



Federal Register

Wednesday,
September 5, 2007

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 411 and 424

**Medicare Program; Physicians' Referrals
to Health Care Entities With Which They
Have Financial Relationships (Phase III);
Final Rule**

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Medicare & Medicaid Services****42 CFR Parts 411 and 424****[CMS-1810-F]****RIN 0938-AK67****Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase III)****AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.**ACTION:** Final rule.

SUMMARY: This final rule is the third phase (Phase III) of a final rulemaking amending our regulations regarding the physician self-referral prohibition in section 1877 of the Social Security Act (the Act). Specifically, this rule finalizes, and responds to public comments regarding, the Phase II interim final rule with comment period published on March 26, 2004, which set forth the self-referral prohibition and applicable definitions, interpreted various statutory exceptions to the prohibition, and created additional regulatory exceptions for arrangements that do not pose a risk of program or patient abuse (69 FR 16054).

In general, in response to public comments, in this Phase III final rule, we have reduced the regulatory burden on the health care industry through the interpretation of statutory exceptions and modification of the exceptions that were created using the Secretary's discretionary authority under section 1877(b)(4) of the Act to promulgate exceptions for financial relationships that pose no risk of program or patient abuse.

DATES: *Effective date:* This final rule is effective on December 4, 2007.

FOR FURTHER INFORMATION CONTACT: Joanne Sinsheimer, (410) 786-4620. Lisa Ohrin, (410) 786-4565.

SUPPLEMENTARY INFORMATION: To help readers locate information in this final rule, we are providing the following Table of Contents.

- I. Background
- II. General Comments
 - A. General
 - B. Compliance With the Anti-Kickback Statute
- III. Definitions—§ 411.351
 - A. Employee
 - B. Entity
 - C. Fair Market Value
 - D. "Incident to" Services
 - E. Physician in the Group Practice

- F. Radiology and Certain Other Imaging Services and Radiation Therapy
- G. Referral
- H. Rural Area
- IV. Group Practice—§ 411.352
- V. Prohibition on Certain Referrals by Physicians and Limitations on Billing—§ 411.353
- VI. Financial Relationship, Compensation, and Ownership or Investment Interest—§ 411.354
 - A. Ownership
 - B. Compensation
 - C. Special Rules on Compensation
- VII. General Exceptions to the Referral Prohibition Related to Both Ownership/Investment and Compensation—§ 411.355
 - A. Physician Services
 - B. In-office Ancillary Services
 - C. Services Furnished by an Organization (or Its Contractors or Subcontractors) to Enrollees
 - D. Reserved
 - E. Academic Medical Centers
 - F. Implants Furnished by an Ambulatory Surgical Center
 - G. EPO and Other Dialysis-Related Drugs Furnished in or by an End-Stage Renal Dialysis Facility
 - H. Preventive Screening Tests, Immunizations, and Vaccines
 - I. Eyeglasses and Contact Lenses Following Cataract Surgery
 - J. Intra-family Rural Referrals
- VIII. Exceptions to the Referral Prohibition Related to Ownership or Investment Interests—§ 411.356
 - A. Publicly-traded Securities and Mutual Funds
 - B. Hospitals Located in Puerto Rico
 - C. Rural Providers
 - D. Ownership Interest in a Whole Hospital
- IX. Exceptions to the Referral Prohibition Related to Compensation Arrangements—§ 411.357
 - A. Rental of Office Space
 - B. Rental of Equipment
 - C. *Bona Fide* Employment Relationships
 - D. Personal Service Arrangements
 - E. Physician Recruitment
 - F. Isolated Transactions
 - G. Remuneration Unrelated to Designated Health Services
 - H. Group Practice Arrangements with a Hospital
 - I. Payments by a Physician
 - J. Charitable Donations by a Physician
 - K. Nonmonetary Compensation
 - L. Fair Market Value Compensation
 - M. Medical Staff Incidental Benefits
 - N. Risk-sharing Arrangements
 - O. Compliance Training
 - P. Indirect Compensation Arrangements
 - Q. Referral Services
 - R. Obstetrical Malpractice Insurance Subsidies
 - S. Professional Courtesy
 - T. Retention Payments in Underserved Areas
 - U. Community-Wide Health Information Systems
- X. Reporting Requirements—§ 411.361
- XI. Miscellaneous (Other)
- XII. Provisions of the Final Rule
- XIII. Technical Corrections

- XIV. Collection of Information Requirements
- XV. Regulatory Impact Analysis
 - A. Overall Impact
 - B. Anticipated Effects
 - C. Alternatives Considered Regulation Text

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 (or billing another individual, entity, or third party payer) for those referred services. 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 program or patient abuse. The current version of section 1877 of the Act, which applies to referrals for 11 DHS, has been in effect and subject to enforcement since January 1, 1995.

This is Phase III of a final rulemaking under section 1877 of the Act. Proposed regulations were published in the **Federal Register** on January 9, 1998 (63 FR 1659). 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, and Phase II of the final rulemaking was published in the **Federal Register** on March 26, 2004 (69 FR 16054) ("Phase II") as an interim final rule with comment period. Due to a printing error, a portion of the Phase II preamble was omitted from the March 26, 2004 **Federal Register** publication. That portion of the preamble, which addressed reporting requirements and sanctions, was published on April 6, 2004 (69 FR 17933).

Except for two provisions, the regulations published in Phase I became effective on January 4, 2002. We delayed the effective date of § 424.22(d), relating to home health services until April 6, 2001 (66 FR 8771.) We also delayed the effective date of the final sentence of § 411.354(d)(1) relating to the definition of "set in advance" until the publication of Phase II; ultimately, it never became effective. The regulations in Phase II became effective on July 26, 2004.

Phase I Covered—

- Sections 1877(a) and 1877(b) of the Act (the general prohibition against physician self-referral 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 using the Secretary's authority under section 1877(b)(4) of the Act.

Phase II Covered—

- All provisions of section 1877 of the Act;
- Additional regulatory definitions;
- Additional new regulatory exceptions issued pursuant to the Secretary's authority under section 1877(b)(4) of the Act; and
- Responses to the public comments on the January 1998 proposed rule and the Phase I regulations.

This Phase III final rule responds to comments on Phase II and, thus, addresses the entire regulatory scheme. In developing Phase III of this rulemaking, we have carefully considered the history and structure of section 1877 of the Act, as well as the comments to the Phase II interim final rule. As with Phase I and Phase II, we believe that Phase III of this rulemaking addresses many of the industry's primary concerns, is consistent with the statute's goals and directives, and protects beneficiaries of Federal health care programs. 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. We have endeavored to simplify the rules and provide additional guidance in response to comments, as well as to reduce any undue burden on the regulated community by modifying exceptions created using the Secretary's authority under section 1877(b)(4) of the Act to promulgate additional exceptions regarding financial relationships that pose no risk of program or patient abuse. As we did in Phase II, in evaluating our regulatory options, we have applied the same criteria that we discussed in detail in the Phase I rule (66 FR 859–863, 69 FR 16056.)

The reasons for dividing the rulemaking into Phases I and II are explained in Phase I (66 FR 859–860). The reason for this Phase III final rule is explained in Phase II (69 FR 16055–16056) and in this preamble. Phases I, II, and III of this rulemaking are intended to be read together as a unified whole. Phase I contains a legislative and regulatory history of the physician self-referral law, which is not repeated here (66 FR 857–859). Unless otherwise expressly noted, to the extent the preamble in Phase III uses different

language to describe a concept addressed in Phase I or Phase II, our intent is to elucidate that discussion, not to change its scope or meaning. For clarity and ease of access for the general public to the entire set of physician self-referral regulations, we are republishing in its entirety in this Phase III final rule the regulatory text for §§ 411.350 through 411.361 (omitting §§ 411.370 through 411.389 relating to advisory opinions, which were the subject of a separate rulemaking and remain unchanged, except for a technical correction to § 411.370 discussed below in section XIII). Please note that, for ease of reference, the regulatory text for § 411.357 includes paragraphs (v) and (w) relating to the exceptions for arrangements involving donations of electronic prescribing and electronic health records technology, respectively. Those two exceptions were proposed and finalized in a separate rulemaking (70 FR 59182, 71 FR 45140.)

This Phase III preamble is generally organized to track the statute and current regulations. We first address the definitions (although certain key definitions, such as “isolated transaction,” are addressed in the discussions of the exceptions to which they mainly relate), then the general prohibition, then the exceptions. Summary discussions 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. General Comments

A. General

Comment: We received numerous comments regarding both ownership and compensation arrangements in which the commenter requested confirmation that the particular arrangement described in the comment met the requirements of an exception and, thus, did not violate section 1877 of the Act.

Response: In this final rule, we provide guidance with respect to the provisions of Phase I and Phase II. When possible, we respond to commenters' specific inquiries regarding compliance with the physician self-referral law. However, several of the inquiries failed to provide sufficient facts to enable us to evaluate or respond to the inquiry. Moreover, we consider several other inquiries to be in the nature of a request for a binding opinion, which, as provided in § 411.386, can be made only through the issuance of a formal advisory opinion.

B. Compliance With the Anti-Kickback Statute

Comment: Numerous commenters objected to the inclusion of the requirement that arrangements must not violate the Federal anti-kickback statute (section 1128B(b) of the Act; 42 U.S.C. 1320a–7b(b), hereinafter referred to as the anti-kickback statute), which appears in the regulatory exceptions created pursuant to the Secretary's authority under section 1877(b)(4) of the Act. According to the commenters, the condition is unnecessary and undercuts our efforts to create “bright lines.”

Response: We disagree with the commenters for the reasons set forth in Phase I (66 FR 863) and Phase II (69 FR 16108). Wherever possible, we have attempted to create bright-line rules. However, given the limitations on our regulatory authority under section 1877(b)(4) of the Act, inclusion of the anti-kickback statute condition is necessary to ensure that the exceptions promulgated under that authority do not pose a risk of program or patient abuse. Moreover, because parties' arrangements must not violate the anti-kickback statute irrespective of whether they satisfy the other requirements of an exception, any additional burden associated with the requirement is minimal.

Comment: Two commenters suggested that the exceptions under the physician self-referral law and safe harbors under the anti-kickback statute should more closely parallel each other. The first commenter stated that, without parallel safe harbors under the anti-kickback statute and exceptions to the physician self-referral law, the physician self-referral law exceptions will be underutilized and ineffective. The second commenter suggested that an arrangement that meets an exception under the physician self-referral law should be deemed to be within a safe harbor under the anti-kickback statute.

