phase I preamble (66 FR 921) that we did not believe that medical transcription services were an incidental benefit of nominal value. The commenter found the statement ambiguous. In particular, the commenter asked us to confirm that the statement is limited to medical transcription services of non-hospital services (for example, services provided by physicians in their private offices).

Response: We do not believe that transcription of hospital medical records dictated by an attending physician is a benefit—incidental or otherwise—to the physician. Thus, such services do not create a compensation arrangement. However, the provision of transcription services for the benefit of the physician, such as transcription of his private office records, does create a compensation arrangement between the hospital and the physician that would need to fit in an exception.

Comment: An association representing hospitals inquired about the treatment under section 1877 of the Act of certain benefits provided to physicians that cannot fit in the non-monetary compensation exception, because they are worth more than $300; the medical staff incidental benefits exception, because they are worth more than $25 per occurrence; or the fair market value exception, because they do not involve a written contract.

These examples include:

- Business meetings with physicians (sometimes including spouses) that include a meal (for example, attendance at a Board of Trustees meeting or dinner with a hospital administrator to discuss operation of a hospital department).
- A dinner to which hospital physicians (and sometimes spouses) are invited to meet and recruit a potential new physician for the staff.
- Free use of a dedicated computer terminal located at the physician's office but usable only in connection with hospital patients and services.

• Free continuing medical education (CME) or other training at the hospital. (The commenter notes that hospitals often obtain educational speakers free of charge, thus enabling them to provide low cost training.)

• Physician referral services to the community in which they reside for which the physician may or may not pay a fee.

Response: The first two examples cited by the commenter involve scenarios that do not lend themselves to categorical answers. The statute defines ''remuneration'' broadly to include any remuneration, directly or indirectly, overtly or covertly, in cash or in kind (Section 1877(h)(1)(B) of the Act). Whether a remunerative arrangement between specific parties would fit in an exception would depend on the particular facts and circumstances. For example, some dinners and meetings might fit in the exception for non-monetary compensation at § 411.357(k) or the exception for fair market value compensation at § 411.357(l); others would not. Nothing in the statute precludes modest meals in connection with services provided by or to Boards of Trustees, Boards of Directors, or hospital administrators, and many of these activities can easily fit in an exception.

The third example cited by the commenter—the free use of a dedicated computer terminal used only for the hospital patients and services strikes us as unlikely to involve remuneration to the physician so long as the computer terminal has no independent value to the physician. Alternatively, the free use of the computer may qualify for the exception for medical staff incidental benefits at § 411.357(m). The fourth example, the free CME, could constitute remuneration to the physician, depending on the content of the program and the physician's obligation to acquire CME credits. With respect to referral services, we believe these services should be excepted under section 1877 of the Act, and, accordingly, we are incorporating the safe harbor under the anti-kickback statute for referral services at § 1001.952(f) into these regulations as a new exception at § 411.357(q). (We note that creation of a referral services exception was supported by a second commenter.)

We recognize that our regulations do not address every possible relationship between physicians and DHS entities of the type addressed by the commenter, nor could they. In some cases, relationships clearly will not involve a transfer of remuneration and thus will not trigger section 1877 of the Act. In others, an activity might involve the transfer of remuneration, and there may be no readily apparent exception. We expect that questions of the kind posed by the commenter will arise with some frequency. Parties may submit advisory opinion requests about specific arrangements according to § 411.370. We will also continue to evaluate whether remunerative arrangements exist for which additional exceptions are necessary and appropriate.

Comment: A commenter urged that long-term care facilities be permitted to use all the exceptions available to other providers, including the medical staff incidental benefits and compliance training exceptions.

Response: As noted in section XII.G, we are expanding the compliance training exception to include all entities. As for the medical staff incidental benefits exception, we agree that certain institutional entities, such as long-term care facilities, FQHCs, and other health care clinics, that have medical staffs should be permitted to provide incidental benefits to those staffs on the same terms and conditions as apply to hospitals under the exception. This exception applies only to *bona fide* medical staffs. Whether a facility has a *bona fide* medical staff will depend on the facts and circumstances. We have modified the regulations accordingly.

Comment: A commenter urged that the Office of Inspector General (OIG) issue a statement that remuneration covered by the non-monetary compensation, medical staff incidental benefits, and compliance training exceptions does not violate the anti-kickback statute.

Response: Whether to issue a statement of the sort requested by the commenter is a decision for the OIG and/or the Department of Justice and is outside the scope of this rulemaking. Parties may seek advisory opinions about their arrangements from the OIG pursuant to regulations at 42 CFR part 1008.

F. Risk-Sharing Arrangements (Phase I—66 FR 912–915; § 411.357(n))

We received several comments to the new risk-sharing arrangements exception in § 411.357(n) established in Phase I. The risk-sharing arrangements exception applies to compensation (including, but not limited to, withholds, bonuses, and risk pools) between a managed care organization or an independent physician's association and a physician (either directly or indirectly through a subcontractor) for services provided to enrollees of a health plan.

Comment: A commenter welcomed the new exception for risk-sharing arrangements, but requested a definition of the term ''managed care organization'' as used in the exception or clarification in preamble language that the new exception is meant to cover all risk-sharing compensation paid to physicians by an entity downstream of any type of health plan, insurance company, or health maintenance organization (HMO). A commenter sought clarification that the downstream entity could itself be an entity that furnishes DHS, such as a hospital.

Response: The new exception is meant to cover all risk-sharing compensation paid to physicians by an entity downstream of any type of health plan, insurance company, HMO, or Independent Practice Association (IPA), provided the arrangement relates to enrollees and meets the conditions set forth in the exception. All downstream entities are included. We purposefully declined to define the term ''managed care organization'' so as to create a broad exception with maximum flexibility.

Comment: A physician association asked that the prepaid plans and risk-sharing arrangements exceptions be expanded to include referrals of patients to entities owned by a managed care organization, even if the patients are not enrollees in the managed care organization. The commenter gave as an example a referral to an orthopedic ASC owned by a managed care organization that is, in turn, owned by the referring physician. The commenter considered it illogical that the physician could refer a health plan enrollee to the ASC, but not a Medicare fee-for-service patient.

Response: Contrary to the commenter's perception, we discern nothing illogical in the result under the example provided. The fee-for-service referral to a DHS entity in which the physician has an indirect ownership interest is precisely the kind of improper referral barred by the statute, whereas the statute includes an exception for referrals of Medicare managed care patients (§ 411.355(c)). (We assume, for purposes of responding to the example, that the ASC furnishes some designated health care service not covered by the ASC composite rate, since composite rate services are not DHS for purposes of section 1877 of the Act).

G. Compliance Training (Phase I—66 FR 921; § 411.357(o))

A number of commenters asked that we expand the new compliance training exception to include compliance training provided by entities other than

hospitals. A commenter asked that the exception be expanded to include training of the physician's office staff. We concur with both comments and have modified the exception in § 411.357(o) to include compliance training provided by any entity that furnishes designated health care services to a physician or a physician's office staff. We are also modifying the regulations to include compliance training addressing the requirements of any Federal, State, or local law, regulation, or rule governing the conduct of the party for whom the training is provided. We do not consider continuing medical education (CME) to be compliance training for purposes of this exception, which is primarily intended to promote legal compliance. In many cases, the provision of CME to physicians could constitute a benefit of significant monetary value to physicians. CME may be covered under the non-monetary compensation up to $300 exception.

H. Anti-Kickback Safe Harbors (Phase II, § 411.357(q) and § 411.357(r))

[If you choose to comment on issues in this section, please include the caption ''Anti-Kickback Safe Harbor Exception'' at the beginning of your comments.]

In the Phase I preamble, we indicated that we were considering an exception for arrangements that fit squarely within an anti-kickback ''safe harbor'' (§ 1001.952 (Exceptions)). We have been urged to do so by providers frustrated by having to apply two sets of conditions to their financial arrangements. Having carefully considered the issue and the industry perspective, we have concluded that a wholesale importation of the anti-kickback safe harbors into the exceptions in section 1877 of the Act would be problematic. In some cases, the statutory requirements of seemingly comparable ''safe harbors'' and exceptions vary. In other cases, the section 1877 exception and the anti-kickback statute ''safe harbor'' for similar conduct differ for reasons attributable to the difference in statutory scope and scheme, core prohibited conduct, or liability standards. In some cases, the section 1877 exception is broader; in other cases, it is narrower. Many of the anti-kickback ''safe harbors'' address activities that do not implicate section 1877 of the Act. In sum, while we are mindful of the concerns expressed by the commenters, we believe it is not feasible to except financial relationships solely because they fit in an anti-kickback ''safe harbor.''

Nevertheless, we have reviewed the existing list of ''safe harbored'' arrangements for which there are no section 1877 analogs and have concluded that the ''safe harbors'' for referral services (§ 1001.952(f)) and obstetrical malpractice insurance subsidies (§ 1001.952(o)) should be incorporated by reference into section 1877 of the Act. We are therefore creating new exceptions in § 411.357(q) and § 411.357(r) for these arrangements. As the anti-kickback ''safe harbor'' regulations are amended and supplemented from time to time, we will consider whether any additional ''safe harbored'' arrangements should be incorporated as exceptions under section 1877 of the Act.

A commenter has also suggested that we create a new exception for any arrangement approved in an OIG advisory opinion regarding the application of the anti-kickback statute to the arrangement. We decline to adopt the commenter's suggestion. OIG advisory opinions may not be relevant in all respects to a determination under section 1877 of the Act. For example, a favorable opinion from the OIG often concludes that a potential remunerative relationship exists, but that the OIG would exercise its discretion and decline to impose sanctions arising from the potential anti-kickback violation (which contains an intent requirement not applicable under section 1877 of the Act). These determinations are not appropriate for blanket protection under section 1877 of the Act.

I. Professional Courtesy (Phase I—66 FR 922; Phase II; § 411.357(s))

[If you choose to comment on issues in this section, please include the caption ''Professional Courtesy Exception'' at the beginning of your comments.]

A number of commenters responded to our call for comments on a possible exception for professional courtesy. These commenters pointed out that free or discounted ''professional courtesy'' to physicians and their family members is a longstanding tradition and remains a widespread practice. Most commenters supported creation of an exception. One commenter suggested the following conditions: The services are routinely provided without charge to physicians and their family members by the provider, without regard to referrals, as part of the provider's standard professional courtesy policy and notice is provided to all applicable public or private third party payers that the services were provided without charge to the physician as a professional courtesy (that is, the co-insurance obligation was waived). A commenter representing a radiology concern recommended that professional courtesy be limited to physicians and dependents for whom the physician would pay the medical bill and that the courtesy be further limited to free services for which no person or entity is billed. Further, the commenter wanted to limit the exception to circumstances where professional courtesy is the prevailing practice in a given marketplace.

Another commenter suggested that the definition of ''professional courtesy'' be limited to partial ''out-of-pocket'' expense reductions (as opposed to total fee waivers or out-of-pocket cost waivers) offered by health care providers for health care services furnished to physicians and their family members who are not employed by the health care provider. The commenter excluded employees because discounts to employees could be protected under the employee exception. The commenter suggested limiting the exception to partial waivers because health care providers are more likely to offer partial waivers across the board; the commenter believed that health care providers are more likely to offer costly full waivers selectively based on referrals. As for specific conditions to apply under an exception, the commenter suggested the following: (1) The discount is offered to all physicians (whether or not affiliated with the health care provider) without regard to the volume or value of referrals or other business generated between the parties; (2) the professional courtesy policy is set out in writing and approved in advance by the governing body of the health care provider; (3) the discount is limited to 25 percent of what would otherwise have been the physician's out-of-pocket expense and subject to an annual cap; (4) the discount is not offered to a physician (or family member) who is a Federal health care program beneficiary (this condition addresses the beneficiary inducement problem raised by professional courtesy arrangements); (5) all discounts are reported as income to the physician in accordance with Federal and State tax requirements; and (6) to avoid insurance fraud, insurers are informed of any reduction of a co-insurance obligation. The commenter notes that providers may want to make an offer of professional courtesy contingent on the insurer's agreement to provide coverage notwithstanding.

Yet another commenter, representing a physician association, suggested that the exception should cover professional courtesy, including fee waivers or discounts up to $300 per year

(consistent with the non-monetary compensation exception). One commenter expressed concern that providers not be required to offer professional courtesy, and that such arrangements should be entered into at the discretion of the parties.

We are persuaded to promulgate an exception for certain services provided to a physician or his or her immediate family members. We are defining ''professional courtesy'' in § 411.351 as the provision of free or discounted health care items or services to a physician or his or her immediate family members or office staff. To qualify for the new exception, the arrangement must meet the following conditions:

1. The professional courtesy is offered to all physicians on the entity's *bona fide* medical staff or in the entity's local community without regard to the volume or value of referrals or other business generated between the parties;
2. The health care items and services provided are of a type routinely provided by the entity;
3. The entity's professional courtesy policy is set out in writing and approved in advance by the governing body of the health care provider;
4. The professional courtesy is not offered to any physician (or immediate family member) who is a Federal health care program beneficiary, unless there has been a good faith showing of financial need;
5. If the professional courtesy involves any whole or partial waiver of any coinsurance obligation, the insurer is informed in writing of that reduction so that the insurer is aware of the arrangement.
6. The professional courtesy arrangement does not violate the anti-kickback statute or any billing or claims submission laws or regulations.

While professional courtesy discounts may be covered under the employee exception, nothing in this new exception precludes hospitals or other entities from extending their professional courtesy policies to employees, including non-physician employees, under the new exception. Nothing in these regulations should be construed as requiring or encouraging professional courtesy arrangements. Moreover, parties are cautioned that some professional courtesy arrangements may violate the anti-kickback statute or the civil monetary penalties law against giving inducements to Medicare and Medicaid beneficiaries (section 1128A(a)(5) of the Act). Concerns regarding those laws should be addressed to the OIG. Private insurers may also have concerns about professional courtesy in the form of coinsurance waivers. The requirement to notify private insurers of a professional courtesy arrangement may provide an additional check against abusive arrangements.

J. Charitable Donations by a Physician (Phase II; § 411.357(j))

[If you choose to comment on issues in this section, please include the caption ''Charitable Donations'' at the beginning of your comments.]

A commenter to the January 1998 proposed rule expressed concern about charitable contributions made by physicians to DHS entities, for example, the purchase of a hospital charity ball ticket or a donation to a charitable health care entity's general fund-raising campaign. The commenter noted that, under section 1877 of the Act, funds flowing from a physician to a DHS entity can create a financial relationship. However, no exception exists for a physician's *bona fide* charitable donations.

We agree that charitable donations from a physician to a DHS entity involve remuneration as defined in the statute, thus creating a compensation arrangement between donor and donee and that an exception for *bona fide* charitable donations is appropriate. Under our authority in section 1877(b)(4) of the Act, we have added a new exception in § 411.357(j) for *bona fide* charitable donations made by a physician (or immediate family member). To qualify, donations must be made to an organization exempt from taxation under the IRS Code (or to an exempt supporting organization, such as a hospital foundation). The new exception provides that the donation may not be solicited or made in any manner that reflects the volume or value of referrals or other business generated from one party for the other. Broad-based solicitations not targeted specifically at physicians, such as sales of charity ball tickets or general fund-raising campaigns, will qualify under this exception. Parties engaged in more selective or targeted fund-raising activities should ensure that those activities are not conducted in any manner that reflects or takes into account referrals or the generation of business between the parties. As with all new regulatory exceptions under section 1877(b)(4) of the Act, a protected arrangement must not violate the anti-kickback statute or billing or claims filing rules.

K. Preventive Screening Tests (Phase I—66 FR 923; § 411.355(h))

[If you choose to comment on issues in this section, please include the caption ''Exceptions Preventive Screening'' at the beginning of your comments.]

In the Phase I final rule, we used our authority under section 1877(b)(4) of the Act to create a regulatory exception (§ 411.355(h)) for certain preventive screening tests, immunizations and vaccines.

Section 411.355(h)(2) of the exception requires that the preventive screening tests, immunizations, and vaccines be reimbursed by Medicare under a fee schedule. It has come to our attention that some of the vaccines covered by the exception may be paid by Medicare using different reimbursement methods. To avoid confusion, we are deleting the fee schedule requirement from the regulation. We believe the remaining conditions in the exception are sufficient to protect against abuse under section 1877 of the Act.

In addition, we received the following comments.