Response: We addressed the issue raised by the first commenter in Phase II (69 FR 16115). As explained in detail there, we do not believe it is feasible to except financial relationships solely because they fit in an anti-kickback statute safe harbor. The second commenter's suggestion is outside the scope of this rulemaking and our authority. We note that several of the regulatory exceptions under the physician self-referral law do, in fact, correspond to safe harbors issued by the Office of Inspector General (OIG). For example, the exceptions for the donation of electronic prescribing items and services (§ 411.357(v)) and electronic health records software and

information technology and training services (§ 411.357(w)) correspond to safe harbors issued by the OIG. In addition, the exceptions for referral services and obstetrical malpractice insurance subsidies in § 411.357(q) and (r), respectively, mirror anti-kickback statute safe harbors.

Comment: One commenter asserted that the exceptions in § 411.357(q) and (r) that cross-reference safe harbors relating to referral services and obstetrical malpractice insurance subsidies, respectively, are too narrow. The commenter stated that any arrangement that has received a favorable advisory opinion from the OIG, even if the agreement in question does not fall within a safe harbor, should be permitted under the self-referral law.

Response: Under section 1877(b)(4) of the Act, we may issue additional exceptions (that is, exceptions not specified in the statute) only where doing so would create no risk of program or patient abuse. As noted above, it is not feasible to except financial relationships under section 1877 of the Act solely because they fit in an anti-kickback statute safe harbor, nor would it be feasible or appropriate to do so because an arrangement is the subject of a favorable OIG advisory opinion on a different statute. As we explained in Phase II, in some instances, it is appropriate for us to refer to the criteria in an anti-kickback safe harbor when creating an exception under the physician self-referral law (69 FR 16115).

III. Definitions—§ 411.351

We received public comments only on the specific definitions set out below. In addition to technical changes to several definitions, we are adding definitions for “downstream contractor,” “physician organization,” and “rural area” and modifying the definitions of “fair market value,” and “incident to services.” The new definitions of “downstream contractor” and “physician organization” are discussed in sections IX.D and VI.B, respectively, below, together with the relevant provisions to which they apply.

A. Employee

We are making no changes to the definition of “employee” in this Phase III final rule.

Comment: One commenter asked us to clarify that, in order to qualify as an employee of a group practice, a group practice must exercise control over the employee; that is, the group practice must supply the equipment, personnel, and support necessary for the individual

to provide the service, and the group practice must control how the work is done and have hiring and firing authority over the individual providing services. The commenter asked for clarification on this issue out of concern regarding arrangements in which a group practice “hires” an individual as a part-time employee of the group practice but, in reality, exercises no control over the individual.

Response: As set forth in section 1877(h)(2) of the Act and the definition of “employee” at § 411.351, an individual is considered an “employee” for purposes of the physician self-referral prohibition if the individual is considered an employee under the common law rules applicable to determining the employer-employee relationship, as applied for purposes of section 3121(d)(2) of the Internal Revenue Code of 1986. We agree with the commenter that the actual conduct of the relationship is determinative. To determine whether an employer-employee relationship exists, the various factors, including those regarding supervision, used by the Internal Revenue Service (IRS) to determine employee status apply. Whereas the receipt of a W-2 from an entity and the written terms of the arrangement are relevant, neither controls whether an individual meets the definition of “employee” for purposes of the physician self-referral law; rather, the focus is on the actual relationship between the parties.

B. Entity

We are making no substantive changes to the definition of “entity” in this Phase III final rule.

Comment: One commenter objected to certain language in the definition of “entity” specifying that, in general, a person or entity is considered to be “furnishing DHS” if CMS makes payment to that person or entity, either directly, upon assignment on the patient’s behalf, or upon reassignment in certain cases. According to the commenter, some arrangements are structured so that referring physicians own entities that lease space, equipment, staff, or management services to entities that furnish DHS, and, in turn, submit claims to Medicare. The commenter suggested that “entity furnishing DHS” should be expanded to include entities that derive a substantial amount of their revenues from the provision of services to entities furnishing DHS.

Response: We note that, after the close of the Phase II comment period, the Medicare Payment Advisory Commission (MedPAC), in its March

2005 Report to Congress, recommended that the Secretary “should expand the definition of physician ownership in the physician self-referral law to include interests in an entity that derives a substantial proportion of its revenue from a provider of designated health services.” Specifically, MedPAC wrote:

Physician ownership of entities that provide services and equipment to imaging centers and other providers creates financial incentives for physicians to refer patients to these providers, which could lead to higher use of services. Prohibiting these arrangements should help ensure that referrals are based on clinical, rather than financial, considerations. It would also help ensure that competition among health care facilities is based on quality and cost, rather than financial arrangements with entities owned by physicians who refer patients to the facility.

(See http://www.medpac.gov/publications/congressional_reports/Mar05_EntireReport.pdf, at page 170.) We agree with the commenter that arrangements structured so that referring physicians own leasing, staffing, and similar entities that furnish items and services to entities furnishing DHS (also referred to herein as “DHS entities”), but do not submit claims raise significant concerns under the fraud and abuse laws and would appear contrary to the plain intent of the physician self-referral law. These structures are particularly problematic because referrals by physician-owners of leasing, staffing, and similar entities to a contracting DHS entity can significantly increase the physician-owned entity’s profits and investor returns, creating incentives for overutilization and corrupting medical decision-making. We intend to study further the types of arrangements described by the commenter and MedPAC, as well as other types of arrangements, to determine the best approach for addressing them in order to protect against program and patient abuse. We would make any change to address this issue, whether through the definition of “entity” or otherwise, in a separate rulemaking that is subject to public comment.

We note that the arrangements described by MedPAC remain subject to the physician self-referral prohibition. In most instances, these structures will constitute indirect compensation arrangements with DHS entities under § 411.354(b) that must satisfy the requirements of the indirect compensation arrangements exception in § 411.357(p). We intend to monitor these arrangements closely for compliance with the physician self-referral law. These arrangements appear

highly suspect under the anti-kickback statute; participants in such arrangements should closely scrutinize the arrangements for compliance with that statute also. Importantly, we note that the indirect compensation arrangements exception in § 411.357(p) includes a requirement that the arrangement not violate the anti-kickback statute.

C. Fair Market Value

In Phase II, we created a “safe harbor” provision in the definition of “fair market value” at § 411.351 for hourly payments to physicians for their personal services. The safe harbor consisted of two methodologies for calculating hourly rates that would be deemed “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 50th percentile national compensation level for physicians in the same specialty, using at least four of six specified salary surveys, and dividing the result by 2,000 hours to establish an hourly rate. If the relevant physician specialty does not appear in one of the recognized surveys, the parties must use the survey’s reported compensation for general practice in order to be within the safe harbor. We emphasized that use of the safe harbor was entirely voluntary and that parties may establish fair market value through other methods. We received a large number of comments questioning the new safe harbor.

Comment: Several commenters disliked the compensation survey methodology. In general, the commenters believed that the methodology was too prescriptive, and they urged more flexibility. Commenters noted that at least one of the listed surveys no longer exists, and that another is out of date. Another commenter stated that many of the survey companies will not sell their surveys to hospitals that do not participate in the surveys. According to the commenters, the available surveys are expensive. Another commenter asserted that other surveys, including the American Medical Group Association survey and *Modern Healthcare’s* annual compilation of surveys, provide similar information at less expense. Several commenters objected to the use of national averages, because the national average masks

significant regional differences in physician compensation.

Some commenters suggested that the compensation survey methodology be modified in other respects. One commenter urged us to expand the fair market value safe harbor to compensation that falls within the 25th to the 75th percentile of physician compensation. Commenters suggested that providers be able to use fewer than four surveys (for example, averaging the 50th percentile of any two surveys). Several commenters suggested that, where specialty-specific data is unavailable, providers should be able to use data from a similar specialty, rather than from general practitioners. According to the commenters, the compensation of physicians in one type of specialty is more similar to the compensation of physicians in other specialties than to the compensation of general practitioners. One commenter asked whether a contract could include a cost of living annual adjustment.

Response: We share the commenters’ concerns regarding the availability of the surveys identified in the safe harbor. We are aware that several of the surveys are no longer available (or may not be readily available to all DHS entities and physicians), making it impractical to utilize the safe harbor. In addition, it may be infeasible to obtain information regarding hourly rates for emergency room physicians at competitor hospitals. Therefore, we are not retaining the safe harbor within the definition of “fair market value” at § 411.351. We emphasize, however, that we will continue to scrutinize the fair market value of arrangements as fair market value is an essential element of many exceptions.

Reference to multiple, objective, independently published salary surveys remains a prudent practice for evaluating fair market value. Ultimately, the appropriate method for determining fair market value for purposes of the physician self-referral law will depend on the nature of the transaction, its location, and other factors. As we explained in Phase II, although a good faith reliance on an independent valuation (such as an appraisal) may be relevant to a party’s intent, it does not establish the ultimate issue of the accuracy of the valuation figure itself (69 FR 16107). Our views regarding fair market value are discussed further in Phase I (66 FR 944) and Phase II (69 FR 16107).

Because we are eliminating the safe harbor, it is unnecessary to address the commenters’ specific suggestions for identifying permissible surveys and expanding the range of acceptable

physician compensation. With respect to the inquiry regarding cost of living adjustments, we note that contracts for physician services may include an annual salary adjustment, provided that the resulting compensation is fair market value and otherwise complies with an exception.

Comment: A large number of nephrologists and groups representing nephrologists complained that the application of the safe harbor to their compensation for medical director duties at renal dialysis centers is inappropriate, especially given that the physician self-referral prohibition does not apply to dialysis services for which payment is made under the ESRD composite rate. According to the commenters, the hourly rate under the safe harbor would not adequately compensate dialysis facility medical directors for the full array of their skills and services. Several commenters expressed concern that, notwithstanding the voluntary nature of the safe harbor, the methodology would become the preferred valuation methodology to the detriment of physicians.

Response: For the reasons noted in the preceding response, we have eliminated the fair market value safe harbor in this Phase III final rule. With respect to existing arrangements, nothing in the physician self-referral regulations required use or application of the fair market value safe harbor; it was a wholly voluntary provision. Moreover, a physician’s compensation arrangement with a dialysis facility implicates section 1877 of the Act only to the extent that the arrangement creates a direct or indirect financial arrangement with an entity that furnishes DHS, such as a dialysis facility that furnishes DHS not covered by the ESRD composite rate or a hospital that provides dialysis (66 FR 923–924).