Comment: Two commenters representing pathologists inquired about the treatment of Pap tests under the final regulations. One association was concerned that only screening Pap tests, but not diagnostic Pap tests, could qualify for the preventive screening tests exception. Another association urged us not to except screening Pap tests because physicians would then have financial incentives to send all screening tests to clinical laboratories with which they have financial relationships and to send all diagnostic tests to different laboratories. In the commenter's view, this might endanger continuity of care and the ability to compare the findings of screening and diagnostic Pap tests.

Response: We can discern no reason to expand the exception to protect referrals for diagnostic Pap tests. As noted above, we created the exception in § 411.355(h) pursuant to our authority under section 1877(b)(4), which authorizes the Secretary to create additional exceptions for financial relationships that do not pose a risk of program or patient abuse. We are not persuaded that diagnostic Pap tests are any different from other diagnostic clinical laboratory tests to which the statutory prohibition applies.

We are unclear as to how the potential use of two different laboratories for two different clinical laboratory tests will compromise continuity of patient care. Moreover, it is our understanding that screening and diagnostic Pap test results are not typically compared. We

continue to believe that the exception as set forth in Phase I is sufficiently limited to pose no risk of program or patient abuse. Accordingly, we are not removing the codes for screening Pap tests from the list of codes identifying those services that may qualify for the exception in § 411.355(h).

Comment: An association representing radiologists supported our decision to include screening mammography in the exception for preventive screening tests at § 411.355(h), but was disappointed that the exception does not cover diagnostic mammography. The association disagreed with our statement that diagnostic mammography could be subject to abuse.

Response: For the reasons stated in Phase I (66 FR 930), diagnostic mammography is treated similarly to all other diagnostic radiology services. In many cases, a radiologist who has performed a screening mammogram will also recommend a diagnostic mammogram. We do not see why diagnostic mammography performed after screening mammography is less subject to abuse than any other diagnostic service that is performed after a screening service. We note that a radiologist who orders a diagnostic mammography pursuant to a consultation does not make a ''referral'' for purposes of section 1877 of the Act.

Comment: A commenter stated that screening tests should not be considered DHS when performed either as screening tests or as part of a patient's ongoing care once a problem has been identified.

Response: We disagree. Consistent with the statutory and regulatory scheme, we have created an exception for a subset of screening tests furnished under circumstances that do not pose a risk of abuse.

Comment: In the Phase I Attachment, we listed the CPT and HCPCS codes for screening tests that may qualify for the exception in § 411.355(h) if all of the criteria for that exception are satisfied (66 FR 965). We included in that list one code for a bone density test (CPT 76977), which the Phase I Attachment also identified as a radiology service. Several commenters believed that the list should also include five other codes for bone density tests (CPT codes 76070, 76075, 76076, 78350, and 78351).

Response: Generally, a test performed for diagnostic reasons is subject to section 1877 of the Act. However, some tests performed as preventive screening tests are not subject to the physician self-referral prohibition if all conditions of the exception in § 411.355(h) are satisfied. None of the five codes identified by the commenters is a screening test, as none is available to the general population without a pre-existing condition. Section 1861(rr) of the Act, which provides for the bone mass measurement benefit, identifies five specific categories of individuals with pre-existing conditions who qualify for the benefit. Accordingly, none of these five codes will be added to the list of codes that may qualify for the exception in § 411.355(h). Also, we are removing CPT code 76977 from the list of services that may qualify for the exception in § 411.355(h) for preventive screening tests because we had incorrectly identified it as a screening test.

After careful review, we have determined that four of the bone density tests cited by the commenters (76070, 76075, 76076, and 78350), fall within the definition of ''radiology and certain other imaging services,'' yet were not included as such on the Phase I attachment or its updates. (Although CPT code 78351 would otherwise fall within the category of ''radiology and certain other imaging services,'' CPT code 78351 is not a Medicare covered service and, thus, is not subject to the statute.)

In the physician fee schedule final rule, published December 31, 2002 (67 FR 79996), we added CPT code 76070 to the list of codes defining ''radiology and certain other imaging services.'' (At that time, we also added as ''radiology and certain other imaging services'' two other codes for bone density tests: CPT codes 76071 and 0028T.)

We are now adding to the definitional code list for ''radiology and certain other imaging services'' the three remaining densitometry scans identified by the commenters (CPT codes 76075, 76076, and 78350) that were inadvertently omitted from the previous list of codes.

Additionally, in reviewing the bone density test codes, we found two codes (CPT code 76078 and HCPCS code G0130) not identified by the commenters. We have determined that these two codes also fall within the category of ''radiology and certain other imaging services'' and are adding them to that category.

The following is a complete list of the densitometry scans that will be included in the definitional code list for ''radiology and certain other imaging services'':

76070	Ct bone density, axial
76071	Ct bone density, peripheral
76075	Dexa, axial skeleton study
76076	Dexa, peripheral study
76078	Radiographic absorptiometry
76977	Us bone density measure
78350	Bone mineral, single photon
0028T	Dexa body composition study
G0130	Single energy x-ray study

As explained above, none of these tests qualifies for the exception in § 411.355(h).

L. EPO and Other Dialysis-Related Outpatient Prescription Drugs Furnished in or by an ESRD Facility (Phase I—66 FR 939; § 411.355(g))

[If you choose to comment on issues in this section, please include the caption ''Exceptions-Dialysis Drugs'' at the beginning of your comments.]

Phase I created a new exception for EPO and certain other dialysis-related outpatient prescription drugs furnished in or by an ESRD facility. The drugs that may qualify for this exception were initially identified by CPT and HCPCS codes in the Phase I Attachment, and updates to that list appear on the CMS Web site and in annual updates published in the **Federal Register**.

Comment: One commenter advocated that we expand the list of codes to include other drugs specifically related to ESRD services if those drugs are used specifically and exclusively for a patient's ESRD treatment. In particular, the commenter believed that the following drugs should be added to the list of drugs that may qualify for the exception in § 411.355(g): heparin (heparin sodium); normal saline (0.9 percent sodium chloride) for catheter maintenance; paricalcitrol; carnitine; and albumin for injection.

Response: We note that, according to section 3168.A of the Medicare Intermediary Manual, heparin and normal saline are included in the ESRD composite rate. Thus, these items do not constitute DHS when reimbursed under the composite rate and therefore did not need to appear on the list of codes that may qualify for the exception in § 411.355(g). In addition, we added paricalcitol to this list of codes in Addendum E of the December 31, 2002 **Federal Register** final rule, Revisions to the Physician Fee Schedule for Calendar Year 2003 (67 FR 79966 and 80172). (Zemplar is the trade name for paricalcitol, which is often referred to as paricalcitrol.)

With respect to the other drugs mentioned by the commenter, we agree that the list of drugs was not broad enough to include all the drugs that should be excepted. We believe it is appropriate to use our authority under section 1877(b)(4) of the Act and the exception at § 411.355(g) to cover these and other outpatient prescription drugs that are required for the efficacy of dialysis, and are not self-administered

(except for EPO and darbepoetin alfa (Aranesp)), provided that all other conditions of the exception are satisfied. Therefore, we are adding to our list albumin and levocarnitine, which is the intravenous form of carnitine.

We are also adding several other drugs to the list. We are including darbepoetin alfa (Aranesp), which is a new drug that is functionally equivalent to EPO although not structurally identical. For physician self-referral purposes, we are using the term EPO to include both epoetin alfa and darbepoetin alfa (Aranesp). Both products use the same biological mechanism to produce stimulation of the bone marrow to produce red blood cells. In addition, we are adding an additional vitamin D drug (calcitonin-salmon), and three additional thrombolytics used to declot central venous catheters. These thrombolytics are streptokinase, urokinase, and retaplase.

We believe that this exception does not pose a risk of patient or program abuse. First, as explained in the Phase I preamble (66 FR 938), we believe that this exception is appropriate because of the high correlation between the use of these drugs and dialysis. Second, strict utilization and coverage criteria for EPO and the other listed medically necessary drugs required for the efficacy of dialysis mitigates the risk of abuse. However, we intend to monitor use of this exception and, if we determine that the exception is abused, we would revisit it. Except as provided in this exception, we believe physician financial interests in the furnishing of self-administered drugs poses a risk of abuse. As we explained in the Phase I preamble (66 FR 938), this exception was never intended to protect drugs or supplies that patients use at home, except EPO in limited circumstances. Accordingly, we want to emphasize that this exception applies only to drugs that are not self-administered except when the facility furnishes EPO or Aranesp to the patient who dialyzes at home. Given the additions to the list of drugs, we are clarifying the regulation text in order to ensure that the exception will continue to pose no risk of program or patient abuse.

M. Intrafamily Referrals (Phase II; § 411.355(j))

[If you choose to comment on issues in this section, please include the caption ''Exceptions Intrafamily Referrals'' at the beginning of your comments.]

This exception is discussed in section VII.B of this preamble.

N. Exception for Certain Arrangements Involving Temporary Noncompliance (Phase II; § 411.353(f))

[If you choose to comment on issues in this section, please include the caption ''Exceptions-Temporary Noncompliance'' at the beginning of your comments.]

This exception is discussed in section II.A of this preamble.

O. Retention Payments in Underserved Areas (Phase I; § 411.357(t))

[If you choose to comment on issues in this section, please include the caption ''Exceptions—Retention Payments in Underserved Areas'' at the beginning of your comments.]

This exception is discussed in section VIII.E of this preamble.

P. Community-Wide Information Systems (Phase II; § 411.357(w))

[If you choose to comment on issues in this section, please include the caption ''Exceptions-Community-wide Information Services'' at the beginning of your comments.]

This exception is discussed in section XII.E of this preamble.

XIII. Technical Corrections

In Phase I, we indicated our intent to remove § 411.360 relating to physician attestations, but the regulatory text did not do so. We have removed § 411.360. We have also changed references from HCFA to CMS, consistent with the final rule published July 31, 2001 (66 FR 39450), which revised the references in accordance with the name change of the Health Care Financing Administration to the Centers for Medicare & Medicaid Services. In addition, we have updated references to Internet Web sites in the Phase I regulations.

We have removed § 411.354(c)(1)(ii) that specified that the shared compensation for consultations conducted via interactive telecommunications systems required by the Medicare program under § 414.65 was not a compensation arrangement. Section 414.65 was substantially revised in the November 1, 2001 physician fee schedule final rule (66 FR 55332). A consultant practitioner is no longer permitted to share payment with the referring practitioner, and thus, a provision for this situation is no longer necessary.

In addition, pursuant to the Balanced Budget Act of 1997 (Pub. L. 105–33) and the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (Pub. L. 106–113), we have replaced references to ''primary care rural hospitals'' with ''critical access hospitals'' in § 411.351.

We have deleted the mailing address and telephone number for the Superintendent of Documents and the National Technical Information Service from § 411.351 since the Medicare Carriers Manual is available free of charge on the CMS Web site. In light of the recent and ongoing reorganization of CMS manuals, we have clarified that references to specific manual provisions incorporate any amendments to those provisions.

We have also revised the title of subpart J to reflect the current scope of section 1877 of the Act and these regulations.

Comment: One commenter noted that the references in § 411.352(d)(1) to § 411.352(d)(2) and § 411.352(d)(3) should be to § 411.352(d)(3), § 411.352(d)(4), and § 411.352(d)(5).

Response: The commenter is correct. We have made the technical correction. We have also made a technical correction in § 411.352(b) by changing the words ''this section'' at the end of § 411.352(b) to ''§ 411.351''.

XIV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

The need for the information collection and its usefulness in carrying out the proper functions of our agency.

- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Therefore, we are soliciting public comments on each of these issues for the information collection requirements discussed below.

The following information collection requirements and associated burdens are subject to the PRA.

Section 411.352 Group Practice

Under paragraph (d), a covered entity is required to document the total time each member spends on patient care services, and to maintain and make available to the Secretary, upon request, documentation concerning compliance

with the substantially ''all test.'' This paragraph also requires that a new member's employment with, or ownership interest in, the group practice be documented in writing no later than the beginning of his or her new employment relationship or ownership or investment interest.

The burden associated with these requirements is that of documentation and making available information to the Secretary. This documentation may be in the form of time cards, appointment schedules, personal diaries, or any alternative measure that is reasonable, fixed in advance of the performance of the services being measured, uniformly applied over time, and verifiable. This is not a new requirement to maintain or collect additional information because these types of records are usually kept by group practices in the normal course of business in order to allocate resources such as time, examination space, remuneration, and productivity bonuses. The documentation requirements reflect usual and customary business practices, and, as such, the burden is not subject to the PRA under 5 CFR 1320.3(b)(5); the burden of making the records available is exempt under 5 CFR 1320.4(a) as that incurred during an administrative action, investigation, or audit involving an agency against specific individuals or entities. In addition, this burden was found to be exempt from the requirements of the PRA in Phase I (66 FR 856).

Section 411.354 Financial Relationship, Compensation, and Ownership or Investment Interest

Paragraph (d)(4) of this section mandates that the requirement to make referrals to a particular provider, practitioner, or supplier be set forth in a written agreement signed by the parties.

We do not believe this requirement imposes any additional burden. Where mandatory referral requirements are used, they are already routinely made part of a more comprehensive service agreement (for example, a contract between a physician and a managed care entity for the provision of physician services, or a preferred provider network agreement). We believe that this burden is a result of usual and customary business practice and, as such, is exempt from the PRA under 5 CFR 1320.3(b)(5).

Section 411.355 General Exceptions to the Referral Prohibition Related to Both Ownership/Investment and Compensation

Paragraph (e)(1)(iii) of this section requires that the relationship of the components of the academic medical center must be set forth in written agreement(s) or other written document(s) that have been adopted by the governing body of each component. If the academic medical center is one legal entity, this requirement will be satisfied if transfers of funds between components of the academic medical center are reflected in the routine financial reports covering the components.

The burden associated with this requirement is that of documenting compliance, either in written documents or routine financial reports. The written documents, adopted by the governing body of each component, detailing the relationship of the components of the academic medical center may be any documents generated in the usual course of business, such as articles of incorporation or bylaws. In response to comments, we have decreased the minimal burden associated with this requirement for academic medical centers that consist of one legal entity. Those academic medical centers will satisfy the requirement if transfers of funds between components of the academic medical center are reflected in routine financial reports generated in the usual course of business. We believe that the burden imposed by § 411.351(e)(1)(iii) is a result of usual and customary business practice and, as such, is exempt from the PRA under 5 CFR 1320.3(b)(5). In addition, this burden (without the relief granted in this interim final rule for certain academic medical centers) was found to be exempt from the requirements of the PRA in Phase I (66 FR 856, 949).

Section 411.357 Exceptions to the Referral Prohibition Related to Compensation Arrangements

This section requires a written agreement signed by the parties for space and equipment rental agreements and arrangements for personal services, physician recruitment, certain group practice arrangements with a hospital, fair market value compensation, and indirect compensation. In addition, an entity's professional courtesy policy must be set out in writing if there is any whole or partial coinsurance reduction, and an entity must notify its insurers that the entity has a professional courtesy policy.

The burden associated with these requirements is that of obtaining agreements in writing, setting out professional courtesy policies in writing and notifying insurers that an entity has a professional courtesy policy. The burden also includes a requirement that all separate personal service arrangements between an entity and a physician or an immediate family member of a physician must incorporate each other by reference or the entity must maintain centrally a master list of contracts that is updated and preserves the historical record of the personal service contracts. The lease of equipment is usually and routinely set forth in a written agreement, as are personal services arrangements, recruitment agreements, and contracts between group practices and hospitals. Therefore, the requirement that these arrangements be set forth in a written agreement does not impose an additional burden beyond usual business practices. In addition, the burden that direct and indirect compensation arrangements be set forth in writing was formerly found to be exempt from the requirements of the PRA in the Phase I final rule (66 FR 856). We believe that the burden of these written agreements is a result of usual and customary business practice and, as such, is exempt from the PRA under 5 CFR 1320.3(b)(5).

The requirement to notify insurance companies that an entity has a professional courtesy policy under which coinsurance is reduced or not collected could be met by creating a model letter or applying an edit to a claim where professional courtesy applies. We estimate that a health care entity would have to spend approximately 25 minutes to draft the model letter and then 5 minutes to prepare a letter for each insurer. We do not know how many of the 1.2 million entities (including approximately 581,108 physicians) that furnish services to Medicare beneficiaries would offer professional courtesy to their bona fide medical staffs or to all physicians in the local community. However, traditionally, only hospitals and physicians have provided professional courtesy to physicians, their immediate family members, and sometimes the physician's staff. We do not expect this pattern to change significantly but, for purposes of this analysis, we estimate that 75 percent of hospitals, 100 percent of physicians, and 10 percent of entities other than physicians and hospitals will offer professional courtesy. We also believe that these numbers are high but we

cannot satisfactorily reduce these estimates. That is, we do not believe that all physicians and all hospitals offer professional courtesy and we do not believe that even 10 percent of entities that have rarely offered professional courtesy will now start offering it.

Most of the 581,108 physicians practice in group practices. Many physicians practice in very large groups, while many practice in multi-specialty practices of 15 to 20 physicians or single specialty groups of fewer than 10 physicians. For purposes of this discussion, we assume that the median number of physicians practicing together is 10. Therefore, we assume there are 58,110 physician entities (groups or sole practitioners) that could and would offer professional courtesy. We also assume that 75 percent of all hospitals (6,018 × 75 percent = 4,514) would offer professional courtesy.

We assume that each hospital, physician group practice, and sole physician practice would have to notify 10 insurers the first year under this interim final rule and that the other health care entities would have to notify 5 insurers. Therefore, for physicians and hospitals that choose to use a model letter, 58,110 physician entities + 4,514 hospitals would each spend a total of 75 minutes [25 minutes to prepare model letter + (10 insurers × 5 minutes for preparing each copy) = 75 minutes] to comply with the notification requirement. This would result in an estimated overall burden on physicians and hospitals of approximately 78,280 hours. The overall burden for entities other than hospitals and physicians should be 51,073 hours. (1,200,000 entities − 581,108 physicians − 6,018 hospitals = 612,874 × (10 percent) × [(25 minutes + (5 insurers × 5 minutes for preparing each copy)] = 51,073). In each subsequent year, we expect that there might be one notification per entity to two new insurance companies, which would amount to 10 minutes per entity × (58,111 physicians + 4,514 hospitals + 612,874 other entities) = 102,898 hours.

Although we have estimated that it would take 25 minutes for each entity to create a model letter, we expect that a chain of hospitals or other entities would choose to prepare one model letter for use by each of its members. Also, we expect that some individual may develop a model letter that would be used by many entities. Although the paperwork burden may seem large, overall, we expect that the burden on an individual entity would be relatively minimal. The provisions in the personal services arrangements exception in this section requires that all separate arrangements between an entity and a physician or an entity and a member of a physician's immediate family must incorporate each other by reference or all separate arrangements must be identified in a master list of contracts that is maintained and updated centrally. This requirement was suggested by the industry because it is less burdensome than the requirement in the proposed rule and because it more closely reflects current business practices (or practices that can be easily adapted). We added the requirements that the master list must be made available for review by the Secretary upon request and that the master list must be maintained in a manner that preserves the historical record. In the alternative, annual or other regular financial statements (such as quarterly statements) that clearly show parties, dates, payments, and purposes of payments separately for each personal service contract can qualify as a master list if the statements are appropriately cross-referenced in the agreement. An entity could meet this requirement by having several master lists that, taken together, cover all of the contracts with the referring physician and immediate family members.

The ''master list'' alternative should impose minimal, if any, burden because it is a usual and customary business practice for a company to maintain records of its contracts. However, for those entities without a master list, multiple lists, or databases, creating a master list will take time. We request comments on these requirements.

Of the approximately 677,002 health care entities (58,110 physician entities + 6,018 hospitals + 612,874 other entities), we estimate that one-quarter, 169,251, contract for personal services with physicians or their immediate family members. We expect that many of these entities are relatively small physician group practices, clinical laboratories or other suppliers that can easily furnish a master list of contracts with physicians and immediate family members or have one contract with a physician or family member that covers everything this individual performs for the small entity. We expect that larger entities can meet this recordkeeping requirement relatively easily by creating a master list of contracts. We recognize that it is possible that some large entities (for example, certain urban hospitals) may have multiple contracts with physicians and family members and not currently meet this requirement.

We estimate that, on average, it would take a large entity 7 hours to meet this requirement and a small entity 2 hours. We assume that, since public commenters recommended the use of cross-referencing to a master list of contracts, many entities already have such a list. Therefore, we estimate that one-half of the 169,251 entities affected by this requirement will have to create a master list. Assuming that one-half of the entities are small and one half are large entities, we estimate that there will be a one-time burden of [(½ × 169,251 × 2 hours) + (½ × 169,251 × 7 hours)] = 677,000 hours. We also estimate that it would take one-half of these entities ½ hour annually to update the master list and it would take one-half of the entities 1 hour annually to update the master list, resulting in an annual burden of 126,938 hours. We note that these are preliminary estimates, so we specifically request comments on these estimates.

Although the overall burden in creating a master list or referencing all other contracts with a physician or immediate family member in each contract might appear sizable, the burden on an individual entity should be relatively minimal.

Under paragraph (d)(2), which allows physician incentive plans under the personal services exception, the entity must give the Secretary access to the plan upon request.

Making the information available (or giving access) to the Secretary should occur rarely and would be exempt from the PRA under 5 CFR 1320.4(a) as information required during an administrative action, investigation, or audit involving an agency against specific individuals or entities.

Section 411.361 Reporting Requirements

This section requires that, except for certain exceptions, all entities furnishing services for which payment may be made under Medicare must submit information to us concerning their financial relationships (as defined in the section), in the form, manner, and at the times that we specify.

The information that we request can include the following:

(1) The name and unique physician identification number (UPIN) of each physician who has a financial relationship with the entity.

(2) The name and UPIN of each physician who has an immediate family member (as defined in § 411.351) who has a financial relationship with the entity.

(3) The covered services furnished by the entity.

(4) With respect to specified physicians, the nature of the financial relationship (including the extent and/or value of the ownership or investment

interest or the compensation arrangement) as evidenced in records that the entity knows or should know about in the course of prudently conducting business, including records that the entity is already required to retain to comply with the rules of the Internal Revenue Service and the Securities and Exchange Commission and other rules of the Medicare and Medicaid programs.

The first 3 requirements above are statutorily mandated. The fourth requirement was proposed in the proposed rule (63 FR 1659) and adopted in this rule with no changes.

Entities that are subject to the requirements of this section must retain the information, and documentation sufficient to verify the information, and, upon request, must make that documentation available to us or to the OIG.

The burden associated with these requirements is that of maintaining documentation and, if necessary, making it available to the Secretary. We believe that the information we are requiring the entities to maintain is information that they would have and maintain already. The proposed rule proposed that entities that are subject to requirements of this section must report to the agency on a prescribed form and thereafter report once a year all changes to the submitted information that occurred in the previous 12 months. In this rule, the requirement has been modified to require entities to make information available only upon request and to maintain the information only for the length of time specified by the applicable regulatory requirements for the information (that is, IRS, SEC, Medicare, Medicaid, or other programs). This substantially reduces the burden on entities, since this is information that is required to be maintained by other regulatory agencies in the usual course of business. We believe that this burden is a result of usual and customary business practice and, as such, is exempt from the PRA under 5 CFR 1320.3(b)(5).

Making information available to the Secretary will rarely be necessary and the information will be collected during the conduct of an administrative action, investigation, or audit involving an agency against specific individuals or entities. It is thus exempt from the PRA under 5 CFR 1320.4(a).

For those requirements that are not exempt from the PRA, we have quantified the burden associated with compliance and have set forth time estimates. The total time estimated to be necessary to comply with the requirements of this section is 806,353 hours for all entities in the country in the first year, and 229,836 hours annually thereafter.

We have submitted a copy of this interim final rule with comment period to OMB for its review of the information collection requirements described above. These requirements are not effective until they have been approved by OMB.

If you comment on any of these information collection and record keeping requirements, please mail copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances, Attn: Reports Clearance Officer, 7500 Security Boulevard, Baltimore, MD 21244–1850, Attn: John Burke, CMS–1810–IFC.

and

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Brenda Aguilar, Desk Officer.

XV. Regulatory Impact Statement

A. Overall Impact

[If you choose to comment on issues in this section, please include the caption ''Impact'' at the beginning of your comments.]

We have examined the impact of Phase II of this rulemaking as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 16, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132.

Executive Order 12866 (as amended by Executive Order 13258, which merely reassigns responsibility of duties) 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 in any 1 year). Although we cannot determine with precise certainty the aggregate economic impact of Phase II of this rulemaking, we do not believe that the impact will approach $100 million or more annually. Physicians and DHS entities have been required to comply with the physician self-referral prohibition for many years. The prohibition has applied to physician referrals for clinical laboratory services since 1992 and to referrals for all other DHS since 1995. Phase I interpreted the prohibition narrowly and the exceptions broadly, and established additional regulatory exceptions for legitimate arrangements that would otherwise violate the prohibition. Phase I covered the following:

- Sections 1877(a) and 1877(b) of the Act (the general prohibition and the exceptions applicable to both ownership and compensation arrangements);
- The statutory definitions at section 1877(h) of the Act;
- Certain additional regulatory definitions; and
- New regulatory exceptions promulgated under section 1877(b)(4) of the Act for certain arrangements involving the following—
- Academic medical centers;
- Implants furnished by an ambulatory surgery center;
- EPO and certain dialysis-related outpatient prescription drugs;
- Preventive screening tests, immunizations, and vaccines;
- Eyeglasses and contact lenses after cataract surgery;
- Non-monetary compensation up to $300;
- Fair market value compensation;
- Medical staff incidental benefits;
- Risk-sharing arrangements;
- Compliance training; and
- Indirect compensation arrangements.

Phase II covers—

- The remaining provisions of section 1877 of the Act (namely, the exceptions for ownership and investment interests and the exceptions for various compensation arrangements);
- Additional regulatory definitions; and
- Additional new regulatory exceptions promulgated under section 1877(b)(4) of the Act for certain arrangements involving the following:
- Temporary noncompliance with an applicable exception;
- Intra-family rural referrals;
- Charitable donations by a physician;
- Referral services;
- Obstetrical malpractice insurance subsidies;
- Professional courtesy;
- Retention payments in underserved areas; and
- Community-wide health information systems.

Phase II also addresses public comments on the Phase I regulations.

Among other things, Phase II revises the Phase I ''set in advance'' definition to permit percentage compensation arrangements; revises the Phase I exception for academic medical centers to make it easier to qualify as an academic medical center or a component of an academic medical center; revises the Phase I ''same building'' definition to provide a simpler, bright-line rule that will substantially decrease the regulatory burden on many physician practices; eliminates the 1998 proposed restriction on productivity bonuses, thereby permitting employees to be paid based on personal productivity (but not ancillary referrals); expands the physician incentive plan exception to downstream contractors in the managed care context; and expands the physician recruitment exception to federally qualified health centers.

Phase II does not generally unsettle existing financial relationships, and it offers sufficient exceptions to enable parties to restructure noncompliant arrangements. Wherever possible, we have accommodated legitimate financial relationships, thereby reducing the regulatory burden. For these reasons, we conclude that this is not a major rule with an economically significant effect of $100 million in any 1 year.

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 because they are nonprofit organizations or because they generate revenues of $6 million to $29 million in any one year. Currently, there are approximately 1.2 million physicians, other health care practitioners, and medical suppliers that receive Medicare payment. For purposes of the RFA, according to the latest numbers from the Small Business Administration's North American Industrial Classification System, 95 per cent of offices of physicians in the U.S. have total revenues of $8.5 million or less and are considered small entities. Individuals and States are not included in the definition of a small entity. We determine that this interim final rule does not have a significant impact on small businesses because it does not increase regulatory burden, but rather reduces it. As noted above, we are generally interpreting the prohibition narrowly and the exceptions broadly. We are creating new exceptions where appropriate, conforming the regulation to existing Medicare payment and coverage policies, and minimizing the possibility of disrupting non-abusive arrangements. Overall, this rule is very accommodating to legitimate industry practices for hospitals and physicians.

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 100 beds. For the same reasons identified above for small businesses, this rule does not significantly impact small rural hospitals. Moreover, rural hospitals benefit in this rule from a new exception permitting certain retention payments for physicians in health professional shortage areas (HPSAs), and a new exception for community-wide health information systems. This interim final rule also revises the physician recruitment exception to permit hospitals to recruit residents and physicians who have been in practice for less than one year but for whom recruitment does not require relocation. This benefits small rural hospitals, which often experience difficulty in recruiting physicians. In summary, this interim final rule does not have a substantial negative 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 one year by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million. Phase II of this rulemaking does not have such an effect on the governments mentioned, and we do not believe the private sector costs meet the $110 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 II of this rulemaking will have a substantial effect on State or local governments.

We are not preparing analyses for either the RFA or section 1102(b) of the Act because, for the reasons identified above, we have determined, and we certify, that this interim final rule 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. For the benefit of the public, we discuss below the anticipated effects of the rule and the alternative regulatory options we considered.

B. Anticipated Effects

This interim final rule with comment period primarily affects physicians and health care entities that furnish items and services to Medicare beneficiaries. For the reasons stated above, we do not anticipate that this rule will have a significant economic impact on a substantial number of small entities. In fact, we expect that Phase II of this rulemaking will have a much smaller impact than the provisions we proposed. Nevertheless, we wish to inform the public of what we regard as the major effects of this rulemaking.

In response to comments on the January 1998 proposed rule, we created in Phase I a more manageable regulation that included ''bright line'' rules to help the health care community determine more easily when a physician's referrals are in compliance with the law. In this interim final rule, we are continuing our efforts to establish ''bright line'' rules, and attempting to minimize the effect of this rule on physicians and DHS entities by interpreting the law in a practical and realistic manner. The result, we believe, is an overall approach that should have far less impact on the business relationships of physicians and DHS entities than the January 1998 proposed rule. We discuss below some of the possible economic effects upon physicians and DHS entities. We also briefly discuss the effects of the rules on Medicare beneficiaries.

1. Effects on Physicians

The primary statutory sanctions for violating the physician self-referral prohibition are nonpayment of claims for DHS furnished as the result of a prohibited referral and the corresponding obligation to refund any amounts collected on those claims. These sanctions target the entities that furnish DHS, including physician group practices. Referring physicians may be sanctioned with the imposition of civil monetary penalties (CMPs) only for knowing violations of the statutory prohibition. Nevertheless, although referring physicians are not the primary targets of the sanctions for violating the statute, their financial relationships with DHS entities must comply with the statute and implementing regulations. Accordingly, this interim final rule may affect a physician's or group practice's decision to enter into a particular

financial relationship and the manner in which the arrangement is structured.

We received voluminous comments on the January 1998 proposed rule from or on behalf of physicians and DHS entities (especially hospitals). 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 conflicted with other longstanding policies on coverage and similar issues; that the rule was unclear in many areas; that ''bright line'' rules were essential in light of the severe statutory penalties (especially payment denial); 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 have made every effort in both Phase I and this Phase II rulemaking to address the concerns of physicians and physician group practices while remaining faithful to the statute. We discuss below the major provisions of this rule that affect physicians.

a. *Compensation.* This interim final rule includes many clarifications and several new exceptions related to physician compensation. For example, this interim final rule revises the set-in advance definition to permit certain fluctuating compensation arrangements if the payment methodology is set in advance; eliminates the proposed restriction on productivity bonuses, and permits employees to be paid bonuses based on personal productivity (but not ancillary referrals). Moreover, the regulations permit group practice and employed physicians, like independent contractors, to be paid under risk-sharing arrangements. Phase II also clarifies the indirect compensation arrangements definition and exception, as well as the definitions of certain key concepts, such as ''volume and value of referrals'' and ''other business generated.'' Phase II also creates a physician hourly compensation ''deeming provision'' that deems certain hourly compensation to physicians to be fair market value for purposes of complying with various exceptions. All of these changes ease the burden and cost of complying with the statutory prohibition by creating or implementing clear rules in such a way that parties can determine more easily and with greater certainty whether their financial relationships comply with an exception. In addition, by expanding some definitions and exceptions, a greater number of legitimate arrangements can comply with the statute.

b. *In-office Ancillary Services.* This interim final rule revises the in-office ancillary services exception. Specifically, this interim final rule eases the same building requirement by substituting simple, more expansive tests. The revised in-office ancillary services exception should also make it less burdensome for radiologists and oncologists to comply with the exception because the revised exception includes more definite standards. Thus, these physicians will have greater certainty that their arrangements comply with the statute.

c. *Physician Recruitment.* This interim final rule revises the physician recruitment relocation exception to focus on relocation of the physician's office and percentage of new patients, rather than the physician's residence. The exception now provides for either a minimum move of the physician's office practice or a substantial percentage (75 percent) of new patients. In addition, the relocation requirement in this exception does not apply to residents and physicians in practice for less than one year. It also now allows certain joint recruiting with existing group practices. Together, these changes permit a greater number of legitimate arrangements to comply with the statute.