Comment: A number of commenters complained that the fair market value safe harbor methodology based on local hourly rates for emergency room physician services creates significant risk under the antitrust laws.

Response: We have eliminated the fair market value safe harbor for payments to physicians.

Comment: Two commenters asked us to comment on other valuation methodologies.

Response: Nothing precludes parties from calculating fair market value using any commercially reasonable methodology that is appropriate under the circumstances and otherwise fits the definition at section 1877(h) of the Act and § 411.351. Ultimately, fair market value is determined based on facts and

circumstances. The appropriate method will depend on the nature of the transaction, its location, and other factors. Because the statute covers a broad range of transactions, we cannot comment definitively on particular valuation methodologies. We refer the commenter to previous discussions in Phase I and Phase II regarding valuation methodologies (66 FR 944–945, 69 FR 16107).

Comment: One commenter wanted confirmation that a fair market value hourly rate could be used to compensate physicians for both administrative and clinical work. Another commenter asked whether the rate could be used to determine an annual salary.

Response: A fair market value hourly rate may be used to compensate physicians for both administrative and clinical work, provided that the rate paid for clinical work is fair market value for the clinical work performed and the rate paid for administrative work is fair market value for the administrative work performed. We note that the fair market value of administrative services may differ from the fair market value of clinical services. A fair market value hourly rate may be used to determine an annual salary, provided that the multiplier used to calculate the annual salary accurately reflects the number of hours actually worked by the physician.

D. “Incident to” Services

Under section 1877 of the Act, group practices are permitted to pay profit shares and productivity bonuses to their physicians in ways that other DHS entities cannot. Unlike other DHS entities, the statute permits group practices to pay a physician in the group a share of the overall profits of the group, or a productivity bonus based on services personally performed or services “incident to” such personally performed services, provided that the profit share or bonus is not determined in any manner that is directly related to the volume or value of the physician’s referrals. At § 411.351, we define “incident to” services to mean those services that meet the requirements of section 1861(s)(2)(A) of the Act, the “incident to” billing rule in § 410.26, and the relevant manual provisions, as those provisions may be amended or replaced from time to time, all of which set forth coverage criteria for “services and supplies” furnished “incident to” a physician’s professional service.

In the calendar year (CY) 2002 physician fee schedule final rule published on November 1, 2001 (66 FR 55246), we amended our “incident to” billing regulation in § 410.26 to provide

that “incident to” services and supplies means those services and supplies that are included in section 1861(s)(2)(A) of the Act and that are not specifically listed in the Act as a separate benefit. In the CY 2003 physician fee schedule final rule (67 FR 79966), we clarified that only those services that do not have their own separate and independently listed benefit category may be billed as “incident to” a physician service, except as otherwise expressly permitted by statute (for example, physical therapy services to the extent authorized under section 1862(a)(20) of the Act) (67 FR 79994). Consequently, diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests, all of which comprise a single benefit category under section 1861(s)(3) of the Act, may not be billed as “incident to” services under section 1861(s)(2)(A) of the Act. Thus, under section 1877 of the Act, a group practice physician may not receive a productivity bonus if the bonus is calculated based on such diagnostic tests, unless the physician personally performed the tests. Moreover, the bonus cannot be related directly to the volume or value of DHS referrals. We discuss the treatment of “incident to” services in further detail in section IV below.

Given our intent to conform the physician self-referral regulations as much as possible to existing Medicare coverage and payment rules, we did not intend in Phase I or Phase II to distinguish between “services” and “supplies” furnished “incident to” a physician’s professional services. Accordingly, as discussed in more detail in section IV of this preamble, we are revising the definition of “incident to” services” at § 411.351 to clarify that the term includes both services and supplies (such as drugs) that meet the applicable requirements set forth in section 1861(s)(2)(A) of the Act, § 410.26 of our regulations, and relevant manual provisions. We are also making a minor revision to make clear that the definition covers the terms “incident to” services” and “services ‘incident to’” for purposes of these regulations.

Comment: A commenter asserted that our interpretation in the CY 2003 physician fee schedule final rule as to what services qualify as “incident to” services (67 FR 79993–79994) is inconsistent with a previous interpretation we made in the CY 2002 physician fee schedule final rule (66 FR 55268). The commenter contends that “incident to” services may include separately listed and independent services, such as diagnostic tests. The commenter contends that our application of the “incident to” billing

rules in the physician self-referral context effectively prohibits group practice physicians from receiving a share of the group’s overall profits or a productivity bonus based on diagnostic tests that were directly supervised by the physician or a member of his or her group practice. The commenter requested that we amend the definition of “incident to” at § 411.351 to cover any services, including services that are listed separately and independently (such as diagnostic tests), that are directly supervised by the physician or a physician in the group practice, provided that they meet all of the other requirements under the “incident to” billing rules. According to the commenter, this interpretation appears consistent with the Congress’ intent under section 1877 of the Act to favor group practice physicians with respect to the distribution of profits and productivity bonuses.

Response: We are not amending the definition of “incident to” services at § 411.351 as suggested by the commenter. We believe it would be confusing to define “incident to” services differently for physician self-referral purposes than for billing purposes. As we stated in Phase I, we intend to interpret the physician self-referral law in a manner that conforms to existing Medicare coverage and payment rules (66 FR 859). We specifically noted in Phase I (66 FR 909) and in the Phase II definition of “incident to services” (69 FR 16128) that the “incident to” services on which group practice physicians could be compensated must comply with existing billing requirements as they may be amended from time to time.

We do not believe that our “incident to” billing rule in § 410.26 is inconsistent with the language of section 1877(h)(4)(B)(i) of the Act. Although “incident to” services are referrals for purposes of section 1877 of the Act, we believe that the Congress intended that these services nonetheless may be considered when calculating a physician’s productivity bonus. For those services that are appropriately billed “incident to” under current Medicare rules, the group practice physician to whose personally performed services the “incident to” services are incidental (that is, the ordering physician) may be paid a productivity bonus or profit share consistent with the special rules for such compensation set forth in § 411.352(i).

As we discussed in the CY 2003 physician fee schedule final rule, we interpret § 410.26(a)(7) literally; that is, “incident to” services and supplies

covered under section 1861(s)(2)(A) of the Act means services and supplies not having their own independent and separately listed statutory benefit category (67 FR 79994.) The commenter provided the example of diagnostic tests performed under the direct supervision of a physician and meeting the requirements under the “incident to” billing rules. Regardless of the physical possibility of diagnostic tests being performed under the direct supervision of a physician and meeting the requirements of certain billing rules, because these services have an independent and separately listed statutory benefit category (section 1861(s)(3) of the Act), they cannot be billed as “incident to” a physician service. (We note that we are deleting § 411.355(a)(3) because it is redundant and incorrectly suggests that diagnostic tests may be billed as “incident to” services.)

E. Physician in the Group Practice

We are modifying the definition of “physician in the group practice” to clarify that an independent contractor physician must furnish patient care services for the group under a contractual arrangement *directly* with the group practice.

Comment: A commenter asked that the definition of “physician in the group practice” be revised to delete the condition that a physician who is an independent contractor of a group practice is considered to be in the group practice only when he or she is performing services on the group practice’s premises. The commenter noted that section 952 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) revised the reassignment provisions in section 1842(b)(6) of the Act to permit independent contractor physicians to reassign their claims to a group practice for services performed off-premises (§ 424.80(b)(2)).

Response: Section 1842(b)(6) of the Act generally prohibits Part B payment to any person or entity other than the beneficiary who received the service or the physician or other supplier who furnished the service. This section of the Act also enumerates specific exceptions, known as the reassignment exceptions, to this general rule. Prior to section 952 of the MMA, we were prohibited from making payment to an entity that received reassigned payments from a contractor physician or other contractor supplier, unless the physician or other supplier performed the service at issue on the premises of the entity billing for the service. Section 952 of the MMA amended section

1842(b)(6) of the Act, so that we are allowed to make payment to an entity that has received reassigned payments pursuant to a contractual arrangement, provided that the contractual arrangement meets the program integrity and other safeguards that the Secretary may determine are appropriate. Thus, although section 1842(b)(6) of the Act grants us general authority to honor certain reassignments made pursuant to a contractual arrangement, it does not require us to honor those we believe are potentially abusive. We note that section 952 of the MMA does not apply exclusively to arrangements with group practices, and, therefore, retains meaning in the context of reassignments between other parties. For these reasons, we do not believe that section 952 of the MMA requires us to change our definition of “physician in the group practice” so that an independent contractor physician qualifies as a “physician in the group practice” irrespective of whether he or she is performing services on or off the group practice’s premises. We draw attention to § 424.80(a), which, in implementing section 952 of the MMA, we amended to state that nothing in § 424.80 relieves a party’s obligations under certain other rules, including the physician self-referral rules.

We continue to believe that it is appropriate to consider an independent contractor physician a “physician in the group practice” only when he or she is performing services in the group practice’s facilities and, thus, has a clear and meaningful nexus with the group’s medical practice. The term “physician in the group practice” is central to the definition of a group practice and significant for purposes of two important exceptions in section 1877 of the Act: The physician services exception and the in-office ancillary services exception. These exceptions enable physicians to make referrals for DHS within their group practices provided that certain requirements are satisfied. Accordingly, the strong nexus with a group practice created by the requirement that an independent contractor physician practice in a group practice’s facilities ensures that the physician is truly practicing “in the group.”

Comment: Two commenters expressed the need for clarification of the requirements for qualification as a “physician in the group practice.” These commenters asserted that a “physician in the group practice” is permitted to furnish only *supervision* services (which are not separately reimbursed by Medicare), and that any services for which a group practice

actually bills Medicare must be provided by a *member* of the group. The commenters requested that we confirm their interpretation of the rules regarding billing for services of physicians in a group practice and members of a group practice. In the alternative, the commenters suggested that we require that any separately-billable services furnished by a “physician in the group practice” be provided in the same building where the group practice provides its full range of services, thus prohibiting a “physician in the group practice” from providing services in a centralized building. According to the commenters, this change would ensure that independent contractor physicians have a sufficient nexus to the group practice to justify the group’s utilization of the in-office ancillary services exception.

Response: The commenters are mistaken that, as defined at § 411.351, a “physician in the group practice” (who can be either a member of the group or an independent contractor) may furnish only non-billable supervision services. The definition makes clear that a “physician in the group practice” can include an independent contractor who is “furnishing patient care services.” “Patient care services” is defined at § 411.351 to encompass a broad range of billable and non-billable services.