This interim final rule also adds an exemption for certain retention payments for physicians in health professional shortage areas (HPSAs) or in an area with demonstrated need for the retained physician as determined by the Secretary in an advisory opinion issued pursuant to section 1877(d)(6) of the Act. This new exception will permit a greater number of legitimate arrangements to comply with the law.

d. *Miscellaneous.* This interim final rule contains a new exception for professional courtesy, and establishes an exception for certain inadvertent and temporary lapses in compliance with an existing exception, both of which should minimize the effect of the final rule. To the extent that new or expanded exceptions permit additional legitimate arrangements to comply with the law, the potential and significant costs of noncompliance (for example, overpayment refunds, civil monetary penalties) are avoided. In addition, these changes will require fewer arrangements to be restructured to comply with an exception, thus reducing the costs of compliance.

2. Effects on Other Health Care Providers and Suppliers

As we stated above, Phase II 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 may also be subject to other sanctions, including fines and exclusion from Federal health care programs, if they knowingly submit a claim in violation of the prohibition. While all physicians and DHS entities are subject to this rule, we lack the data to determine the number of entities whose financial relationships with physicians must be terminated or revised to comply with this rule. However, we believe the number will be fewer than we had anticipated in the January 1998 proposed rule and the January 4, 2001 Phase I final rule because, as with Phase I, we have interpreted the prohibition narrowly and the exceptions broadly.

There are a few provisions that will be especially beneficial to hospitals and other DHS entities. The first of these is the creation of safe harbors for different types of hourly compensation. This minimizes the risk for physicians, their employers, and DHS entities that contract with physicians to provide services. This interim final rule sets forth a physician hourly compensation deeming provision that deems hourly payments to a physician to be fair market value if the payment equals (i) the community hourly rate for ER doctors, or (ii) the average hourly rate for specialties as determined by averaging certain national physician compensation surveys. This interim final rule also addresses the issue of reporting requirements by requiring that DHS entities retain relevant information and make it available upon request by the Secretary. By not requiring periodic reporting, we have significantly eased the cost and burden of compliance. In addition, Phase II includes ownership exceptions for publicly-traded securities and mutual funds, rural providers, and hospitals. Additional exceptions that benefit DHS entities include the intra-family referrals exception, the physician retention in underserved areas exception, the community-wide health information systems exception, and the temporary grace period exception. Again, to the extent that new or expanded exceptions permit additional legitimate arrangements to comply with the law, the potential and significant costs of restructuring arrangements is reduced, and the costs of noncompliance are avoided entirely.

3. Effects on the Medicare and Medicaid Programs

Section 1877 of the Act was enacted to address over-utilization, anti-competitive behavior, and other abuses of health care services that occur when physicians have financial relationships with certain ancillary services entities to which they refer Medicare or Medicaid patients. Physician financial arrangements may have some anti-competitive effects to the extent that those relationships discourage other providers from entering a market in which patients are primarily referred to physician-owned entities or DHS entities that maintain generous compensation arrangements with physicians. Anti-competitive behavior can increase program costs if the DHS entities with which physicians have financial relationships are favored over other, more cost-efficient providers or providers that furnish higher quality care. Overutilization increases program costs because Medicare (or Medicaid) pays for more items or services than are medically necessary.

We expect that Phase II of this rulemaking will result in savings to the program by minimizing anti-competitive business arrangements as well as over-utilization or other abuse of covered services. For example, the new ''same building'' definition will prohibit arrangements in which DHS are insufficiently tied to the referring physician's core medical practice and essentially constitute separate business enterprises. We have made clear that these arrangements, which could otherwise encourage overutilization and anti-competitive behavior, will not qualify for the in-office ancillary services exception. We cannot gauge with any certainty the extent of these savings to the program at this time.

We note that while we have delayed rulemaking with respect to portions of the application of section 1903(s)(2) of the Act, the fact that most providers and suppliers of Medicaid services also furnish Medicare services means that the Medicaid programs should indirectly benefit from compliance on the Medicare side. Thus, Phase II of this rulemaking should result in savings to the Medicaid program, but we cannot gauge with any certainty the extent of these savings at this time.

4. Effects on Beneficiaries

Some commenters thought the January 1998 proposed rule exceeded our statutory authority and imposed unnecessary and costly burdens on physicians and other health care providers/suppliers that would harm patient access to health care facilities and services. We have tried to ensure that this rule will not adversely impact the medical care of Federal health care program beneficiaries. Where we have determined that Phase II of this rulemaking may have an impact on 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 may continue to receive services in the same location. In almost all cases, we believe Phase II of this rulemaking should not require substantial changes in delivery arrangements. For the same reasons noted above under ''Effects on the Medicare and Medicaid Programs,'' we believe that this interim final rule will help minimize anti-competitive behavior that can affect where a beneficiary receives health care services and possibly the quality of the services furnished, and we believe this rule will minimize the number of medically unnecessary tests performed or items or services ordered on Federal health care program beneficiaries.

C. Alternatives Considered

In drafting the January 1998 proposed rule, we interpreted the statute strictly and literally. After reviewing the voluminous number of comments we received, we considered in Phase I many alternatives to accommodate the practical problems that commenters raised, while still remaining true to the statutory language and intent. As noted throughout the Phase II preamble, we continued to consider alternatives raised in comments submitted on the January 1998 proposed rule and, where applicable, comments received on Phase I. For example, we received many comments requesting modifications to various provisions concerning academic medical centers. In Phase I, we added a new regulatory exception for academic medical center arrangements, pursuant to section 1877(b)(4) of the Act. In response to objections from Phase I commenters about the definition of an academic medical center in § 411.355(e)(2), we are revising the definition in Phase II to more accurately reflect the nature of these entities. The new definition permits hospitals or health systems that sponsor four or more approved medical education programs to qualify as an academic medical center, provided they meet the other criteria in the exception. We considered requiring the hospital or health system to sponsor five or more approved medical education programs. However, after reviewing the issue more carefully, we decided that a requirement for four programs would adequately ensure that the hospital or health system has a substantial teaching mission and would not disqualify institutions that otherwise appeared to be *bona fide* academic medical centers.

We received comments suggesting that we revise the ''same building'' requirement in the in-office ancillary services exception to allow non-abusive arrangements or to clarify terms that commenters claimed were ambiguous. We considered maintaining the Phase I ''same building'' test, but realized that we would be unable to protect legitimate arrangements involving the specialty groups that primarily furnish DHS such as oncology and radiology. For example, under the Phase I definition, 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. At the suggestion of commenters, we considered replacements for the term ''substantial,'' including ''any,'' ''more than incidental,'' ''10 percent,'' and ''significant.'' Ultimately, we decided that these replacement terms were not sufficiently bright-line and would not necessarily protect legitimate arrangements involving radiologists and oncologists. We replaced the Phase I same building test with three separate options, one of which was specifically designed to permit legitimate arrangements involving radiologists and oncologists. Under that test, a designated health service is furnished in the ''same building'' if the building is one in which the referring physician or his or her group practice has an office that is normally open to their patients at least 35 hours per week, and the referring physician or one or more members of his or her group regularly practices medicine and furnishes physician services to patients in that office at least 30 hours per week. However, the revised provision should not unsettle legitimate arrangements under the Phase I definition. In fact, the new ''same building'' test should permit some legitimate arrangements not protected by Phase I.

Many Phase I commenters objected to the definition of compensation that is ''set in advance'' because it did not permit certain percentage compensation arrangements. We considered maintaining the Phase I definition of ''set in advance,'' but realized that hospitals, academic medical centers, and other entities would have to renegotiate numerous legitimate contracts for physician services, potentially causing significant

disruption within the health care industry without a corresponding program integrity benefit. We were concerned that such disruption could unnecessarily inconvenience Medicare beneficiaries. Accordingly, reviewing this subject more thoroughly, we are revising the definition of ''set in advance.'' Compensation will be considered ''set in advance'' if the aggregate compensation, or a time-based or unit-of-service-based (whether per-use or per-service) amount, or a specific formula for calculating certain fluctuating compensation, is set forth in the initial agreement between the parties (and before the furnishing of the items or services for which the compensation is to be paid).

Commenters on the January 1998 proposed rule expressed considerable concern that the proposed reporting requirements were unduly burdensome. In response, we are making a number of changes to the reporting requirements. Most significantly, we are eliminating the requirement to report periodically information regarding financial relationships. Instead, we are requiring that entities retain certain information regarding their financial relationships with referring physicians and submit that information only upon request. The information required to be retained is that which the entity knows or should know about in the course of prudently conducting business, including records that the entity is already required to retain in accordance with the rules of the Internal Revenue Service, the Securities and Exchange Commission, and the Medicare and Medicaid programs. We are also specifying that ownership or investment interests in publicly-traded securities and mutual funds need not be reported if they satisfy the exceptions for such financial relationships in § 411.356(a) and § 411.356(b).

We considered maintaining the original reporting requirements, but decided that periodic reporting would not be particularly helpful to the agency. CMS and its contractors would be overwhelmed by the number of reports and financial relationships that would need to be analyzed. We decided that we would make better use of our available resources if we collected information on financial relationships in a more focused manner (such as during a fraud investigation of a particular provider or group of providers).

In response to comments, we considered allowing a referring physician to ''stand in the shoes'' of his group practice or wholly-owned professional corporation (PC) when the only intervening entity between the referring physician and the DHS entity is his or her PC. Under such a rule, what would otherwise be analyzed as an indirect compensation arrangement could instead be analyzed as a direct compensation arrangement. We recognize in this interim final rule that it is not necessary to treat a referring physician as separate from his or her wholly-owned PC, and we have revised the definition of ''referring physician'' accordingly. However, we decided not to make any changes to the Phase I rule with respect to the issue of indirect compensation arrangements that are created when a group practice is an intervening entity in the chain between the DHS entity and the referring physicians who are members of the group. We believe that such a change would unnecessarily complicate the final rule and create confusion. Moreover, we believe such a change is unnecessary, since the knowledge standard in the indirect compensation arrangements definition and exception adequately protects DHS entities.

We have created an exception for certain referrals from a referring physician to a DHS entity with which his or her immediate family member has a financial relationship, if the patient being referred resides in a rural area and there is no DHS entity available in a timely manner in light of the patient's condition to furnish the DHS to the patient in his or her home or within 25 miles of the patient's home. In creating this exception for intra-family rural referrals, we considered permitting such referrals regardless of whether the patient resides in a rural area. Although intra-family referrals may be relatively infrequent, we decided to limit the exception to rural referrals because we cannot create a new regulatory exception if it poses any risk of program or patient abuse. In drafting the exception, we also considered using a 15-mile standard. Ultimately, we decided that a 25-mile standard would be more consistent with similar standards elsewhere in the regulation and would minimize any unfair competitive effect on non-physician owned DHS entities that may seek to provide services in rural areas.

As these examples demonstrate, our approach in Phase II of this rulemaking is to address as many of the industry's concerns as possible. As noted throughout this preamble, we considered a variety of suggestions and alternatives, selecting only those that are consistent with the statute's goals and directives and that will protect Federal health care program beneficiaries' access to services.

XVI. Waiver of Proposed Rulemaking

Section 902 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) provides that, effective December 8, 2003, the Secretary, in consultation with the Director of the Office of Management and Budget (OMB), shall establish and publish a regular timeline for the publication of final regulations based on the previous publication of a proposed regulation or an interim final regulation. Section 902 further provides that the timeline may vary among different regulations, but shall not be longer than three years except under exceptional circumstances.

Part of this Phase II rule finalizes portions of a proposed rule that was published in January 1998. Although we do not believe that section 902 prohibits the Secretary from finalizing every proposed rule that was published more than three years before December 8, 2003, we recognize that section 902 may be susceptible to more than one interpretation. Accordingly, out of an abundance of caution, we are not publishing this rule as a final rule. Instead, we are waiving notice of proposed rulemaking and publishing this rule as an interim final rule with comment period. Under the Administrative Procedures Act (5 U.S.C. 553(b)), an agency may waive publication of a notice of proposed rulemaking if the agency finds good cause that the notice and comment procedure is impracticable, unnecessary, or contrary to the public interest and the agency incorporates into the rule a statement of, and the reasons for, such a finding. For the reasons discussed below, we find that it would be impracticable and contrary to the public interest to publish as a proposed rule approximately half of the material contained in this interim final rule with comment period.

The physician self-referral prohibition is implicated in nearly every financial relationship between and among physicians and entities that furnish DHS. Violations of the law (regardless of the intent of the parties) have substantial financial consequences, including denial of payment (or refunding of payments received) for DHS claims; civil monetary penalties; and program exclusion. The imposition of these sanctions can result in multi-million dollar liability. Violations of the physician self-referral prohibition may also be pursued under the False Claims Act, 31 U.S.C. 3729–3733. Given the scope and strict liability nature of the prohibition and the significant financial consequences of noncompliance, the

industry has asked for ''bright-line'' rules and new regulatory exceptions for nonabusive arrangements.

We believe it is impracticable and not in the public interest to offer what would essentially constitute a third opportunity to comment on much of the material in this rule and thereby delay finalizing useful exceptions and the many ''bright-line'' rules necessary either to protect the Medicare program from fraud and abuse or permit nonabusive arrangements. We have already issued a proposed rule, major portions of which were finalized upon publication of the Phase I final rule with comment period and became effective on January 4, 2002. This interim final rule responds to public comments received on the January 1998 proposed rule as well as public comments received on Phase I. Phase I comments necessarily informed our rulemaking with respect to finalizing the remainder of the January 1998 proposed rule because those comments addressed definitions and other matters that apply throughout the regulatory scheme. To publish yet another proposed rule on this matter would prevent affected parties from using important new or expanded exceptions. Even if we were able to finalize a proposed rule in an expedited fashion, the inability to use the new or expanded exceptions could expose DHS entities to significant financial liability for otherwise nonabusive relationships. Moreover, the public will not be denied the opportunity to comment on this rule because we are publishing it as an interim final rule with comment period. In accordance with section 902 of MMA, we are obligated to consider comments on this interim final rule and publish a final rule addressing those comments within three years.

In the Phase I preamble, we informed the public that we intended to publish a second final rule with comment period (Phase II) that would address the remainder of the proposed rule as well as comments on Phase I. The additional regulatory definitions and new regulatory exceptions in Phase II are inextricably intertwined with the Phase I final rule. The industry has patiently and eagerly awaited the publication of a single, comprehensive Phase II regulation that would provide the guidance and finality necessary for physicians and health care providers to structure their financial relationships in a manner that assures each party's compliance with the statutory prohibition. It would be contrary to the public interest to upset expectations by publishing another proposed rule thereby denying affected parties the clarity and finality they expected to obtain with this rule. In addition, to extract a significant portion of the material in this interim final rule (much, if not all, of which will not be controversial) and to publish it separately in another proposed rule would thwart our efforts to present the unified and complete regulatory scheme necessary to support both compliance and enforcement efforts.

In addition, further delay could disrupt or hinder our programmatic objective of improving beneficiaries' access to care. For instance, this interim final rule with comment period creates a new exception for certain payments made by a hospital or federally qualified health center to a physician to retain the physician's medical practice in a health professional shortage area. In addition, this interim final rule creates an exception for intra-family rural referrals and obstetrical malpractice insurance subsidies. Beneficiary access to care in underserved or rural areas is a critical programmatic objective. It is not in the public interest to delay finalizing the new exceptions designed to serve this purpose.

For the reasons explained above, we find good cause to waive notice of proposed rulemaking and to issue this rule as an interim final rule with comment period.

In accordance with the provisions of Executive Order 12866, Phase II 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, CMS amends 42 CFR chapter IV as set forth below:

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

■ 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 Exclusion of Particular Services

■ 2. In § 411.1, paragraph (a) is republished 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—Financial Relationships Between Physicians and Entities Furnishing Designated Health Services

■ 3. The heading for subpart J is revised as set forth above, and subpart J is revised to read as follows:

Subpart J—Financial Relationships Between Physicians and Entities Furnishing Designated Health Services

Sec.

411.350 Scope of subpart.
411.351 Definitions.
411.352 Group practice.
411.353 Prohibition on certain referrals by physicians and limitations on billing.
411.354 Financial relationship, compensation, and ownership or investment interest.
411.355 General exceptions to the referral prohibition related to both ownership/investment and compensation.
411.356 Exceptions to the referral prohibition related to ownership or investment interests.
411.357 Exceptions to the referral prohibition related to compensation arrangements.
411.361 Reporting requirements.

Subpart J—Financial Relationships Between Physicians and Entities Furnishing Designated Health Services

§ 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 ownership, investment, or compensation arrangements in the form, in the manner, and at the times specified by CMS.

§ 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 subpart 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 or supplier (for example, a diagnostic imaging facility) is not a centralized building for purposes of this subpart. This provision does not preclude a group practice from providing services to other providers or suppliers (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 List of CPT/HCPCS Codes. All services so identified on the List of CPT/HCPCS Codes are clinical laboratory services for purposes of this subpart. Any service not specifically identified as a clinical laboratory service on the List of CPT/HCPCS Codes is not a clinical laboratory service for purposes of this subpart.

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 this subpart, the term ''designated health services'' or 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 (for example, all services provided as home health services or inpatient and outpatient hospital services are DHS).

Does not violate the anti-kickback statute, as used in this subpart only, means that the particular arrangement—

(1) Meets a safe harbor under the anti-kickback statute in § 1001.952 of this title, ''Exceptions'';

(2) Has been specifically approved by the OIG in a favorable advisory opinion issued to a party to the particular arrangement (*e.g.*, the entity furnishing DHS) with respect to the particular arrangement (and not a similar arrangement), provided that the arrangement is conducted in accordance with the facts certified by the requesting party and the opinion is otherwise issued in accordance with part 1008 of this title, ''Advisory Opinions by the OIG''; or

(3) Does not violate the anti-kickback provisions in section 1128B(b) of the Act.

A favorable advisory opinion for purposes of this definition means an opinion in which the OIG opines that—

(1) The party's specific arrangement does not implicate the anti-kickback statute, does not constitute prohibited remuneration, or fits in a safe harbor under § 1001.952 of this title; or

(2) The party will not be subject to any OIG sanctions arising under the anti-kickback statute (for example, under sections 1128(a)(7) and 1128a(b)(7) of the Act) in connection with the party's specific arrangement.

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—

(1) 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. 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-

(i) Is the person or entity to which CMS makes payment for the DHS, directly or upon assignment on the patient's behalf; or

(ii) Is the person or entity to which the right to payment for the DHS has been reassigned pursuant to § 424.80(b)(1) (employer), (b)(2) (facility), or (b)(3) (health care delivery system) of this chapter (other than a health care delivery system that is a health plan (as defined in § 1001.952(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).

(2) 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, with respect to any designated health services provided by that supplier.

(3) For purposes of this subpart, ''entity'' does not include a physician's practice when it bills Medicare for a diagnostic test in accordance with § 414.50 of this chapter (Physician billing for purchased diagnostic tests) and section 3060.4 of the Medicare Carriers Manual (Purchased diagnostic tests), as amended or replaced from time to time.

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, where the price or compensation has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals. With respect to rentals and leases described in § 411.357(a), (b), and (l) (as to equipment leases only), ''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 definition, 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.

An hourly payment for a physician's personal services (that is, services performed by the physician personally and not by employees, contractors, or others) shall be considered to be fair market value if the hourly payment is established using either of the following two methodologies:

(1) The hourly rate is less than or equal to the average hourly rate for emergency room physician services in the relevant physician market, provided there are at least three hospitals providing emergency room services in the market.

(2) The hourly rate is determined by averaging the 50th percentile national compensation level for physicians with the same physician specialty (or, if the specialty is not identified in the survey, for general practice) in at least four of the following surveys and dividing by 2,000 hours. The surveys are:

- Sullivan, Cotter & Associates, Inc.—Physician Compensation and Productivity Survey
- Hay Group—Physicians Compensation Survey
- Hospital and Healthcare Compensation Services—Physician Salary Survey Report
- Medical Group Management Association—Physician Compensation and Productivity Survey
- ECS Watson Wyatt—Hospital and Health Care Management Compensation Report
- William M. Mercer—Integrated Health Networks Compensation Survey

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 ''critical access 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, 42 CFR § 410.26, and section 2050 of the Medicare Carriers (CMS Pub. 14–3), Part 3—Claims Process, as amended or replaced from time to time.

Inpatient hospital services means those services defined in section 1861(b) of the Act and § 409.10(a) and (b) of this chapter and include inpatient psychiatric hospital services listed in section 1861(c) of the Act and inpatient critical access 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. ''Inpatient hospital 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 are furnished either by the hospital directly or under arrangements made by the hospital with others. ''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 means the list of CPT and HCPCS codes that identifies those items and services that are designated health services under section 1877 of the Act or that may qualify for certain exceptions under section 1877 of the Act. It is updated annually, as published in the **Federal Register**, and is posted on the CMS Web site at *http://www.cms.gov/medlearn/refphys.asp.*

Locum tenens physician means a physician who substitutes (that is, ''stands in the shoes'') in exigent circumstances for a physician, in accordance with applicable reassignment rules and regulations, including section 3060.7 of the Medicare Carriers Manual (CMS Pub. 14–3), Part 3—Claims Process, as amended or replaced from time to time.

Member of the group or member of a group practice means, for purposes of this subpart, 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 (unless the leased employee meets the definition of an ''employee'' under this § 411.351).

Outpatient hospital services means the therapeutic, diagnostic, and partial hospitalization services listed under sections 1861(s)(2)(B) and (s)(2)(C) of the Act; outpatient services furnished by a psychiatric hospital, as defined in section 1861(f) of the Act; and outpatient critical access hospital services, as defined in section 1861(mm)(3) of the Act. ''Outpatient hospital services'' do not include emergency services furnished by nonparticipating hospitals and covered under the conditions described in section 1835(b) of the Act and subpart G of part 424 of this chapter. ''Outpatient hospital services'' include services that are furnished either by the hospital directly or under arrangements made by the hospital with others. ''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 (CMS Pub. 6), as amended or replaced from time to time; 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 (CMS Pub. 6), as amended or replaced from time to time.

Patient care services means any task(s) 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 so identified on the List of CPT/HCPCS Codes. All services so identified on the List of CPT/HCPCS Codes are physical therapy, occupational therapy, and speech-language pathology services for purposes of this subpart. Any service not specifically identified as physical therapy, occupational therapy or speech-language pathology on the List of CPT/HCPCS Codes is not a physical therapy, occupational therapy, or speech-language pathology service for purposes of this subpart. The list of codes identifying physical therapy, occupational therapy, and speech-language pathology services for purposes of this regulation 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) for 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 must fit 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 (CMS Pub. 14–3), Part 3—Claims Process, as amended or replaced from time to time). Referrals from an independent contractor who is a physician in the group practice 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 (or downstream subcontractor) 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.

Professional courtesy means the provision of free or discounted health care items or services to a physician or his or her immediate family members or office staff.

Prosthetics, Orthotics, and Prosthetic Devices and Supplies means the following services (including all HCPCS level 2 codes for these items and 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 so identified on the List of CPT/HCPCS Codes. All services and supplies so identified on the List of CPT/HCPCS Codes are radiation therapy services and supplies for purposes of this subpart. Any service or supply not specifically identified as radiation therapy services or supplies on the List of CPT/HCPCS Codes is not a radiation therapy service or supply for purposes of this subpart. The list of codes identifying radiation therapy services and supplies 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 so identified on the List of CPT/HCPCS Codes. All services so identified on the List of CPT/HCPCS Codes are radiology and certain other imaging services for purposes of this subpart. Any service not specifically identified as radiology and certain other imaging services on the List of CPT/HCPCS Codes, is not a radiology or certain other imaging service for purposes of this subpart. The list of codes identifying radiology and certain other imaging services 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 ultrasound 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 a nonradiological medical procedure and performed—

(i) During the nonradiological medical procedure; or

(ii) Immediately following the nonradiological medical procedure when necessary to confirm placement of an item placed during the nonradiological medical procedure; and

(3) Diagnostic 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, or under the supervision of a pathologist, radiologist, or radiation oncologist, respectively, in the same group practice as 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. A referring physician and the professional corporation of which he or she is a sole owner are the same for purposes of this subpart.

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 (or a subcontractor of the insurer or 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 (or a subcontractor of the insurer or 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 loading docks or parking garages. For purposes of this section, the ''same building'' does not include a mobile vehicle, van, or trailer.

Specialty hospital means a subsection (d) hospital (as defined in section 1886(d)(1)(B)) that is primarily or exclusively engaged in the care and treatment of one of the following: Patients with a cardiac condition; patients with an orthopedic condition; patients receiving a surgical procedure; or any other specialized category of services that the Secretary designates as inconsistent with the purpose of permitting physician ownership and investment interests in a hospital. A ''specialty hospital'' does not include any hospital—

(1) Determined by the Secretary to be in operation before or under development as of November 18, 2003;

(2) For which the number of physician investors at any time on or after such date is no greater than the number of such investors as of such date;

(3) For which the type of categories described above is no different at any time on or after such date than the type of such categories as of such date;

(4) For which any increase in the number of beds occurs only in the facilities on the main campus of the hospital and does not exceed 50 percent of the number of beds in the hospital as of November 18, 2003, or 5 beds, whichever is greater; and

(5) that meets such other requirements as the Secretary may specify.

Transaction means an instance or process of two or more persons or entities doing business. An isolated transaction means one involving a single payment between two or more persons or entities or a transaction that involves integrally related installment payments provided that—

(1) The total aggregate payment is fixed before the first payment is made and does not take into account, directly or indirectly, the volume or value of referrals or other business generated by the referring physician; and

(2) The payments are immediately negotiable or are guaranteed by a third party, secured by a negotiable promissory note, or subject to a similar mechanism to assure payment even in the event of default by the purchaser or obligated party. § 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 operating 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 be organized or owned (in whole or in part) by another medical practice, provided that the other medical practice is not an operating physician practice (and regardless of whether the medical practice meets the conditions for a group practice under this section). For purposes of this subpart, 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. A group practice operating in more than one State will be considered to be a single legal entity notwithstanding that it is composed of multiple legal entities, provided that—

(1) The States in which the group practice is operating are contiguous (although each State need not be contiguous to every other State);

(2) The legal entities are absolutely identical as to ownership, governance, and operation; and

(3) Organization of the group practice into multiple entities is necessary to comply with jurisdictional licensing laws of the States in which the group practice operates.

(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 § 411.351.

(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 otherwise provided in paragraphs (d)(3), (d)(4), (d)(5), and (d)(6) 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 a week 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'' set forth in paragraph (d)(1) of this section 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 ''substantially all'' test 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 reorganizes.

(6)(i) If the addition to an existing group practice of a new member who would be considered to have relocated his or her practice under § 411.457(e)(2) would result in the existing group practice not meeting the ''substantially all'' test set forth in paragraph (d)(1) of this section, the group practice will have 12 months following the addition of the new member to come back into full compliance, provided that—

(A) For the 12-month period the group practice is fully compliant with the ''substantially all'' test if the new member is not counted as a member of the group for purposes of § 411.352; and

(B) The new member's employment with, or ownership interest in, the group practice is documented in writing no later than the beginning of his or her new employment, ownership, or investment.

(ii) This paragraph (d)(6) does not apply when an existing group practice reorganizes or admits a new member who is not relocating his or her practice.

(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 section prevents a group practice from adjusting its compensation methodology prospectively, subject to restrictions on the distribution of revenue from DHS under § 411.352(i).

(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); and

(ii) Consolidated billing, accounting, and financial reporting.

(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 § 411.352(i).

(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 § 411.352(i).

(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. Overall profits should be divided in a reasonable and verifiable manner that is not directly related to the volume or value of the physician's referrals of DHS. 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.

(3) A productivity bonus should be calculated in a reasonable and verifiable manner that is not directly related to the volume or value of the physician's referrals of DHS. A productivity bonus 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.

(4) Supporting documentation verifying the method used to calculate the profit share 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.

§ 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 and State laws, rules, and regulations.

(f) *Exception for certain arrangements involving temporary noncompliance.* (1) Except as provided in paragraphs (f)(2), (f)(3), and (f)(4) of this section, an entity may submit a claim or bill and payment may be made to an entity that submits a claim or bill for a designated health service if—

(i) The financial relationship between the entity and the referring physician fully complied with an applicable exception under § 411.355, § 411.356, or § 411.357 for at least 180 consecutive calendar days immediately preceding the date on which the financial relationship became noncompliant with the exception;

(ii) The financial relationship has fallen out of compliance with the exception for reasons beyond the control of the entity, and the entity promptly takes steps to rectify the noncompliance; and

(iii) The financial relationship does not violate the anti-kickback statute (section 1128B(b) of the Act), and the claim or bill otherwise complies with all applicable Federal and State laws, rules, and regulations.

(2) Paragraph (f)(1) of this section applies only to DHS furnished during the period of time it takes the entity to rectify the noncompliance, which must not exceed 90 consecutive calendar days following the date on which the financial relationship became noncompliant with an exception.

(3) This paragraph (f) may only be used by an entity once every 3 years with respect to the same referring physician.

(4) This paragraph (f) does not apply if the exception with which the financial relationship previously complied was § 411.357(k) or (m).

§ 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. (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, stock options other than those described in § 411.354(b)(3)(ii), 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 received as compensation until the stock options are exercised or the convertible securities are converted to equity (before this time the stock options or convertible securities 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'' with the hospital (such a contract is a compensation arrangement as defined in paragraph (c) of this section).

(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, or interest payments on secured obligations.

(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; 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) An indirect ownership or investment interest exists even though the entity furnishing DHS does 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.

(iii) Notwithstanding anything in this paragraph (b)(5), common ownership or investment in an entity does not, in and of itself, establish an indirect ownership or investment interest by one common owner or investor in another common owner or investor.

(iv) An indirect ownership or investment interest requires an unbroken chain of ownership interests between the referring physician and the entity furnishing DHS such that the referring physician has an indirect ownership or investment interest *in* the entity furnishing DHS.

(c) *Compensation arrangement.* A compensation arrangement is 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 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.)

(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, regardless of whether the individual unit of compensation satisfies the special rules on unit-based compensation under § 411.354(d)(2) or (d)(3). 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 volume or value 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 subpart J of this part.

(1) Compensation will be considered ''set in advance'' if the aggregate compensation, a time-based or per unit of service based (whether per-use or per-service) amount, or a specific formula for calculating the compensation is set in an agreement between the parties before the furnishing of the items or services for which the compensation is to be paid. The formula for determining the compensation must be set forth in sufficient detail so that it can be objectively verified, and the formula may not be changed or modified during the course of the agreement in any manner that reflects the volume or value of referrals or other business generated by the referring physician.

(2) Unit-based 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) Unit-based compensation (including time-based or per unit of service based compensation) will be deemed to not take into account ''other business generated between the parties'' so long as the compensation is fair market value for items and services actually provided and does not vary during the course of the compensation arrangement in any manner that takes into account referrals or other business generated by the referring physician, including private pay health care business (except for services personally performed by the referring physician, which will not be considered ''other business generated'' by the referring physician).

(4) A physician's compensation from a *bona fide* employer or under a managed care or other contract may be conditioned on the physician's referrals to a particular provider, practitioner, or supplier, so long as the compensation arrangement—

(i) Is set 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) Otherwise complies with an applicable exception under § 411.355 or § 411.357;

(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 judgment; and

(v) The required referrals relate solely to the physician's services covered by the scope of the employment or the contract and the referral requirement is reasonably necessary to effectuate the legitimate business purposes of the compensation relationship. In no event may the physician be required to make referrals that relate to services that are not provided by the physician under the scope of his or her employment or

contract. § 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 at § 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, sbull; physician services'' include 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, if the referring physician is in a group practice, 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 all of the conditions of paragraph (b)(2)(i)(A), (b)(2)(i)(B), *or* (b)(2)(i)(C) of this section are satisfied:

(A)(*1*) The referring physician or his or her group practice (if any) has an office that is normally open to the physician's or group's patients for medical services at least 35 hours per week; *and*

(*2*) The referring physician or one or more members of the referring physician's group practice regularly practices medicine and furnishes physician services to patients at least 30 hours per week. The 30 hours must include some 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 physician services may lead to the ordering of DHS; or

(B)(*1*) The patient receiving the DHS usually receives physician services from the referring physician or members of the referring physician's group practice (if any);

(*2*) The referring physician or the referring physician's group practice owns or rents an office that is normally open to the physician's or group's patients for medical services at least 8 hours per week; *and*

(*3*) The referring physician regularly practices medicine and furnishes physician services to patients at least 6 hours per week. The 6 hours must include some 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 physician services may lead to the ordering of DHS; or

(C)(*1*) The referring physician is present and orders the DHS during a patient visit on the premises as set forth in paragraph (b)(2)(i)(C)(*2*) of this section *or* the referring physician or a member of the referring physician's group practice (if any) is present while the DHS is furnished during occupancy of the premises as set forth in paragraph (b)(2)(i)(C)(*2*) of this section;

(*2*) The referring physician or the referring physician's group practice owns or rents an office that is normally open to the physician's or group's patients for medical services at least 8 hours per week; and

(*3*) The referring physician or one or more members of the referring physician's group practice regularly practices medicine and furnishes physician services to patients at least 6 hours per week. The 6 hours must include some 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 physician services may lead to the ordering of DHS.