In order to qualify as a “group practice” under § 411.352, only members of the group practice (and not independent contractor physicians in the group practice) are required to 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.” In other words, an independent contractor “physician in the group practice” may furnish billable services, and may furnish services—in the group practice’s facilities—that comprise less than the full range of the patient care services that he or she usually furnishes. This enables a group practice to hire, on a contract basis, a specialist or other physician without jeopardizing the group’s ability to qualify as a group practice and utilize the in-office ancillary services exception, even if the contracted physician works for several physician practices or facilities. We note that qualifying as a group practice is not in and of itself sufficient to comply with the physician self-referral rules, and that use of the in-office ancillary services exception requires compliance with all of the conditions of that exception.

Under our regulations, an independent contractor physician is a “physician in the group practice” only when he or she is performing services in the group practice’s facilities. We are concerned about reports that some group practices purport to rely on the in-office ancillary services exception in § 411.355(b) when they: (1) Nominally comply with the centralized building requirements in § 411.355(b)(2)(ii) and (b)(2)(iii); (2) contract with independent contractor physicians to furnish or supervise services in the centralized building as “physicians in the group practice”; (3) accept reassignment of the right to payment from those physicians; and (4) realize profits based on the services they refer to the independent contractor “physicians in the group practice” stationed in the centralized building. In the physician fee schedule proposed rule for CY 2007, we proposed changes to our reassignment rules and to the definition of “centralized building” to address potentially abusive arrangements (71 FR 48981, 49054–49057). We are reviewing the public comments to our proposal and intend to issue a final rulemaking on this subject.

Comment: One commenter noted that the definition of “member of the group” at § 411.351 specifically excludes leased employees who do not meet the definition of an “employee” at § 411.351. The commenter questioned whether a leased employee who does not meet the definition of an employee may nevertheless meet the definition of a “physician in the group practice.” The commenter noted that an independent contractor physician may be a “physician in the group practice” and asserted that there does not appear to be any distinction between an independent contractor and a leased employee who does not meet the definition of an “employee” that would justify excluding the latter type of individual from being a “physician in the group practice.”

Response: The definition of “physician in the group practice” clearly encompasses only members (that is, owners and employees) and independent contractors. We are not persuaded to include other types of employment relationships (such as arrangements involving a group practice “leasing” or borrowing a physician who is an employee or contractor of some other entity. In order to fit within the definition of “physician in the group practice,” an independent contractor must have “a contractual arrangement with the group practice.” We interpret this to require that the contractual arrangement be directly between the group practice and the independent

contractor physician, and not between the group practice and another entity, such as a staffing company. We are expressly incorporating this interpretation into the regulations by modifying the definition of “physician in the group practice” at § 411.351.

Group practices receive favorable treatment under the physician self-referral law with respect to physician compensation. Accordingly, we believe that, in order to qualify as a group practice and receive such favorable treatment, the group practice’s physicians must have a strong and meaningful nexus to the group practice. An independent contractor in direct contractual privity with a group practice has such a nexus; employees leased from other entities do not. We believe this justifies excluding a leased employee from being a “physician in the group practice,” contrary to the commenter’s assertion that there is no distinction between an independent contractor and a leased employee. Moreover, we are concerned about potentially abusive arrangements, such as a situation in which a physician is employed by (and receives one W–2 from) a staffing company that leases the physician to numerous group practices, none of which has to enter into an individual contract with the physician but all of which can consider the physician a “physician in the group practice” with the attendant benefits of such categorization.

F. Radiology and Certain Other Imaging Services and Radiation Therapy

In Phase II, we defined “radiology and certain other imaging services” to exclude radiology procedures that are integral to the performance of a nonradiological medical procedure and performed during the nonradiological procedure, or immediately following the nonradiological procedure when necessary to confirm placement of an item placed during the nonradiological procedure (69 FR 16103). We declined to include nuclear medicine in the DHS category of “radiology and certain other imaging services,” but stated that we would continue to study the issue. One commenter stated that it disagreed with our decision. Based on this comment and further study, in the CY 2006 physician fee schedule proposed rule, we proposed to include diagnostic nuclear medicine services within the meaning of “radiology and certain other imaging services,” and to include therapeutic nuclear medicine services within the meaning of “radiation therapy and supplies” (70 FR 45854–45856). We adopted our proposal in the CY 2006 physician fee schedule final

rule (70 FR 70283–70289), effective January 1, 2007.

We are making no changes to the definition of “radiology and certain other imaging services” in this Phase III final rule.

Comment: One commenter noted that, in Phase II, we specifically declined to exclude ophthalmic A-scans and B-scans from the definition of “radiology and certain other imaging services” (69 FR 16103). The commenter disagreed with our conclusion, particularly with respect to A-scans. The commenter stated that the applicable standard of care dictates that A-scans are integral to cataract and other refractive surgeries and that they are not diagnostic in nature because they guide *how* surgery will be performed, not *whether* surgery will be performed. According to the commenter, although the scan is not done during the operation, it is an integral part of the surgery and raises little risk of abuse or overutilization because it will be done only if cataract surgery has already been prescribed.

Response: An A-scan involves the transmission of high-frequency sound waves through the eye and the measurement of their reflection from ocular structures. An A-scan provides a one-dimensional picture, most commonly used to measure the eye length and provide the data needed to calculate the power of the optical correction of the intraocular lens implant for cataract surgery. A B-scan, which is a two-dimensional cross section view of the eye, is used if the view inside the eye is obstructed by blood, an extremely dense cataract, or other cloudy media.

The definition of “radiology and certain other imaging services” at § 411.351 does not include radiology procedures that are integral to the performance of a nonradiological medical procedure and performed: (1) During the nonradiological medical procedure, or (2) immediately following the nonradiological medical procedure when necessary to confirm placement of an item placed during the nonradiological medical procedure. The commenter correctly states that often an A-scan (and a B-scan, as appropriate) is a pre-operative procedure performed prior to cataract surgery (which is a scheduled elective surgery). These scans are not performed during or just after cataract surgery. A-scans and B-scans are included in the definition of “radiology and certain other imaging services” because, even though they are integral to the performance of a nonradiological medical procedure, they are not performed during the nonradiological medical procedure or

immediately following it to confirm placement of an item placed during the nonradiological medical procedure. However, in the CY 2008 Outpatient Prospective Payment System notice of proposed rulemaking, we proposed to exclude from the definition of “radiology and certain other imaging services” at § 411.351 radiology procedures that are “covered ancillary services”, as defined at § 416.164(b) of this chapter for purposes of the revised ASC payment system. The term “covered ancillary services” includes certain radiology services that are integral to, and performed on the same day as, a covered ambulatory surgical procedure.

Comment: One commenter stated that it welcomed the exclusion from the definition of “radiology and certain other imaging services” of radiology services performed immediately after nonradiology services. The commenter asserted that it is standard protocol to order a CT scan in the aftermath of prostate brachytherapy in order to ensure that the radioisotopes have been placed properly. The commenter asserted that, although some may prefer to perform this service immediately after the procedure, it is better from a clinical standpoint to wait several weeks because the additional time allows for the prostate to become less swollen, thereby enabling the physician to determine more accurately whether the seeds were placed correctly. Therefore, the commenter suggested that we expand the exclusion from the definition to also include a CT scan taken within 6 weeks after the prostate brachytherapy to confirm proper placement of the isotopes.

Response: We decline to adopt the commenter’s proposal. As we stated in Phase I, where the radiology procedure is performed after the nonradiology procedure (as opposed to radiology procedures integral to and performed during a nonradiological procedure), referring physicians have discretion in choosing the entity that provides the radiology service independent of the entity providing the nonradiology procedure (66 FR 929). In Phase II, we excluded from the definition of “radiology and certain other imaging services” radiology procedures performed immediately after the nonradiology procedure in order to confirm placement of an item because we believed there would be no risk of program or patient abuse by doing so (69 FR 16103). Where a radiology procedure is not performed *immediately* after the nonradiology procedure to confirm placement of an item, we believe there is a risk that the referring

physician may direct referrals to an entity with which he or she has a financial interest, the very conduct addressed by the statute. As we noted in Phase II, depending on the facts and circumstances, exceptions, such as the in-office ancillary services exception in § 411.355(b) or the rural provider exception in § 411.356(c)(1), may apply to referrals for radiology services furnished before or after the nonradiology procedure (69 FR 16103).

We note also that, depending on the facts and circumstances, CT scans or other imaging ordered in the aftermath of prostate brachytherapy may qualify as “necessary and integral” ancillary services so as to come within the consultation exclusion from the definition of “referral.” We question whether a CT scan or other imaging performed as late as 6 weeks after the brachytherapy would be “necessary and integral” to the brachytherapy, but decline to say that such a CT scan or other imaging could never be “necessary and integral” to the original procedure (and, thus, not be considered a “referral” for purposes of the physician self-referral law); rather, the specific facts and circumstances control.

G. Referral

Section 1877(h)(5)(c) of the Act defines “referral” as 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 and any DHS 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 a small subset of services provided or ordered by pathologists, diagnostic radiologists, and radiation oncologists in accordance with a consultation requested by another physician.

In Phase I, we defined “referral” to exclude services personally performed by a physician who ordered the services, but to include DHS provided by the physician’s employees or contractors or by other members of the physician’s group practice (66 FR 871–872). In Phase II, we confirmed that a “referral” includes services performed by others “incident to” the physician’s services (69 FR 16063). Phase II also clarified that the definition of “referral” excludes referrals for necessary and integral DHS ordered and appropriately supervised by a radiation oncologist pursuant to a consultation (69 FR 16065).

We received several comments addressing the issue of services

performed by a physician’s employees that are “incident to” the physician’s personally-performed services. Other comments addressed the exclusions from the definition of “referral” for certain DHS requested by radiologists, pathologists, and radiation oncologists pursuant to a consultation. We are making no changes to the definition of “referral” in this Phase III final rule.

Comment: Several commenters requested clarification of the statement in Phase II regarding whether there is a “referral” when antigens are prepared and furnished by a physician, or whether there is a “referral” when a physician refills an implantable pump (69 FR 16063). The response in Phase II appeared, in the commenters’ view, to indicate that, if a physician personally prepares and furnishes antigens or personally refills an implanted pump for a patient, there is no “referral” for purposes of the physician self-referral statute. From this statement, the commenter concluded that the physician could bill for these DHS without consideration as to whether the referrals satisfy the requirements of an exception.