(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 are billed by one of the following:

(i) The physician performing or supervising the service.

(ii) The group practice of which the performing or supervising physician is a member under a billing number assigned to the group practice.

(iii) The group practice if the supervising physician is a ''physician in the group practice'' (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 Federal or State 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 only, a private home does not include a nursing, long-term care, or other facility or institution, except that a patient may have a private home in an assisted living or independent living facility.

(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 CMS under section 1876 of the Act and part 417, subparts J through M of this chapter.

(2) A health care prepayment plan in accordance with an agreement with CMS 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 CMS under section 1857 of the Act and part 422 of this chapter.

(6) A managed care organization (MCO) contracting with a State under section 1903(m) of the Act.

(7) A prepaid inpatient health plan (PIHP) or prepaid ambulance health plan (PAHP) contracting with a State under part 438 of this chapter.

(8) A health insuring organization (HIO) contracting with a State under part 438, subpart D of this chapter.

(9) An entity operating under a demonstration project under sections 1115(a), 1915(a), 1915(b), or 1932(a) of the Act.

(d) [Reserved]

(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. (A ''component'' of an academic medical center means an affiliated medical school, faculty practice plan, hospital, teaching facility, institution of higher education, departmental professional corporation, or nonprofit support organization whose primary purpose is supporting the teaching mission of the academic medical center.) The components need not be separate legal entities;

(B) Is licensed to practice medicine in the State(s) in which he or she practices medicine;

(C) Has a *bona fide* faculty appointment at the affiliated medical school or at one or more of the educational programs at the accredited academic hospital; and

(D) Provides either substantial academic services or substantial clinical teaching services (or a combination of academic services and clinical teaching services) for which the faculty member receives compensation as part of his or her employment relationship with the academic medical center. Parties should use a reasonable and consistent method for calculating a physician's academic services and clinical teaching services. A physician will be deemed to meet this requirement if he or she spends at least 20 percent of his or her professional time or 8 hours per week providing academic services or clinical teaching services (or a combination of academic services or clinical teaching services). A physician who does not spend at least 20 percent of his or her professional time or 8 hours per week providing academic services or clinical teaching services (or a combination of academic services or clinical teaching services) is not precluded from qualifying under this paragraph (e)(1)(i)(D).

(ii) The total compensation paid by 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 written agreement(s) or other written document(s) that have been adopted by the governing body of each component. If the academic medical center is one legal entity, this requirement will be satisfied if transfers of funds between components of the academic medical center are reflected in the routine financial reports covering the components.

(C) All money paid to a referring physician for research must be used solely to support *bona fide* research or teaching and must be consistent with the terms and conditions of the grant.

(iv) The referring physician's compensation arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.

(2) The ''academic medical center'' for purposes of this section consists of—

(i) An accredited medical school (including a university, when appropriate) or an accredited academic hospital (as defined at § 411.355(e)(3));

(ii) One or more faculty practice plans affiliated with the medical school, the affiliated hospital(s), or the accredited academic hospital; and

(iii) One or more affiliated hospital(s) in which a majority of the physicians on the medical staff consists of physicians who are faculty members and a majority

of all hospital admissions are made by physicians who are faculty members. The hospital for purposes of this paragraph (e)(2)(iii) may be the same hospital that satisfies the requirement of paragraph (e)(2)(i) of this section. For purposes of this provision, a faculty member is a physician who is either on the faculty of the affiliated medical school or on the faculty of one or more of the educational programs at the accredited academic hospital. In meeting this paragraph (e)(2)(iii), faculty from any affiliated medical school or accredited academic hospital education program may be aggregated, and residents and non-physician professionals need not be counted. Any faculty member may be counted, including courtesy and volunteer faculty.

(3) An accredited academic hospital for purposes of this section means a hospital or a health system that sponsors four or more approved medical education programs.

(f) *Implants furnished by an ASC.* Implants furnished by an ASC, 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 implanted 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 paid by Medicare to the ASC as an ASC procedure under § 416.65.

(3) The arrangement for the furnishing of the implant does not violate the anti-kickback statute (section 1128B(b) of the Act).

(4) All billing and claims submission for the implants does not violate any Federal or State law or regulation governing billing or claims submission.

(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 drugs furnished in or by an ESRD facility.* EPO and other dialysis-related drugs 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 (g): ''EPO and other dialysis-related drugs'' means certain outpatient prescription drugs that are required for the efficacy of dialysis and identified as eligible for this exception on the List of CPT/HCPCS Codes; and ''furnished'' means that the EPO or dialysis-related drugs are administered to a patient in the ESRD facility, or, in the case of EPO or Aranesp (or equivalent drug identified on the List of CPT/HCPCS Codes) only, are dispensed by the ESRD facility for use at home.

(2) The arrangement for the furnishing of the EPO and other dialysis-related drugs does not violate the anti-kickback statute (section 1128B(b) of the Act).

(3) All billing and claims submission for the EPO and other dialysis-related drugs does not violate any Federal or State law or regulation governing billing or claims submission.

(4) The exception set forth in this paragraph (g) does not apply to any financial relationship 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 meet the following conditions:

(1) The preventive screening tests, immunizations, and vaccines are subject to CMS-mandated frequency limits.

(2) The arrangement for the provision of the preventive screening tests, immunizations, and vaccines does not violate the anti-kickback statute (section 1128B(b) of the Act).

(3) All billing and claims submission for the preventive screening tests, immunizations, and vaccines does not violate any Federal or State law or regulation governing billing or claims submission.

(4) The preventive screening tests, immunizations, and vaccines must be covered by Medicare and must be listed as eligible for this exception on the List of CPT/HCPCS Codes.

(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 anti-kickback statute (section 1128B(b) of the Act).

(3) All billing and claims submission for the eyeglasses or contact lenses does not violate any Federal or State law or regulation governing billing or claims submission.

(j) *Intra-family rural referrals.* (1) Services provided pursuant to a referral from a referring physician to his or her immediate family member or to an entity furnishing DHS with which the immediate family member has a financial relationship, if all of the following conditions are met:

(i) The patient who is referred resides in a rural area as defined in § 411.356(c)(1);

(ii) Except as provided in paragraph (j)(1)(iii) of this section, no other person or entity is available to furnish the services in a timely manner in light of the patient's condition within 25 miles of the patient's residence;

(iii) In the case of services furnished to patients where they reside (for example, home health services or in-home DME), no other person or entity is available to furnish the services in a timely manner in light of the patient's condition; and

(iv) The financial relationship does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission;

(2) The referring physician or the immediate family member must make reasonable inquiries as to the availability of other persons or entities to furnish the DHS. However, neither the referring physician nor the immediate family member has any obligation to inquire as to the availability of persons or entities located farther than 25 miles from the patient's residence.

§ 411.356 Exceptions to the referral prohibition related to ownership or investment interests.

For purposes of § 411.353, the following ownership or investment interests do not constitute a financial relationship:

(a) *Publicly-traded securities.* Ownership of investment securities (including shares or bonds, debentures, notes, or other debt instruments) that at the time the DHS referral was made could be purchased on the open market and that meet the requirements of paragraphs (a)(1) and (a)(2) of this section.

(1) They are either—

(i) Listed for trading on the New York Stock Exchange, the American Stock Exchange, or any regional exchange in which quotations are published on a daily basis, or foreign securities listed on a recognized foreign, national, or regional exchange in which quotations are published on a daily basis; or

(ii) Traded under an automated interdealer quotation system operated

by the National Association of Securities Dealers.

(2) They are in a corporation that had stockholder equity exceeding $75 million at the end of the corporation's most recent fiscal year or on average during the previous 3 fiscal years. ''Stockholder equity'' is the difference in value between a corporation's total assets and total liabilities.

(b) *Mutual funds.* Ownership of shares in a regulated investment company as defined in section 851(a) of the Internal Revenue Code of 1986, if the company had, at the end of its most recent fiscal year, or on average during the previous 3 fiscal years, total assets exceeding $75 million.

(c) *Specific providers.* Ownership or investment interest in the following entities, for purposes of the services specified:

(1) A rural provider, in the case of DHS furnished in a rural area by the provider. A ''rural provider'' is an entity that furnishes substantially all (not less than 75 percent) of the DHS that it furnishes to residents of a rural area and, for the 18-month period beginning on December 8, 2003 (or such other period as Congress may specify), is not a specialty hospital. A rural area for purposes of this paragraph (c)(1) is an area that is not an urban area as defined in § 412.62(f)(1)(ii) of this chapter.

(2) A hospital that is located in Puerto Rico, in the case of DHS furnished by such a hospital.

(3) A hospital that is located outside of Puerto Rico, in the case of DHS furnished by such a hospital, if—

(i) the referring physician is authorized to perform services at the hospital;

(ii) effective for the 18-month period beginning on December 8, 2003 (or such other period as Congress may specify), the hospital is not a specialty hospital; and

(iii) the ownership or investment interest is in the entire hospital and not merely in a distinct part or department of the hospital.

§ 411.357 Exceptions to the referral prohibition related to compensation arrangements.

For purposes of § 411.353, the following compensation arrangements do not constitute a financial relationship:

(a) *Rental of office space.* Payments for the use of office space made by a lessee to a lessor if there is a rental or lease agreement that meets the following requirements:

(1) The agreement is set out in writing, is signed by the parties, and specifies the premises it covers.

(2) The term of the agreement is at least 1 year. To meet this requirement, if the agreement is terminated during the term with or without cause, the parties may not enter into a new agreement during the first year of the original term of the agreement.

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

(4) The rental charges over the term of the agreement are set in advance and are consistent with fair market value.

(5) The rental charges over the term of the agreement are not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.

(6) The agreement would be commercially reasonable even if no referrals were made between the lessee and the lessor.

(7) A holdover month-to-month rental for up to 6 months immediately following an agreement of at least 1 year that met the conditions of this paragraph (a) will satisfy this paragraph (a), provided the holdover rental is on the same terms and conditions as the immediately preceding agreement.

(b) *Rental of equipment.* Payments made by a lessee to a lessor for the use of equipment under the following conditions:

(1) A rental or lease agreement is set out in writing, is signed by the parties, and specifies the equipment it covers.

(2) The equipment rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease or rental and is used exclusively by the lessee when being used by the lessee and is not shared with or used by the lessor or any person or entity related to the lessor.

(3) The agreement provides for a term of rental or lease of at least 1 year. To meet this requirement, if the agreement is terminated during the term with or without cause, the parties may not enter into a new agreement during the first year of the original term of the agreement.

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

(5) The agreement would be commercially reasonable even if no referrals were made between the parties.

(6) A holdover month-to-month rental for up to 6 months immediately following an agreement of at least 1 year that met the conditions of this paragraph (b) will satisfy this paragraph (b), provided the holdover rental is on the same terms and conditions as the immediately preceding agreement.

(c) *Bona fide employment relationships.* Any amount paid by an employer to a physician (or immediate family member) who has a *bona fide* employment relationship with the employer for the provision of services if the following conditions are met:

(1) The employment is for identifiable services.

(2) The amount of the remuneration under the employment is—

(i) Consistent with the fair market value of the services; and

(ii) Except as provided in paragraph (c)(4) of this section, is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician.

(3) The remuneration is provided under an agreement that would be commercially reasonable even if no referrals were made to the employer.

(4) Paragraph (c)(2)(ii) of this section does not prohibit payment of remuneration in the form of a productivity bonus based on services performed personally by the physician (or immediate family member of the physician).

(d) *Personal service arrangements. (1) General*—Remuneration from an entity under an arrangement or multiple arrangements to a physician, an immediate family member of the physician, or to a group practice, including remuneration for specific physician services furnished to a nonprofit blood center, if the following conditions are met:

(i) Each arrangement is set out in writing, is signed by the parties, and specifies the services covered by the arrangement.

(ii) The arrangement(s) covers all of the services to be furnished by the physician (or an immediate family member of the physician) to the entity. This requirement will be met if all separate arrangements between the entity and the physician and the entity

and any family members incorporate each other by reference or if they cross-reference a master list of contracts that is maintained and updated centrally and is available for review by the Secretary upon request. The master list should be maintained in a manner that preserves the historical record of contracts. A physician or family member can ''furnish'' services through employees whom they have hired for the purpose of performing the services; through a wholly owned entity; or through *locum tenens* physicians (as defined in § 411.351, except that the regular physician need not be a member of a group practice).

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

(iv) The term of each arrangement is for at least 1 year. To meet this requirement, if an arrangement is terminated during the term with or without cause, the parties may not enter into the same or substantially the same arrangement during the first year of the original term of the arrangement.

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

(vi) The services to be furnished under each arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law.

(2) *Physician incentive plan exception.* In the case of a physician incentive plan (as defined in § 411.351) between a physician and an entity (or downstream subcontractor), the compensation may be determined in a manner (through a withhold, capitation, bonus, or otherwise) that takes into account directly or indirectly the volume or value of any referrals or other business generated between the parties, if the plan meets the following requirements:

(i) No specific payment is made directly or indirectly under the plan to a physician or a physician group as an inducement to reduce or limit medically necessary services furnished with respect to a specific individual enrolled with the entity.

(ii) Upon request of the Secretary, the entity provides the Secretary with access to information regarding the plan (including any downstream subcontractor plans), in order to permit the Secretary to determine whether the plan is in compliance with paragraph (d)(2) of this section.

(iii) In the case of a plan that places a physician or a physician group at substantial financial risk as defined in § 422.208, the entity (and/or any downstream contractor) complies with the requirements concerning physician incentive plans set forth at § 422.208 and § 422.210 of this chapter.

(e) *Physician recruitment.* (1) Remuneration provided by a hospital to recruit a physician that is paid directly to the physician and that is intended to induce the physician to relocate his or her medical practice to the geographic area served by the hospital in order to become a member of the hospital's medical staff, if all of the following conditions are met:

(i) The arrangement is set out in writing and signed by both parties;

(ii) The arrangement is not conditioned on the physician's referral of patients to the hospital;

(iii) The hospital does not determine (directly or indirectly) the amount of the remuneration to the physician based on the volume or value of any actual or anticipated referrals by the physician or other business generated between the parties; and

(iv) The physician is allowed to establish staff privileges at any other hospital(s) and to refer business to any other entities (except as referrals may be restricted under a separate employment or services contract that complies with § 411.354(d)(4)).

(2) The ''geographic area served by the hospital'' is the area composed of the lowest number of contiguous zip codes from which the hospital draws at least 75 percent of its inpatients. A physician will be considered to have relocated his or her medical practice if—

(i) The physician moves his or her medical practice at least 25 miles; or

(ii) The physician's new medical practice derives at least 75 percent of its revenues from professional services furnished to patients (including hospital inpatients) not seen or treated by the physician at his or her prior medical practice site during the preceding 3 years, measured on an annual basis (fiscal or calendar year). For the initial ''start up'' year of the recruited physician's practice, the 75 percent test in the preceding sentence will be satisfied if there is a reasonable expectation that the recruited physician's medical practice for the year will derive at least 75 percent of its revenues from professional services furnished to patients not seen or treated by the physician at his or her prior medical practice site during the preceding 3 years.

(3) Residents and physicians who have been in practice 1 year or less will not be subject to the relocation requirement of this paragraph, except that the recruited resident or physician must establish his or her medical practice in the geographic area served by the hospital.