Response: In Phase II, we stated that the definition of “referral” excludes services personally performed or provided by the referring physician, but specifically includes any services performed or provided by anyone else (69 FR 16063). This interpretation is codified in the definition of “referral” at § 411.351. It is possible for a physician to order and personally furnish antigens to a patient and to order a refill for, and personally refill, an implantable pump. In such instances, there would be no “referral” for a designated health service, and no exception is needed.

We note that the furnishing of durable medical equipment (DME) and supplies by a referring physician requires a different analysis than the mere refilling of an implantable pump. There are few, if any, situations in which a referring physician would personally furnish DME and supplies to a patient, because doing so would require that the physician himself or herself be enrolled in Medicare as a DME supplier and personally perform all of the duties of a supplier as set forth in the supplier standards in § 424.57(c).

DME suppliers are entities that provide services under the specific Part B benefit for the provision of medical equipment and supplies for use in the patient’s home. These entities must be enrolled with the appropriate Medicare contractor as a DME supplier and must meet all of the professional supplier standards and quality standards that we require through regulations and

administrative or program instructions. The enrollment requirements and professional supplier standards are not waived in those situations in which a physician furnishes DME directly to the patient. The services to be personally performed by the physician would include, but not be limited to, the following, as appropriate—

- Personally fit the item for the beneficiary;
- Provide necessary information and instructions concerning use of the DME;
- Advise the beneficiary that he or she may either rent or purchase inexpensive or routinely purchased DME;
- Explain the purchase option for capped rental DME;
- Explain all warranties;
- (Usually) deliver the DME to the beneficiary at home; and
- Explain to the beneficiary at the time of delivery how to contact the physician in his or her capacity as a DME supplier by telephone.

A referring physician claiming to provide DME personally would need to maintain adequate documentation to establish that the physician personally performed these and other required DME supplier activities. All of these supplier requirements would need to be satisfied in order for a physician to be considered to be providing personally DME items and supplies. This is true for all DME furnished by a physician, including, for example, continuous positive airway pressure (CPAP) equipment. We believe that it is highly unlikely that a referring physician would meet the criteria for personally performed services when dispensing CPAP or other DME equipment. Thus, the dispensing of CPAP equipment by a physician would almost always constitute a “referral” for purposes of the physician self-referral statute, as would the dispensing of CPAP equipment by anyone else affiliated with the referring physician, such as a nurse or physician assistant. We note that CPAP equipment is DME that does not qualify for the in-office ancillary services exception.

Comment: One commenter suggested that a “referral” should not include “incident to” services requested by a physician and performed by an employee or contractor, unless the services are performed by an employee or contractor who is licensed to provide the services without physician supervision and who could otherwise bill separately for the services. The commenter also requested that we provide further education to physicians on how these “incident to” services

would fit into the in-office ancillary services exception.

Response: The commenter provided no support for its suggestion, nor did the commenter explain why the in-office ancillary services exception does not provide adequate protection under the circumstances described. We decline to change our interpretation of “referral” as requested by the commenter. As we stated in Phase II:

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 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 [exception] or another exception.

(69 FR 16063.) We continue to conclude that requests for DHS performed by a physician’s employees or independent contractors are “referrals” within the meaning of the physician self-referral prohibition, although these referrals may satisfy the requirements of an exception, including the in-office ancillary services exception in § 411.355(b).

Comment: Several commenters pointed out that, although we stated in Phase II that we were expanding the consultation exclusion to protect ancillary services that were necessary and integral to the provision of radiation therapy, the regulation text did not include any language to that effect (69 FR 16065). One commenter requested that the regulatory definition be amended to conform to the preamble discussion. Another commenter complained that the expansion of the consultation exclusion to include ancillary services that are necessary and integral to radiation oncology would increase utilization and Federal health care program costs and defeat the purposes of section 1877 of the Act. Two commenters, one representing brachytherapy providers, requested that interventional radiologists be permitted to provide diagnostic imaging services that are necessary and integral to their procedures.

Response: In Phase II, we intended to revise the definition of “referral” at § 411.351 to exclude from the definition ancillary services that are necessary and integral to the provision of radiation therapy, but inadvertently neglected to amend the regulatory text. In the CY 2006 physician fee schedule final rule published November 21, 2005, we made a technical correction that modified the language in paragraph (2) of the

definition of “referral” at § 411.351 to clarify that ancillary services necessary for and integral to the provision of radiation therapy are also protected by the consultation provision (70 FR 70330). We believe that the clarification was necessary to effectuate the statutory exclusion, and that it is sufficiently narrow to prevent abuse. No additional change is needed.

We do not believe that it is appropriate to exclude from the definition of “referral” ancillary testing necessary and integral to interventional radiology procedures performed as a result of a consultation. Interventional radiologists perform minimally invasive procedures using imaging for guidance. Examples of these procedures include angiography, angioplasty, biopsy, stenting, cryotherapy, and embolization. Because it is our understanding that interventional radiology is surgical in nature, we believe that any necessary and integral services would be ancillary to a surgical procedure, rather than to a radiology procedure. Thus, the consultation provision would not apply. Depending on the facts and circumstances, diagnostic imaging services performed by interventional radiologists may fit within the exclusion from the definition of “radiology and certain other imaging services” for radiology procedures that are integral to the performance of a nonradiological medical procedure and performed during the procedure or immediately following the procedure to confirm placement of an item placed during the procedure.

Comment: One commenter asked us to clarify whether the consultation exclusion for radiation oncologists in the definition of “referral” at § 411.351 protects radiation oncology services personally performed by the radiation oncologist or by a radiation oncologist in the same group practice. The commenter noted that Phase II expanded the consultation exclusion from the definition of “referral” to permit radiation therapy requested by a radiation oncologist to be performed by or under the supervision of the radiation oncologist, or under the supervision of a radiation oncologist in the same group practice (69 FR 16131). The commenter stated that, read literally, the exclusion from the definition of “referral,” as amended, would allow a radiation oncologist in the consulting radiation oncologist’s group practice to supervise the radiation therapy, but not to perform it.

Response: The commenters’ reading of the definition of “referral” at § 411.351 is correct. The consultation exclusion for radiation oncologists in

the definition of “referral” protects only radiation oncology services personally performed or supervised by the radiation oncologist or services supervised by a radiation oncologist in the same group practice. Requests by a pathologist for clinical diagnostic laboratory tests and pathological examination services and requests by a radiologist for diagnostic radiology services are treated similarly.

Comment: Several commenters asked that we expand the consultation provision to include “walk-in” patients (that is, patients who are seen by a physician without having been referred to that physician by another physician), as well as patients referred by other physicians. According to the commenters, there is no reason these patients are more likely to receive unnecessary treatment.

Response: We decline to make the change suggested by the commenters. We believe that walk-in patients for pathology, radiology, and radiation oncology are not common. Moreover, the fact that a patient “walks in” to a physician’s office (whether a pathologist, radiologist, radiation oncologist, or other type of physician) is not determinative under the physician self-referral law with respect to DHS referrals made by the physician whose services are sought by the walk-in patient. Thus, even if a patient initially self-refers to a pathologist, radiologist, or radiation oncologist, subsequent orders of items or services by the pathologist, radiologist, or radiation oncologist are referrals of DHS. Moreover, these referrals are subject to potential overutilization or other abuse.

As we noted in Phase I (66 FR 874), the Congress regarded the specialists excepted under the definition of “consultation” as physicians who were not initiating a referral for services, but merely implementing the request of another physician who has already determined that the patient is likely to need the specialist’s services. In these situations, the Congress indicated its belief that overutilization would not be likely. As we noted in Phase II (69 FR 16064), the statutory consultation exception “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.” The additional protection against overutilization of diagnostic radiology, pathology, and radiation therapy services implicit when a radiologist, pathologist, or radiation oncologist merely implements a determination made by another physician that the patient is likely to need the specialist’s

services (and those services meet the requirements of a consultation) are not present in the case of a patient who “walks in” for these services.

We are mindful that services provided to walk-in patients will not meet the definition of “consultation,” and any subsequent DHS will, therefore, be the subject of a referral by the pathologist, radiologist, or radiation oncologist. Depending on the circumstances, these referrals may satisfy the requirements of an exception to the prohibition on physician self-referral. As noted in Phase II in response to similar concerns about self-referred patients (69 FR 16066), changes made to the in-office ancillary services exception in Phase II should, in many circumstances, enable DHS referrals for self-referred patients to fit in that exception.

Comment: Several commenters requested that we clarify that the consultation exclusion covers the technical component of DHS ordered by hospital-based pathologists and radiologists pursuant to a consultation. Another commenter suggested that DHS ordered by anesthesiologists pursuant to a consultation should also be excluded from the definition of a referral.

Response: We have previously considered the first issue and continue to believe that, where a physician orders the technical component of a designated health service (for example, an x-ray) and someone other than the physician performs the technical component, there is a referral to which section 1877 of the Act applies (66 FR 871, 69 FR 16063). However, the commenters are correct with respect to the technical component of a designated health service ordered by a hospital-based pathologist, radiologist, or radiation oncologist, if the requirements of the consultation exclusion otherwise apply. Specifically, the technical components of DHS ordered by these types of physicians pursuant to a consultation are subject to the consultation exclusion from the definition of a “referral” at § 411.351.

With respect to extending the consultation provision to DHS ordered by anesthesiologists, we note that the statutory exception is limited to pathologists, radiologists, and radiation oncologists who meet certain criteria. We do not have the authority to extend the statutory consultation exception in the definition of “referral” to specialists other than those enumerated by the Congress. Moreover, we are not persuaded that any special regulatory exception is warranted for DHS referrals made by an anesthesiologist to an entity with which he or she (or his or her immediate family member) has a financial relationship. Depending on the

circumstances, anesthesiologist referrals for DHS may qualify for an existing exception, including, for example, the exception for personal service arrangements or the exception for *bona fide* employment relationships.

Comment: One commenter asked that the consultation exclusion from the definition of “referral,” which, according to the commenter, protects tests performed by other pathologists, radiologists, or radiation oncologists in the same group practice, be expanded to protect services furnished by physicians who are employees of the same entity, such as a hospital. The commenter gave the example of a hospital-employed radiologist who receives an order for diagnostic services and subsequently directs a second radiologist employed by the same hospital to perform the services. According to the commenter, there is no possibility of abuse in this situation, and the change is necessary to permit hospital-employed pathologists, radiologists, and radiation oncologists to provide coverage for each other.