(4) In the case of remuneration provided by a hospital to a physician either indirectly through payments made to another physician or physician practice, or directly to a physician who joins a physician practice, the following additional conditions must be met:

(i) The written agreement in § 411.357(e)(1) is also signed by the party to whom the payments are directly made;

(ii) Except for actual costs incurred by the physician or physician practice in recruiting the new physician, the remuneration is passed directly through to or remains with the recruited physician;

(iii) In the case of an income guarantee made by the hospital to a recruited physician who joins a physician or physician practice, the costs allocated by the physician or physician practice to the recruited physician do not exceed the actual additional incremental costs attributable to the recruited physician;

(iv) Records of the actual costs and the passed through amounts are maintained for a period of at least 5 years and made available to the Secretary upon request;

(v) The remuneration from the hospital under the arrangement is not to be determined in a manner that takes into account (directly or indirectly) the volume or value of any actual or anticipated referrals by the recruited physician or the physician practice (or any physician affiliated with the physician practice) receiving the direct payments from the hospital;

(vi) The physician or physician practice may not impose additional practice restrictions on the recruited physician other than conditions related to quality of care; and

(vii) The arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.

(5) This paragraph (e) applies to remuneration provided by a federally qualified health center in the same manner as it applies to remuneration provided by a hospital, so long as the arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or

regulation governing billing or claims submission.

(f) *Isolated transactions.* Isolated financial transactions, such as a one-time sale of property or a practice, if all of the following conditions are met:

(1) The amount of remuneration under the isolated transaction is—

(i) Consistent with the fair market value of the transaction; and

(ii) Not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician or other business generated between the parties.

(2) The remuneration is provided under an agreement that would be commercially reasonable even if the physician made no referrals.

(3) There are no additional transactions between the parties for 6 months after the isolated transaction, except for transactions that are specifically excepted under the other provisions in § 411.355 through § 411.357 and except for commercially reasonable post-closing adjustments that do not take into account (directly or indirectly) the volume or value of referrals or other business generated by the referring physician.

(g) *Certain arrangements with hospitals.* Remuneration provided by a hospital to a physician if the remuneration does not relate, directly or indirectly, to the furnishing of DHS. To qualify as ''unrelated,'' remuneration must be wholly unrelated to the furnishing of DHS and must not in any way take into account the volume or value of a physician's referrals. Remuneration relates to the furnishing of DHS if it—

(1) Is an item, service, or cost that could be allocated in whole or in part to Medicare or Medicaid under cost reporting principles;

(2) Is furnished, directly or indirectly, explicitly or implicitly, in a selective, targeted, preferential, or conditioned manner to medical staff or other persons in a position to make or influence referrals; or

(3) Otherwise takes into account the volume or value of referrals or other business generated by the referring physician.

(h) *Group practice arrangements with a hospital.* An arrangement between a hospital and a group practice under which DHS are furnished by the group but are billed by the hospital if the following conditions are met:

(1) With respect to services furnished to an inpatient of the hospital, the arrangement is pursuant to the provision of inpatient hospital services under section 1861(b)(3) of the Act.

(2) The arrangement began before, and has continued in effect without interruption since, December 19, 1989.

(3) With respect to the DHS covered under the arrangement, at least 75 percent of these services furnished to patients of the hospital are furnished by the group under the arrangement.

(4) The arrangement is in accordance with a written agreement that specifies the services to be furnished by the parties and the compensation for services furnished under the agreement.

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

(6) The compensation is provided in accordance with an agreement that would be commercially reasonable even if no referrals were made to the entity.

(i) *Payments by a physician.* Payments made by a physician (or his or her immediate family member)—

(1) To a laboratory in exchange for the provision of clinical laboratory services; or

(2) To an entity as compensation for any other items or services that are furnished at a price that is consistent with fair market value, and that are not specifically excepted under another provision in § 411.355 through § 411.357 (including, but not limited to, § 411.357(l)). ''Services'' in this context means services of any kind (not just those defined as ''services'' for purposes of the Medicare program in § 400.202).

(j) *Charitable donations by a physician. Bona fide* charitable donations made by a physician (or immediate family member) to an entity if all of the following conditions are satisfied:

(1) The charitable donation is made to an organization exempt from taxation under the Internal Revenue Code (or to a supporting organization);

(2) The donation is neither solicited, nor made, in any manner that takes into account the volume or value of referrals or other business generated between the physician and the entity; and

(3) The donation arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.

(k) *Non-monetary compensation up to $300.* (1) 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:

(i) 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.

(ii) The compensation may not be solicited by the physician or the physician's practice (including employees and staff members).

(iii) The compensation arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act) or any Federal or State law or regulation governing billing or claims submission.

(2) The $300 limit in this paragraph (k) will be adjusted each calendar year to the nearest whole dollar by the increase in the Consumer Price Index-Urban All Items (CPI–U) for the 12–month period ending the preceding September 30. CMS intends to display as soon as possible after September 30 each year, both the increase in the CPI–U for the 12–month period and the new non-monetary compensation limit on the physician self-referral Web site: *http://cms.hhs.gov/medlearn/refphys.asp.*

(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 § 411.352) for the provision of items or services by the physician (or an immediate family member) or group of physicians to the entity, if the arrangement is set forth in an agreement that meets the following conditions:

(1) The arrangement is in writing, signed by the parties, and covers only identifiable items or services, all of which are specified in the agreement.

(2) The writing 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) The writing specifies the compensation that will be provided under the arrangement. The compensation must be set in advance, consistent with fair market value, and not determined in a manner that takes into account the volume or value of referrals or other business generated by the referring physician.

(4) The arrangement would be commercially reasonable (taking into account the nature and scope of the

transaction) and furthers the legitimate business purposes of the parties.

(5) It does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.

(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 provided to all members of the medical staff practicing in the same specialty (but not necessarily accepted by every member to whom it is offered) without regard to the volume or value of referrals or other business generated between the parties.

(2) Except with respect to identification of medical staff on a hospital Web site or in hospital advertising, the compensation is provided only during periods when the medical staff members are making rounds or are engaged in other services or activities 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. Compensation, including, but not limited to, Internet access, pagers, or two-way radios, used away from the campus only to access hospital medical records or information or to access patients or personnel who are on the hospital campus, as well as the identification of the medical staff on a hospital Web site or in hospital advertising, will meet the ''on campus'' requirement of this paragraph (m).

(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 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). The $25 limit in this paragraph (m)(5) will be adjusted each calendar year to the nearest whole dollar by the increase in the Consumer Price Index-Urban All Items (CPI–U) for the 12–month period ending the preceding September 30. CMS intends to display as soon as possible after September 30 each year both the increase in the CPI–U for the 12–month period and the new limits on the physician self-referral Web site: *http://cms.hhs.gov/medlearn/refphys.asp*.

(6) 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.

(7) The compensation arrangement does not violate the anti-kickback statute, (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.

(8) Other facilities and health care clinics (including, but not limited to, federally qualified health centers) that have *bona fide* medical staffs may provide compensation under this paragraph (m) on the same terms and conditions applied to hospitals under this paragraph (m).

(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 anti-kickback statute (section 1128B(b) of the Act), or any Federal or State 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 an entity to a physician (or to the physician's immediate family member or office staff) who practices in the entity'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); specific training regarding the requirements of Federal and State health care programs (for example, billing, coding, reasonable and necessary services, documentation, unlawful referral arrangements); or training regarding other Federal, State, or local laws, regulations, or rules governing the conduct of the party for whom the training is provided (but not including continuing medical education).

(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 and not determined in any manner that takes 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 (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.

(q) *Referral services.* Remuneration that meets all of the conditions set forth in § 1001.952(f) of this title.

(r) *Obstetrical malpractice insurance subsidies.* Remuneration to the referring physician that meets all of the conditions set forth in § 1001.952(o) of this title.

(s) *Professional courtesy.* Professional courtesy (as defined in § 411.351) offered by an entity to a physician or a physician's immediate family member or office staff if all of the following conditions are met:

(1) The professional courtesy is offered to all physicians on the entity's *bona fide* medical staff or in the entity's local community or service area without regard to the volume or value of referrals or other business generated between the parties;

(2) The health care items and services provided are of a type routinely provided by the entity;

(3) The entity's professional courtesy policy is set out in writing and approved in advance by the entity's governing body;

(4) The professional courtesy is not offered to a physician (or immediate family member) who is a Federal health care program beneficiary, unless there has been a good faith showing of financial need;

(5) If the professional courtesy involves any whole or partial reduction of any coinsurance obligation, the insurer is informed in writing of the reduction; and

(6) The arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.

(t) *Retention payments in underserved areas.* (1) Remuneration provided by a hospital or federally qualified health center directly to a physician on the hospital's or federally qualified health center's medical staff to retain the physician's medical practice in the geographic area served by the hospital or federally qualified health center (as defined in paragraph (e)(2) of this section), if all of the following conditions are met:

(i) Paragraphs 411.357(e)(1)(i) through 411.357(e)(1)(iv) are satisfied;

(ii) The geographic area served by the hospital or federally qualified health center is a HPSA (regardless of the physician's specialty) or is an area with demonstrated need for the physician as determined by the Secretary in an advisory opinion issued according to section 1877(g)(6) of the Act;

(iii) The physician has a *bona fide* firm, written recruitment offer from a hospital or federally qualified health center that is not related to the hospital or the federally qualified health center making the payment, and the offer specifies the remuneration being offered and would require the physician to move the location of his or her practice at least 25 miles *and* outside of the geographic area served by the hospital or federally qualified health center making the retention payment;

(iv) The retention payment is limited to the lower of—

(A) The amount obtained by subtracting (1) the physician's current income from physician and related services from (2) the income the physician would receive from comparable physician and related services in the *bona fide* recruitment offer, provided that the respective incomes are determined using a reasonable and consistent methodology, and that they are calculated uniformly over no more than a 24-month period; or

(B) The reasonable costs the hospital or federally qualified health center would otherwise have to expend to recruit a new physician to the geographic area served by the hospital or federally qualified health center in order to join the medical staff of the hospital or federally qualified health center to replace the retained physician;

(v) Any retention payment is subject to the same obligations and restrictions, if any, on repayment or forgiveness of indebtedness as the *bona fide* recruitment offer;

(vi) The hospital or federally qualified health center does not enter into a retention arrangement with a particular referring physician more frequently than once every 5 years and the amount and terms of the retention payment are not altered during the term of the arrangement in any manner that takes into account the volume or value of referrals or other business generated by the physician;

(vii) The arrangement otherwise complies with all of the conditions of this section; and

(viii) The arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.

(2) The Secretary may waive the relocation requirement of paragraph (t)(1) of this section for payments made to physicians practicing in a HPSA or an area with demonstrated need for the physician through an advisory opinion issued according to section 1877(g)(6) of the Act, if the retention payment arrangement otherwise complies with all of the conditions of this paragraph.

(u) *Community-wide health information systems.* Items or services of information technology provided by an entity to a physician that allow access to, and sharing of, electronic health care records and any complementary drug information systems, general health information, medical alerts, and related information for patients served by community providers and practitioners, in order to enhance the community's overall health, provided that—

(1) The items or services are available as necessary to enable the physician to participate in a community-wide health information system, are principally used by the physician as part of the community-wide health information system, and are not provided to the physician in any manner that takes into account the volume or value of referrals or other business generated by the physician;

(2) The community-wide health information systems are available to all providers, practitioners, and residents of the community who desire to participate; and

(3) The arrangement does not violate the anti-kickback statute, (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission. § 411.361 Reporting requirements.

(a) *Basic rule.* Except as provided in paragraph (b) of this section, all entities furnishing services for which payment may be made under Medicare must submit information to CMS or to the Office of Inspector General (OIG) concerning their reportable financial relationships (as defined in paragraph (d) of this section), in the form, manner, and at the times that CMS or OIG specifies.

(b) *Exception.* The requirements of paragraph (a) of this section do not apply to entities that furnish 20 or fewer Part A and Part B services during a calendar year, or to any Medicare covered services furnished outside the United States.

(c) *Required information.* The information requested by CMS or OIG can include the following:

(1) The name and unique physician identification number (UPIN) of each physician who has a reportable financial relationship with the entity.

(2) The name and UPIN of each physician who has an immediate family member (as defined in § 411.351) who has a reportable financial relationship with the entity.

(3) The covered services furnished by the entity.

(4) With respect to each physician identified under paragraphs (c)(1) and (c)(2) of this section, the nature of the financial relationship (including the extent and/or value of the ownership or investment interest or the compensation arrangement) as evidenced in records that the entity knows or should know about in the course of prudently conducting business, including, but not limited to, records that the entity is already required to retain to comply with the rules of the Internal Revenue Service and the Securities and Exchange Commission and other rules of the Medicare and Medicaid programs.

(d) *Reportable financial relationships.* For purposes of this section, a reportable financial relationship is any ownership or investment interest, as defined in § 411.354(b) or any compensation arrangement, as defined in § 411.354(c), except for ownership or investment interests that satisfy the exceptions set forth in § 411.356(a) or § 411.356(b) regarding publicly-traded securities and mutual funds.

(e) *Form and timing of reports.* Entities that are subject to the requirements of this section must submit the required information, upon request, within the time period specified by the request. Entities are given at least 30 days from the date of the request to provide the information. Entities must retain the information, and documentation sufficient to verify the information, for the length of time specified by the applicable regulatory requirements for the information, and, upon request, must make that

information and documentation available to CMS or OIG.

(f) *Consequences of failure to report.* Any person who is required, but fails, to submit information concerning his or her financial relationships in accordance with this section is subject to a civil money penalty of up to $10,000 for each day following the deadline established under paragraph (e) of this section until the information is submitted. Assessment of these penalties will comply with the applicable provisions of part 1003 of this title.

(g) *Public disclosure.* Information furnished to CMS or OIG under this section is subject to public disclosure in accordance with the provisions of part 401 of this chapter.

PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 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 republished to read as set forth below.

§ 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; and Program No. 93.774, Medicare-Supplementary Medical Insurance Program)

Dated: February 13, 2003.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

Dated: October 23, 2003.

Tommy G. Thompson,

Secretary.

Note: The following attachment will not appear in the Code of Federal Regulations.

Attachment—List of CPT [1]/HCPCS Codes for Purposes of Section 1877 of the Social Security Act—Effective July 26, 2004

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
86927 Plasma, fresh frozen
86930 Frozen blood prep
86931 Frozen blood thaw
86932 Frozen blood freeze/thaw
86945 Blood product/irradiation
86950 Leukacyte transfusion
86965 Pooling blood platelets
86985 Split blood or products

Include the following CPT and HCPCS level 2 codes for other clinical laboratory services:

0010T TB test, gamma interferon
0023T Phenotype drug test, hiv 1
0026T Measure remnant lipoproteins
0030T Antiprothrombin antibody
0041T Detect ur infect agnt w/cpas
0043T Co expired gas analysis
0058T Cryopreservation, ovary tiss
0059T Cryopreservation, oocyte
G0001 Drawing blood for specimen
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 Scr c/v cyto, thinlayer, rescr
G0144 Scr c/v cyto, thinlayer, rescr
G0145 Scr c/v cyto, thinlayer, rescr
G0147 Scr c/v cyto, automated sys
G0148 Scr c/v cyto, autosys, rescr
G0306 CBC/diffwbc w/o platelet
G0307 CBC without platelet
G0328 Fecal blood scrn immunoassay
P2028 Cephalin floculation test
P2029 Congo red blood test
P2033 Blood thymol turbidity
P2038 Blood mucoprotein
P3000 Screen pap by tech w md supv
P3001 Screening pap smear by phys
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

[1] CPT codes and descriptions only are copyright 2003 American Medical Association. All rights are reserved and applicable FARS/DFARS clauses apply.