Response: We do not agree that an expansion of the consultation exception is warranted. Where physicians have a common hospital employer that bills for the technical components of a test (that is, the hospital is the DHS entity), the hospital and the referring physicians may avail themselves of the exception for *bona fide* employment relationships in § 411.357(c). With respect to any professional component of the services that are DHS, the hospital should be able to bill pursuant to a reassignment (which would make the hospital the DHS entity), and the arrangement could be structured to satisfy the requirements of the exception for *bona fide* employment relationships.

H. Rural Area

The term “rural area” is used throughout the physician self-referral regulations. For ease of reference and to simplify the regulations, we are moving the definition to § 411.351. For physician self-referral purposes, we are defining “rural area” as an area that is not an urban area as defined at § 412.62(f)(1)(ii). The definition is consistent with the definition in the statutory exception for rural providers at section 1877(d)(2) of the Act.

IV. Group Practice—§ 411.352

The determination of which organizations qualify as group practices for purposes of section 1877 of the Act is critical for several exceptions, including the in-office ancillary services exception. In addition, section 1877 of the Act allows group practices more flexibility in compensating physicians

(for example, only group practice physicians may be compensated in a manner that takes into account services furnished “incident to” a physician’s personally performed services).

Phase I addressed the requirements for qualification as a group practice under section 1877(h)(4) of the Act. (The regulatory requirements appear in § 411.352.) Most commenters commended the changes made in Phase I. In Phase II, we made several minor changes to § 411.352.

This Phase III final rule makes one minor change to § 411.352 to reflect more closely the statutory scheme and our original intent in the Phase I final regulation that the “incident to” services need not themselves be personally performed by the referring physician: we are changing the parenthetical language in § 411.352(i)(1) to permit a physician in the group to be paid a productivity bonus based on services that he or she has personally performed, or services “incident to” such personally performed services or both.

Comment: One commenter asked for confirmation that a separate corporation that is formed by a hospital and that has as its primary purpose being a physician group and employing physicians would meet the single legal entity requirement even if the physicians are divided into different divisions based on specialty.

Response: A separate corporation formed by a hospital to employ physicians can constitute a single legal entity, provided that the specialty divisions are not separate legal entities and the arrangement otherwise satisfies the requirements of § 411.352.

Comment: One commenter asked that we clarify that a medical foundation qualifies as a group practice.

Response: For the reasons noted in Phase I (66 FR 902–903) and Phase II (69 FR 16077), including those discussed below, we do not believe it is feasible to make a blanket determination that all medical foundations qualify as group practices. Moreover, we see no need to revisit the requirements for qualification as a group practice under § 411.352 or the discussion in Phase II regarding whether a foundation can meet those requirements.

The commenter has failed to convince us that many typical foundation-model practice arrangements satisfy the requirements for qualification as a group practice. Section 1877(h)(4)(A) of the Act defines “group practice” to include, *inter alia*, two or more physicians legally organized as a foundation. In one common variation of a foundation-model arrangement, it is the foundation, and not the physicians, that owns the

medical practice; thus, the *physicians* are not legally organized as a “foundation” as that term is used in section 1877(h)(4)(A) of the Act. Instead, the *foundation* owns and operates all elements of the practice. However, because it cannot provide physician services, the foundation employs or contracts with physicians to furnish patient care services (66 FR 902.) In States in which a foundation (or other corporation) may provide physician services, a medical foundation may be a group practice if all of the group practice requirements are satisfied.

As we noted in Phase II, if a particular foundation-model arrangement meets the single legal entity test (and has at least two physician employees), it may qualify as a group practice under § 411.352 and use the in-office ancillary services exception in § 411.355(b), provided that all other requirements of § 411.352 and the in-office ancillary services exception are met (69 FR 16077).

Comment: Two commenters inquired about the application of the indirect compensation arrangements exception and personal service arrangements exception to foundation-model practices. One commenter questioned whether foundation-model structures create indirect compensation arrangements between referring physicians and the DHS entity that owns the foundation, thus implicating the indirect compensation arrangements exception requirements.

Response: With respect to the application of the indirect compensation arrangements exception and personal service arrangements exception to arrangements involving medical foundations, we reiterate that an arrangement need not satisfy the requirements of a *specific* exception to comply with the physician self-referral rules. An entity may rely on any exception that an arrangement satisfies (66 FR 916, 919; 69 FR 16086.) With the new “stand in the shoes” provision (discussed below in section VI.B), many arrangements involving foundation-model structures may be deemed to be direct compensation arrangements and potentially qualify for the personal service arrangements exception. Whether a particular arrangement constitutes an indirect compensation arrangement pursuant to § 411.354(c) will continue to depend on the specific facts and circumstances of the arrangement.

Comment: One commenter asserted that a “typical” medical foundation arrangement is structured as follows: a nonprofit medical foundation owns and operates a nonprofit health care clinic

and contracts with a medical group (organized as a professional corporation) to provide the professional services of the group’s employed physicians at the foundation’s clinic. The medical foundation pays the group aggregate compensation that is then divided among the group’s physicians. The commenter inquired whether the medical group can qualify as a group practice within the meaning of the physician self-referral rules if the medical foundation bills and collects for the professional services of the medical group using a provider number assigned to the foundation.

Response: As we observed in Phase II (69 FR 16077), foundation-model physician practices exist in a variety of forms, depending on jurisdiction and other factors; therefore, it is difficult to generalize about these arrangements. Nothing in the physician self-referral regulations precludes a foundation-model physician practice from qualifying as a “group practice” if it can satisfy every element of the requirements in § 411.352.

The fact that a medical foundation bills and collects for the professional services of the physicians in the medical group who provide services at the foundation’s clinic using a billing number assigned to the foundation rather than a billing number assigned to the group does not necessarily disqualify the medical group from satisfying the requirements of § 411.352. However, the fact that professional services of members of the medical practice are billed by the foundation using a billing number assigned to the foundation pursuant to a reassignment may affect the ability of the medical practice to satisfy the “substantially all” test in § 411.352(d), which requires that substantially all (that is, at least 75 percent) of the patient care services of the physicians who are members of the group practice (for example, owners or employees) are provided through the group and are billed under a billing number assigned to the group and amounts so received are treated as receipts of the group. Where professional services are provided to a foundation clinic pursuant to a services contract between the group practice and the foundation, a group practice may count such services as services the physician provides through the group. For further explanation of the “substantially all” test, see 66 FR 904–905 and 69 FR 16079.

We note that, if a foundation-model practice qualifies as a group practice under § 411.352, the practice may be able to use the physician services or in-office ancillary services exceptions for

DHS referrals where the group practice is the entity furnishing the DHS (that is, where the DHS are billed under the group practice's billing number, not the foundation's billing number). Referrals of DHS billed by the foundation would not qualify for these exceptions.

Comment: One commenter asserted that faculty practice plans should be entitled to the same treatment as group practices with respect to methodologies for compensating the plan physicians. According to the commenter, the inclusion of faculty practice plans as entities eligible under the statutory definition of "group practice" in section 1877(h)(4)(A) of the Act evidences the Congress's intent that faculty practice plans be treated as group practices. The commenters asserted that the failure to include faculty practice plans as group practices disadvantages physicians in academic practice.

Response: Nothing in the regulations prevents a faculty practice plan from qualifying as a group practice if it can satisfy the conditions in § 411.352 (66 FR 917). If these conditions are satisfied, the faculty practice plan may avail itself of the physician services exception in § 411.355(a) and the in-office ancillary services exception in § 411.355(b) for DHS referrals within the faculty practice plan, as well as the special rule for productivity bonuses and profit shares in § 411.352(i). We note that neither the physician services exception, nor the in-office ancillary services exception, would protect referrals by faculty practice plan physicians to other components of an academic medical center, such as the affiliated hospital. In such circumstances, the academic medical center services exception may be useful.

Comment: One commenter asked for clarification of the unified business test requirement that a group practice have centralized decision-making by a body representative of the group practice and its application to a nonprofit corporation. Under IRS rules, a majority of the board of a tax-exempt, nonprofit corporation must be composed of disinterested representatives of the community. The commenter suggested that, in these situations, the individuals that are representative of the group practice should not have to constitute a majority of the board.

Response: The regulations in § 411.352(f)(1)(i) require that the decision-making body be representative of the group practice and that the decision-making body, not the group practice, maintain effective control over the group's assets and liabilities. Nothing in the regulations requires that a majority of the decision-making body

be physicians (although this might be a reasonable and prudent way to ensure fair representation). In Phase II, we noted that "there must be substantial 'group level' management and operation," but did not prescribe any particular process (69 FR 16080). Nothing in the regulations would preclude a tax-exempt, nonprofit group practice with a majority of its board composed of disinterested representatives of the community from satisfying the requirements of § 411.352(f)(1)(i) if the board maintains effective control over the group's assets and liabilities and is representative of the group practice.

Comment: Several commenters requested confirmation that a group practice can compensate its members (including employed physicians) and "physicians in the group practice" by directly taking into account the volume and value of items and services that are provided "incident to" the physicians' professional services. Commenters questioned the interplay between language in § 411.352(g) that prohibits group members from receiving any compensation based directly or indirectly on the volume or value of referrals by the physician and the special rule for productivity bonuses and profit shares in § 411.352(i), which provides:

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 [at] § 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.

Response: The "volume or value of referrals" provision in § 411.352(g) (section 1877(h)(4)(A)(iv) of the Act) describes a ban, for purposes of the group practice definition, on compensating members of the group practice in any way that relates directly or indirectly to the volume or value of their DHS referrals. Notwithstanding this restriction, the "special rule" in § 411.352(i) (section 1877(h)(4)(B)(i) of the Act) permits group practices to compensate their physicians using profit shares and productivity bonuses that indirectly relate to DHS referrals without jeopardizing their ability to qualify as a group practice.

Specifically, in order to qualify as a group practice, a physician practice may not compensate a physician who is a member of the practice *directly or indirectly* based on the volume or value of referrals by the physician. However, under the special rule for profit shares

and productivity bonuses, a group practice may pay a physician in the group practice a share of overall profits of the group provided that the share is not determined in any manner that is *directly* related to the volume or value of referrals of DHS by the physician. A group practice may also pay a physician in the group practice a productivity bonus based on services that the physician has personally performed or services "incident to" such personally performed services, or both, provided that the bonus is not determined in any manner that is directly related to the volume or value of referrals of DHS by the physician.

With respect to productivity bonuses based on "incident to" services, we stated in Phase I (66 FR 909) our view that group practice physicians can receive compensation directly related to the physician's personal productivity and to services incident to the physician's personally performed services. We noted that the services would have to comply with the requirements of section 1861(s)(2)(A) of the Act and section 2050 of the Carriers Manual (now section 60.1 of the CMS Internet-only Manual, publication 100-02, Medicare Benefit Policy Manual, Chapter 15 (Covered Medical and Other Health Services)) or other HHS rules and regulations affecting "incident to" billing. That is, the services would have to be directly supervised by the physician under the "incident to" billing rules (the physician must be present in the office suite and immediately available). We believe that this heightened supervision requirement provides some assurance that the "incident to" DHS would not be the primary incentive for a self-referral. In Phase II, we reaffirmed this interpretation and indicated that we were revising the regulations to make clear that productivity bonuses can be based directly on "incident to" services that are incidental to a physician's personally performed services (69 FR 16080).

Based on comments to the Phase II rule, we believe additional regulatory text refinement is warranted. Accordingly, we have revised § 411.352(i) to read:

A physician in the group practice may be paid a share of overall profits of the group, provided that the share is not determined in any manner that is directly related to the volume or value of referrals of DHS by the physician. A physician in the group may be paid a productivity bonus based on services that he or she has personally performed (or services "incident to" such personally performed services), provided that the bonus is not determined in any manner that is

directly related to the volume or value of referrals of DHS by the physician (except that the bonus may directly relate to the volume or value of DHS referrals by the physician if the referrals are for services "incident to" the physician's personally performed services).

The revised regulatory text makes clear that productivity bonuses can be based directly on "incident to" services that are incidental to the physician's personally performed services, even if those "incident to" services are otherwise DHS referrals (for example, physical therapy or outpatient prescription drugs). The productivity bonus cannot be directly related to any other DHS referrals, such as diagnostic tests or hospital admissions. We note that in Phase II (69 FR 16080), we also indicated that overall profit shares could relate directly to "incident to" services. Upon further reflection, we have concluded that this interpretation is inconsistent with the clear statutory language, which includes "incident to" services only in the context of productivity bonuses, and with our Phase I interpretation (66 FR 908-909). Thus, we are withdrawing our statement in Phase II at 69 FR 16080 with respect to overall profit shares and "incident to" services. Because an overall profit share under § 411.352(i)(2) means the aggregation of profits derived from DHS of the group as a whole or of a component of at least five physicians, an overall profit share will necessarily include profits from DHS that are billed as "incident to" services (66 FR 876,909). Under this Phase III final rule, profits must be allocated in a manner that does not relate directly to DHS referrals, including any DHS that is billed as an "incident to" service. We note that the regulations provide a number of methods that satisfy this requirement.

Comment: One commenter requested clarification that "incident to" drugs may be factored directly into productivity bonuses, given that § 411.352(i) speaks only of "services" and not "items."

Response: A physician in a group practice may be paid a productivity bonus based on services and supplies furnished "incident to" a physician's personally performed services. We defined "'incident to' services" at § 411.351 to mean those services that meet the requirements of section 1861(s)(2)(A) of the Act and § 410.26 of our regulations, both of which set forth coverage criteria for "services and supplies" furnished incident to a physician's professional services. Given our intent to conform the physician self-referral regulations as much as possible to existing Medicare coverage and

payment rules, we did not intend in Phase I or Phase II to distinguish between "services" and "supplies" furnished incident to a physician's professional services. Accordingly, we are revising the definition of "'incident to' services" at § 411.351 to clarify that the term includes both services and supplies (such as drugs) that meet the applicable requirements set forth in section 1877(h)(4)(B)(i) of the Act and § 410.26 of our regulations.

Comment: One commenter stated that many group practices, in order to avoid taxes, do not allocate "profits" to their members, but distribute "bonuses." The commenter asked if the group practice has complied with § 411.352(i) if it calculates its "bonuses" in a manner that complies with the profit-sharing requirements.

Response: A group practice may compensate physicians with overall profit shares or productivity bonuses, or some combination of the two, provided that the allocation methodology complies with § 411.352(i)(2) or (i)(3), respectively. Whether the characterization of funds distributed to physicians as "bonuses" rather than "profits" meets IRS rules is outside the scope of this rulemaking.

Comment: A commenter requested that the minimum size of a group practice component for purposes of profit-sharing under § 411.352(i)(2) be fewer than the current requirement of at least five physicians where the grouping constitutes an identifiable specialty or practice focus within the group practice. According to the commenter, one of every four orthopedic groups has two or three physicians, and many larger groups have subspecialties of fewer than five members.

Response: We stated in Phase I (66 FR 908) and Phase II (69 FR 16080-16081) that we saw no reason to reduce the minimum number of physicians in a component for profit-sharing purposes. We maintain this position. Our concern remains that smaller components increase the risk of overutilization of DHS and other abuse by strengthening the ties between an individual physician's compensation and his or her referrals. Setting the minimum number of physicians in a group practice component at five reduces the likelihood that a physician will be directly compensated for his or her own referrals.

V. Prohibition on Certain Referrals by Physicians and Limitations on Billing—§ 411.353

Section 411.353 sets out the basic prohibition on physician self-referral under section 1877 of the Act. Two

provisions, § 411.353(e) and § 411.353(f), address the potentially harsh results from inadvertent violations of the prohibition. Section 411.353(e), which was added in Phase I, provides that payment may be made to an entity that submits a claim to Medicare for DHS if 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 referred the DHS to the entity, provided that the claim otherwise complies with all applicable Federal laws and regulations. Section 411.353(f), which was added in Phase II, permits DHS entities to submit claims and receive payment for DHS furnished during certain instances of temporary noncompliance. Specifically, § 411.353(f) permits DHS entities to submit claims and receive payment for such claims if: (1) The arrangement had been in full compliance with an applicable exception for at least 180 consecutive calendar days immediately preceding the date on which the financial relationship became noncompliant; (2) the financial relationship fell out of compliance for reasons beyond the entity's control and the entity promptly moved to address the noncompliance; and (3) the financial relationship does not violate the anti-kickback statute and complies with all applicable Federal and State laws, rules, and regulations. Section 411.353(f) applies only to DHS furnished during the 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. We specified that an entity could not use the exception in § 411.353(f) more than once every 3-years with respect to the same referring physician, and the provision could not be used if the exception with which the financial relationship previously complied was either § 411.357(k) or (m) (regarding nonmonetary compensation and medical staff incidental benefits, respectively). In general, commenters welcomed the protections of § 411.353(e) and (f), but asked that they be broadened. We are making no substantive changes to § 411.353(e) or (f) in this Phase III final rule.

Comment: Some commenters asked for clarification regarding how long a DHS entity would be precluded from submitting claims for DHS referred by a physician with whom the DHS entity had a financial relationship that failed to comply with an exception and for which § 411.353(f) or § 411.357(f) either may not be applicable or may not

provide what the commenters believed would be sufficient protection.

Response: The statute provides no explicit limitation on the billing and claims submission prohibition. We are addressing this issue in another rulemaking.

Comment: Some commenters objected to our decision not to extend to referring physicians the protection of § 411.353(e) (regarding payments made to an entity that does not have knowledge of the identity of the physician who made the referral for DHS). The commenters acknowledged that a referring physician would not be subject to sanction under section 1877 of the Act unless the physician knowingly caused an improper claim or bill to be submitted (or knowingly engaged in a circumvention scheme). The commenters were concerned, however, that the referring physician who had no such intent could nevertheless be subject to liability under the civil False Claims Act, 31 U.S.C. 3729.

Response: Liability under the civil False Claims Act requires that the violator act knowingly. Only a physician who knowingly causes the submission of a bill or claim for a service for which payment may not be made under section 1877 of the Act would be subject to sanction under the civil False Claims Act for such conduct. Similarly, as the commenters' observe, a referring physician would not be subject to sanction under section 1877(g) of the Act unless the physician knowingly causes an improper claim or bill to be submitted (or knowingly engages in a circumvention scheme). Accordingly, we are not expanding the provision as suggested by the commenters.

Comment: Several commenters asked that we extend for a longer period of time the 90-day window in § 411.353(f)(2), which permits a physician and DHS entity that are parties to an arrangement that no longer satisfies the requirements of an exception to refer and submit claims, respectively, for DHS. Some commenters asked that the window run from the date of noncompliance until 30 or 90 days after the date on which the noncompliance was discovered. Commenters asserted that the other requirements of the exception, namely that the arrangement had to have been in compliance with an exception for at least 180-consecutive calendar days immediately preceding the date on which the financial relationship became noncompliant and that the noncompliance was due to actions beyond the control of the DHS entity, were sufficient to protect against possible program or patient abuse. One

commenter suggested that the expanded noncompliance window be conditioned on the good faith of the DHS entity and the immateriality or inadvertence of the noncompliance. One commenter acknowledged that starting the window from the time of discovery of the noncompliance may provide an incentive for hospitals and physicians to remain ignorant about noncompliant arrangements, but stated that this "minor" risk could be mitigated by a condition that would negate the use of the exception if that behavior exists. Another commenter recommended that, in a situation in which an arrangement is out of compliance, but the physician is unable to make referrals due to a disability, active military duty, or some other reason, the time for correcting the noncompliance be tolled until the point at which the physician is again reasonably able to make referrals.

Response: We disagree with the commenters that proposed a "discovery-based" rule, as well as with the commenter that recommended that the period in which noncompliance must be corrected be tolled during the time in which (for whatever reason) referrals are not being made. Section 1877 of the Act is intended to deter inappropriate financial relationships through a strict liability regime. A discovery-based rule is contrary to the statutory scheme. Moreover, such a rule creates a perverse incentive not to diligently monitor and enforce compliance. Tolling the time period for rectifying the noncompliance while a physician is unable to make referrals due to disability, military duty, or another reason is not necessary because it is not likely that the parties would violate the physician self-referral statute if no referrals are being made.

The commenters' suggestions would create substantial enforcement problems because it may be difficult to establish the date on which the noncompliance was discovered. Imposing standards regarding the materiality of the noncompliance or the good faith of the parties would present similar enforcement difficulties and would be contrary to the statutory scheme. Finally, we do not believe that extending the noncompliance window in § 411.353(f)(2) beyond the current 90-days is either warranted or necessary. Parties to an arrangement should monitor the continued compliance of the arrangement with the conditions of an applicable exception. We note, however, as discussed below at section IX.D, that we are establishing a 6-month holdover provision for personal service arrangements that otherwise meet the requirements in § 411.357(d). We believe that this provision, along with

the holdover provisions already available in the exceptions for the rental of office space and equipment in § 411.357(a) and (b), should provide adequate relief to parties to arrangements of these types that would otherwise temporarily fall out of compliance with the physician self-referral law.