Physical Therapy, Occupational Therapy, and 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
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 mngment training
97537 Community/work reintegration
97542 Wheelchair mngment training
97545 Work hardening
97546 Work hardening add-on
97601 Wound(s) care, selective
97602 Wound(s) care, nonselective
97703 Prosthetic checkout
97750 Physical performance test
97755 Assistive technology assess
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
92507 Speech/hearing therapy
92508 Speech/hearing therapy
92526 Oral function therapy
92597 Oral speech device eval
92607 Ex for speech device rx, 1hr
92608 Ex for speech device rx addl
92609 Use of speech device service
92610 Evaluate swallowing function
92611 Motion fluoroscopy/swallow
92612 Endoscopy swallow tst (fees)
92614 Laryngoscopic sensory test
92616 Fees w/laryngeal sense test
93797 Cardiac rehab
93798 Cardiac rehab/monitor
94667 Chest wall manipulation
94668 Chest wall manipulation
95831 Limb muscle testing, manual
95832 Hand muscle testing, manual
95833 Body muscle testing, manual
95834 Body muscle testing, manual

95851 Range of motion measurements
95852 Range of motion measurements
96000 Motion analysis, video/3d
96001 Motion test w/ft press meas
96002 Dynamic surface emg
96003 Dynamic fine wire emg
96105 Assessment of aphasia
96110 Developmental test, lim
96111 Developmental test, extend
96115 Neurobehavior status exam
0029T Magnetic tx for incontinence

Include HCPCS level 2 codes for the following physical therapy/occupational therapy/speech-language pathology services:

G0279 Excorp shock tx, elbow epi
G0280 Excorp shock tx other than
G0281 Elec stim unattend for press
G0283 Elec stim other than wound

Radiology and Certain Other Imaging Services

Include the following codes in the CPT 70000 series:

70100 X-ray exam of jaw
70110 X-ray exam of jaw
70120 X-ray exam of mastoids
70130 X-ray exam of mastoids
70134 X-ray exam of middle ear
70140 X-ray exam of facial bones
70150 X-ray exam of facial bones
70160 X-ray exam of nasal bones
70190 X-ray exam of eye sockets
70200 X-ray exam of eye sockets
70210 X-ray exam of sinuses
70220 X-ray exam of sinuses
70240 X-ray exam, pituitary saddle
70250 X-ray exam of skull
70260 X-ray exam of skull
70300 X-ray exam of teeth
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
70486 Ct maxillofacial w/o dye
70487 Ct maxillofacial w/dye
70488 Ct maxillofacial w/o & w/dye
70490 Ct soft tissue neck w/o dye
70491 Ct soft tissue neck w/dye
70492 Ct sft tsue nck w/o & w/dye
70496 Ct angiography, head
70498 Ct angiography, neck
70540 Mri orbit/face/neck w/o dye
70542 Mri orbit/face/neck w/dye
70543 Mri orbt/fac/nck w/o & w/dye
70544 Mr angiography head w/o dye
70545 Mr angiography head w/dye
70546 Mr angiograph head w/o & w/dye
70547 Mr angiography neck w/o dye
70548 Mr angiography neck w/dye
70549 Mr angiograph neck w/o & w/dye
70551 Mri brain w/o dye
70552 Mri brain w/dye
70553 Mri brain w/o & w/dye
71010 Chest x-ray
71015 Chest x-ray
71020 Chest x-ray
71021 Chest x-ray
71022 Chest x-ray
71023 Chest x-ray and fluoroscopy
71030 Chest x-ray
71034 Chest x-ray and fluoroscopy
71035 Chest x-ray
71100 X-ray exam of ribs
71101 X-ray exam of ribs/chest
71110 X-ray exam of ribs
71111 X-ray exam of ribs/chest
71120 X-ray exam of breastbone
71130 X-ray exam of breastbone
71250 Ct thorax w/o dye
71260 Ct thorax w/dye
71270 Ct thorax w/o & w/dye
71275 Ct angiography, chest
71550 Mri chest w/o dye
71551 Mri chest w/dye
71552 Mri chest w/o & w/dye
71555 Mri angio chest w or w/o dye
72010 X-ray exam of spine
72020 X-ray exam of spine
72040 X-ray exam of neck spine
72050 X-ray exam of neck spine
72052 X-ray exam of neck spine
72069 X-ray exam of trunk spine
72070 X-ray exam of thoracic spine
72072 X-ray exam of thoracic spine
72074 X-ray exam of thoracic spine
72080 X-ray exam of trunk spine
72090 X-ray exam of trunk spine
72100 X-ray exam of lower spine
72110 X-ray exam of lower spine
72114 X-ray exam of lower spine
72120 X-ray exam of lower spine
72125 Ct neck spine w/o dye
72126 Ct neck spine w/dye
72127 Ct neck spine w/o & w/dye
72128 Ct chest spine w/o dye
72129 Ct chest spine w/dye
72130 Ct chest spine w/o & w/dye
72131 Ct lumbar spine w/o dye
72132 Ct lumbar spine w/dye
72133 Ct lumbar spine w/o & w/dye
72141 Mri neck spine w/o dye
72142 Mri neck spine w/dye
72146 Mri chest spine w/o dye
72147 Mri chest spine w/dye
72148 Mri lumbar spine w/o dye
72149 Mri lumbar spine w/dye
72156 Mri neck spine w/o & w/dye
72157 Mri chest spine w/o & w/dye
72158 Mri lumbar spine w/o & w/dye
72170 X-ray exam of pelvis
72190 X-ray exam of pelvis
72191 Ct angiograph pelv w/o & w/dye
72192 Ct pelvis w/o dye
72193 Ct pelvis w/dye
72194 Ct pelvis w/o & w/dye
72195 Mri pelvis w/o dye
72196 Mri pelvis w/dye
72197 Mri pelvis w/o & w/dye
72198 Mr angio pelvis w/o & w/dye
72200 X-ray exam sacroiliac joints
72202 X-ray exam sacroiliac joints
72220 X-ray exam of tailbone
73000 X-ray exam of collar bone
73010 X-ray exam of shoulder blade
73020 X-ray exam of shoulder
73030 X-ray exam of shoulder
73050 X-ray exam of shoulders
73060 X-ray exam of humerus
73070 X-ray exam of elbow
73080 X-ray exam of elbow
73090 X-ray exam of forearm
73092 X-ray exam of arm, infant
73100 X-ray exam of wrist
73110 X-ray exam of wrist
73120 X-ray exam of hand
73130 X-ray exam of hand
73140 X-ray exam of finger(s)
73200 Ct upper extremity w/o dye
73201 Ct upper extremity w/dye
73202 Ct uppr extremity w/o & w/dye
73206 Ct angio upr extrm w/o & w/dye
73218 MRI upper extremity w/o dye
73219 MRI upper extremity w/dye
73220 MRI uppr extremity w/o & w/dye
73221 MRI joint upr extrem w/o dye
73222 MRI joint upr extrem w/dye
73223 MRI joint upr extr w/o & w/dye
73500 X-ray exam of hip
73510 X-ray exam of hip
73520 X-ray exam of hips
73540 X-ray exam of pelvis & hips
73550 X-ray exam of thigh
73560 X-ray exam of knee, 1 or 2
73562 X-ray exam of knee, 3
73564 X-ray exam, knee, 4 or more
73565 X-ray exam of knees
73590 X-ray exam of lower leg
73592 X-ray exam of leg, infant
73600 X-ray exam of ankle
73610 X-ray exam of ankle
73620 X-ray exam of foot
73630 X-ray exam of foot
73650 X-ray exam of heel
73660 X-ray exam of toe(s)
73700 Ct lower extremity w/o dye
73701 Ct lower extremity w/dye
73702 Ct lwr extremity w/o & w/dye
73706 Ct angio lwr extr w/o & w/dye
73718 MRI lower extremity w/o dye
73719 MRI lower extremity w/dye
73720 MRI lwr extremity w/o & w/dye
73721 MRI jnt of lwr extre w/o dye
73722 MRI joint of lwr extr w/dye
73723 MRI joint lwr extr w/o & w/dye
73725 Mr ang lwr ext w or w/o dye
74000 X-ray exam of abdomen
74010 X-ray exam of abdomen
74020 X-ray exam of abdomen
74022 X-ray exam series, abdomen
74150 Ct abdomen w/o dye
74160 Ct abdomen w/dye
74170 Ct abdomen w/o & w/dye
74175 Ct angio abdom w/o & w/dye
74181 MRI abdomen w/o dye
74182 MRI abdomen w/dye
74183 MRI abdomen w/o & w/dye
74185 MRI angio, abdom w or w/o dye
74210 Contrst x-ray exam of throat
74220 Contrast x-ray, esophagus
74230 Cine/vid x-ray, throat/esoph
74240 X-ray exam, upper gi tract
74241 X-ray exam, upper gi tract
74245 X-ray exam, upper gi tract
74246 Contrst x-ray uppr gi tract
74247 Contrst x-ray uppr gi tract
74249 Contrst x-ray uppr gi tract
74250 X-ray exam of small bowel
74290 Contrast x-ray, gallbladder
74291 Contrast x-rays, gallbladder
74710 X-ray measurement of pelvis
75552 Heart mri for morph w/o dye
75553 Heart mri for morph w/dye
75554 Cardiac MRI/function
75555 Cardiac MRI/limited study
75635 Ct angio abdominal arteries

76000 Fluoroscope examination
76006 X-ray stress view
76010 X-ray, nose to rectum
76020 X-rays for bone age
76040 X-rays, bone evaluation
76061 X-rays, bone survey
76062 X-rays, bone survey
76065 X-rays, bone evaluation
76066 Joint survey, single view
76070 Ct bone density, axial
76071 Ct bone density, peripheral
76075 Dexa, axial skeleton study
76076 Dexa, peripheral study
76078 Radiographic absorptiometry
76082 Computer mammogram add-on
76083 Computer mammogram add-on
76090 Mammogram, one breast
76091 Mammogram, both breasts
76092 Mammogram, screening
76093 Magnetic image, breast
76094 Magnetic image, both breasts
76100 X-ray exam of body section
76101 Complex body section x-ray
76102 Complex body section x-rays
76120 Cine/video x-rays
76125 Cine/video x-rays add-on
76150 X-ray exam, dry process
76370 Ct scan for therapy guide
76375 3d/holograph reconstr add-on
76380 CAT scan follow-up study
76400 Magnetic image, bone marrow
76499 Radiographic procedure
76506 Echo exam of head
76511 Echo exam of eye
76512 Echo exam of eye
76513 Echo exam of eye, water bath
76514 Echo exam of eye, thickness
76516 Echo exam of eye
76519 Echo exam of eye
76536 Us Exam of head and neck
76604 Us exam, chest, b-scan
76645 Us exam, breast(s)
76700 Us exam, abdom, complete
76705 Echo exam of abdomen
76770 Us exam abdo back wall, comp
76775 Us exam abdo back wall, lim
76778 Us exam kidney transplant
76800 Us exam, spinal canal
76801 Ob us < 14 wks, single fetus
76802 Ob us < 14 wks, add'l fetus
76805 Ob us >/= 14 wks, sngl fetus
76810 Ob us >/= 14 wks, addl fetus
76811 Ob us, detailed, sngl fetus
76812 Ob us, detailed, addl fetus
76815 Ob us, limited, fetus(s)
76816 Ob us, follow-up, per fetus
76818 Fetal biophys profile w/nst
76819 Fetal biophys profil w/o nst
76825 Echo exam of fetal heart
76826 Echo exam of fetal heart
76827 Echo exam of fetal heart
76828 Echo exam of fetal heart
76856 Us exam, pelvic, complete
76857 Us exam, pelvic, limited
76870 Us exam, scrotum
76880 Us exam, extremity
76885 Us exam infant hips, dynamic
76886 Us exam infant hips, static
76970 Ultrasound exam follow-up
76977 Us bone density measure
76999 Echo examination procedure

Include the following CPT codes for echocardiography and vascular ultrasound:

93303 Echo transthoracic
93304 Echo transthoracic
93307 Echo exam of heart
93308 Echo exam of heart
93320 Doppler echo exam, heart [if used in conjunction with 93303–93308]
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 Extracranial study
93880 Extracranial study
93882 Extracranial study
93886 Intracranial study
93888 Intracranial study
93922 Extremity study
93923 Extremity study
93924 Extremity study
93925 Lower extremity study
93926 Lower extremity study
93930 Upper extremity study
93931 Upper extremity study
93965 Extremity study
93970 Extremity study
93971 Extremity study
93975 Vascular study
93976 Vascular study
93978 Vascular study
93979 Vascular study
93980 Penile vascular study
93981 Penile vascular study
93990 Doppler flow testing

Include the following CPT and HCPCS level 2 codes:

51798 Us urine capacity measure
78350 Bone mineral, single photon
91110 Gi tract capsule endoscopy
0028T Dexa body composition study
0042T Ct perfusion w/contrast, cbf
G0130 Single energy x-ray study
G0202 Screening mammography digital
G0204 Diagnostic mammography digital
G0206 Diagnostic mammography digital
G0288 Recon, CTA for surg plan
R0070 Transport portable x-ray
R0075 Transport port x-ray multipl

Radiation Therapy Services and Supplies

Include the following codes in the CPT 70000 series:

77261 Radiation therapy planning
77262 Radiation therapy planning
77263 Radiation therapy planning
77280 Set radiation therapy field
77285 Set radiation therapy field
77290 Set radiation therapy field
77295 Set radiation therapy field
77299 Radiation therapy planning
77300 Radiation therapy dose plan
77301 Radiotherapy dose plan, imrt
77305 Teletx isodose plan simple
77310 Teletx isodose plan intermed
77315 Teletx isodose plan complex
77321 Special teletx port plan
77326 Brachytx isodose calc simp
77327 Brachytx isodose calc interm
77328 Brachytx isodose plan compl
77331 Special radiation dosimetry
77332 Radiation treatment aid(s)
77333 Radiation treatment aid(s)
77334 Radiation treatment aid(s)
77336 Radiation physics consult
77370 Radiation physics consult
77399 External radiation dosimetry
77401 Radiation treatment delivery
77402 Radiation treatment delivery
77403 Radiation treatment delivery
77404 Radiation treatment delivery
77406 Radiation treatment delivery
77407 Radiation treatment delivery
77408 Radiation treatment delivery
77409 Radiation treatment delivery
77411 Radiation treatment delivery
77412 Radiation treatment delivery
77413 Radiation treatment delivery
77414 Radiation treatment delivery
77416 Radiation treatment delivery
77417 Radiology port film(s)
77418 Radiation tx delivery, imrt
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 Hyperthermia treatment
77605 Hyperthermia treatment
77610 Hyperthermia treatment
77615 Hyperthermia treatment
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 interstit radiat compl
77781 High intensity brachytherapy
77782 High intensity brachytherapy
77783 High intensity brachytherapy
77784 High intensity brachytherapy
77789 Apply surface radiation
77790 Radiation handling
77799 Radium/radioisotope therapy

Include the following CPT and HCPCS level 2 codes classified elsewhere:

31643 Diag bronchoscope/catheter
50559 Renal endoscopy/radiotracer
55859 Percut/needle insert, pros
61770 Incise skull for treatment
61793 Focus radiation beam
92974 Cath place, cardio brachytx
G0173 Stereo radiosurgery, complete
G0242 Multisource photon ster plan
G0243 Multisour photon stero treat
G0251 Linear acc based stero radio
G0338 Linear accelerator stero pln
G0339 Robot lin-radsurg com, first
G0340 Robt lin-radsurg fractx 2–5

EPO and Other Dialysis-Related Drugs

The physician self-referral prohibition does not apply to the following codes for EPO and other dialysis-related drugs furnished in or by an ESRD facility if the conditions in § 411.355(g) are satisfied:

J0630 Calcitonin salmon injection
J0636 Inj calcitriol per 0.1 mcg
J0895 Deferoxamine mesylate inj
J1270 Injection, doxercalciferol
J1750 Iron dextran
J1756 Iron sucrose injection
J1955 Inj levocarnitine per 1 gm
J2501 Paricalcitol
J2916 Na ferric gluconate complex
J2993 Reteplase injection
J2995 Inj streptokinase /250000 IU
J2997 Alteplase recombinant
J3364 Urokinase 5000 IU injection
P9041 Albumin (human), 5%, 50ml
P9045 Albumin (human), 5%, 250ml
P9046 Albumin (human), 25%, 20ml

P9047 Albumin (human), 25%, 50ml
Q4054 Darbepoetin alfa, esrd use
Q4055 Epoetin alfa, esrd use

Preventive Screening Tests, Immunizations and Vaccines

The physician self-referral prohibition does not apply to the following tests if they are performed for screening purposes and satisfy the conditions in § 411.355(h):

76083 Computer mammogram add-on
76092 Mammogram, screening
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 Scr c/v cyto, thinlayer, rescr
G0144 Scr c/v cyto, thinlayer, rescr
G0145 Scr c/v cyto, thinlayer, rescr
G0147 Scr c/v cyto, automated sys
G0148 Scr c/v cyto, autosys, rescr
G0202 Screening mammographydigital
G0328 Fecal blood scrn immunoassay
P3000 Screen pap by tech w md supv
P3001 Screening pap smear by phys

The physician self-referral prohibition does not apply to the following immunization and vaccine codes if they satisfy the conditions in § 411.355(h):

90655 Flu vaccine, 6–35 mo, im
90657 Flu vaccine, 6–35 mo, im
90658 Flu vaccine, 3 yrs, im
90732 Pneumococcal vaccine
90740 Hepb vacc, ill pat dose im
90743 Hep b vacc, adol, 2 dose im
90744 Hepb vacc ped/adol 3 dose im
90746 Hepb vaccine, adult, im
90747 Hepb vacc, ill pat 4 dose im

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