Comment: A hospital trade association asked that we delete the requirement in § 411.353(f)(1)(ii) that the noncompliance be due to reasons beyond the entity's control. Several commenters sought clarification as to what actions were beyond the control of the DHS entity. Two commenters asked whether a physician's failure to sign promptly a written contract that the hospital had sent in a timely manner and that otherwise complied with the personal service arrangements exception would be considered beyond the hospital's control. One commenter asked whether, in evaluating the failure to continue to satisfy the requirements of an exception, it made a difference that the hospital needed the services immediately, such as for on-call coverage. Specifically, the commenter gave the example of the provision of needed on-call coverage services prior to the formal execution of a written agreement for those services. Another commenter suggested that we clarify that an arrangement is eligible for the temporary noncompliance exception if it falls out of compliance with an exception due to the actions of a third party, such as the actions of the government through a change in the regulations or the removal of a Health Professional Shortage Area (HPSA) designation of an area for purposes of the physician retention exception.

Response: We discussed in detail the application of the temporary noncompliance exception in Phase II (69 FR 16057.) We are not repeating that explanation here. With respect to the inquiry regarding on-call coverage for which there is an immediate need, we reiterate that the DHS entity may avail itself of the temporary noncompliance exception only when the arrangement was in full compliance with an exception to the physician self-referral law under § 411.355, § 411.356, or § 411.357 prior to the temporary noncompliance. In the example provided by the commenter, the arrangement was never in compliance with the law, and therefore the temporary noncompliance exception would be unavailable to the DHS entity. With respect to the second commenter's example regarding noncompliance occurring due to loss of a HPSA designation, as we noted in Phase II,

such noncompliance would be considered beyond the entity's control (69 FR 16057). With respect to other instances of noncompliance caused by third parties, a determination of whether such noncompliance was beyond the entity's control would have to be made on a case-by-case basis. Finally, we do not believe it necessary or practical to give specific guidance on documentation of the steps taken to rectify temporary noncompliance. Entities should maintain adequate and contemporaneous documentation of all financial relationships with referring physicians, including—

- The terms of each arrangement;
- Whether and how an arrangement fell out of compliance with an exception;
- The reasons for the arrangement falling out of compliance;
- Steps taken to bring the arrangement into compliance;
- Relevant dates; and
- Similar information.

Comment: Two commenters recommended eliminating the requirement in § 411.353(f) that the arrangement must have been in compliance with an applicable exception for 180 consecutive calendar days immediately preceding the date on which the financial relationship became noncompliant. According to the commenter, the program is adequately protected by the requirement that the noncompliance had to occur for reasons beyond the entity's control.

Response: For the reasons noted in Phase II, we are retaining the requirement that the arrangement must have been in compliance with an exception under § 411.355, § 411.356, or § 411.357 for 180 consecutive calendar days (69 FR 16057). We continue to believe that the requirement is necessary to ensure that the temporary noncompliance exception is not subject to abuse.

Comment: A commenter recommended that enforcement officials exercise their discretion by declining to pursue minor and technical violations. Another commenter stated that we should consider adding an exception that would permit physicians to refer for DHS and DHS entities to submit and receive payment for DHS claims if, in our sole discretion, there was no abuse. The commenter suggested that such an exception should be available only after: (1) receipt by the entity of a favorable advisory opinion; or (2) a voluntary disclosure by the entity or upon audit or investigation by the government.

Response: The physician self-referral law is a strict liability statute, and we therefore do not have authority to waive

the nonpayment sanction under the statute for “minor” and “technical” violations, or violations stemming from non-abusive arrangements. We lack the statutory authority to promulgate the exception suggested by the commenter, but we are open to creating additional regulatory exceptions that pose no risk of program or patient abuse.

VI. Financial Relationship, Compensation, and Ownership or Investment Interest—§ 411.354

Section 411.354 defines the financial arrangements that are subject to the statutory prohibition. The section defines direct and indirect ownership and investment interests, and direct and indirect compensation arrangements. The section also establishes a number of rules governing various aspects of compensation arrangements.

In Phase I, we established a three-part, “bright line” test for defining an “indirect compensation arrangement” that incorporates a knowledge element. To satisfy the knowledge element, a DHS entity must have actual knowledge of, or act in reckless disregard or deliberate ignorance of, the fact that the referring physician receives aggregate compensation that varies with or otherwise reflects the volume or value of referrals or other business generated for the DHS entity. Phase I established a corresponding new exception for indirect compensation arrangements. By (1) defining the universe of “indirect compensation arrangements” that potentially trigger disallowance of claims and penalties, and (2) creating an exception for the subset of “indirect compensation arrangements” that would *not* trigger disallowance or penalties, we structured the treatment of indirect compensation arrangements under section 1877 of the Act to parallel closely the treatment of direct compensation arrangements.

Phase I also established several special rules applicable to certain key requirements in the various definitions and exceptions related to compensation arrangements, including when an arrangement was “set in advance” and whether time-based or unit-based compensation methodologies took into account “the volume or value” of referrals or “other business generated between the parties.” Finally, Phase I established that, in some limited instances, it is permissible for an employer, managed care organization, or entity with which a physician contracts to require a physician to refer to a particular DHS entity as part of certain compensation arrangements.

Phase II addressed concerns raised by commenters regarding the Phase I

definitions of the various types of financial relationships. The modifications set forth in Phase II included—

- Clarifying the meaning of direct and indirect ownership and affirming that, absent unusual circumstances, common ownership of an entity does not create an ownership interest by one common investor in another (69 FR 16061);
- Clarifying the relationship between the “indirect compensation arrangement” definition and the “volume or value” and “other business generated” standards (69 FR 16061);
- Revising the definition of “referring physician” at § 411.351 to provide that a referring physician is treated as “standing in the shoes” of his or her wholly-owned professional corporation (PC) (69 FR 16125).

We also solicited comments on whether to permit a physician to “stand in the shoes” of a group practice of which he or she is a member (69 FR 16060). (Our response to comments on this issue is set forth in detail below in section VI.B of this preamble.)

In response to Phase II, we received comments regarding aspects of the ownership provisions. Most comments, however, related to various aspects of the “indirect compensation arrangement” definition and the related exception.

We are making two substantive and several minor changes to § 411.354. First, we are revising the regulation text in § 411.354(b)(3)(v) to provide that an ownership or investment interest does not include a security interest in the equipment of a hospital held by a physician who both sold the equipment to the hospital and financed its purchase through a loan to the hospital. (However, such transactions will create compensation arrangements.) Second, we are amending the regulations in § 411.354(c) to add a “stand in the shoes” provision under which referring physicians will be treated as “standing in the shoes” of their group practices (and certain other physician organizations) for purposes of applying the rules that describe direct and indirect compensation arrangements in § 411.354. As explained in greater detail below in response to comments, this change will reduce the risk of fraud and abuse by closing an unintended loophole in the definition of “indirect compensation arrangement” (by deeming more arrangements to be direct compensation arrangements) and will ease compliance by simplifying the analysis of many arrangements. This revised approach is conceptually an extension of the Phase II rule that treated referring physicians as standing

in the shoes of their professional corporations.

In addition, we are making non-substantive changes to clarify that we do not interpret “otherwise reflects” and “takes into account” (with respect to referrals and as these terms are used in certain exceptions) as having separate and different meanings. That is, the terms were used interchangeably in Phase II, and we have made conforming changes for consistency. Other changes are discussed below.

A. Ownership

Comment: One commenter stated that secured loans should not automatically create an ownership or investment interest in the entity granting the security interest (absent other indicia of ownership such as voting or other governance rights, profit participation, etc.). For example, a contract for a physician’s sale of equipment to a hospital on an installment payment basis will commonly include a security interest in the equipment in case of nonpayment. According to the commenter, under the Phase II rule, such a security interest would create an ownership interest in part of a hospital, and thus create a prohibited financial relationship (69 FR 16063). The commenter believed that this interpretation is at odds with our indication in Phase II that a one-time sale using installment payments that are protected by a security interest could be eligible for the isolated transactions exception in § 411.357(f). The commenter asserted that this type of arrangement should instead be viewed as a compensation arrangement, potentially qualifying for the isolated transactions exception. The commenter referenced our Phase II remarks with respect to the types of transactions that qualify for the protection of the exception for isolated transactions at § 411.357(f) (69 FR 16098).

Response: In Phase II, we indicated that loans or bonds secured by, or otherwise linked to, a particular piece of equipment or the revenue of a department or other discrete hospital operations would be considered an ownership interest in part of a hospital (69 FR 16063). We also stated that a one-time sale of property (which could be equipment), using installment payments that are appropriately secured, for example by a security interest taken in the property, could qualify for the isolated transactions exception in § 411.357(f) if all other requirements of the exception are satisfied (69 FR 16098). After reconsidering the issue, we do not believe that the Congress intended a security interest taken by a

physician in equipment sold to a hospital and financed by a loan from the physician to the hospital to create an ownership or investment interest in the hospital’s property or a portion of the hospital’s property (subject to a contrary provision in the security instrument or agreement of the parties). Instead, such a transaction is more appropriately analyzed as a compensation arrangement that must satisfy the requirements of an applicable exception if the physician-seller refers DHS to the hospital-purchaser. We have modified § 411.354(b)(3), accordingly. We continue to believe that loans or bonds secured by, or otherwise linked to, the revenue of a department or other discrete hospital operations would be considered an ownership interest in a part of a hospital. Such interests would not qualify for protection under the whole hospital exception in § 411.356(c)(3).

Comment: A commenter objected to the treatment of bonds as an ownership interest in § 411.354(b)(1) and suggested that there should be an exception for bonds issued by a tax-exempt entity that has a non-participatory interest. For example, an ownership interest should not include a bond issued by a tax-exempt entity if interest is not calculated on the earnings of the institution.

Response: Section 1877 of the Act includes as a “financial relationship” both ownership *and* investment interests, except for those specifically excluded under sections 1877(c) and (d) of the Act. Section 1877 of the Act provides that ownership or investment interests can be through equity, debt, or other means. Because bonds are an investment interest based on debt, the purchase of bonds (regardless of whether the issuing entity is tax-exempt) creates an ownership or investment interest for purposes of the physician self-referral law.

Comment: One commenter stated that some physicians were interpreting improperly the language in the Phase I preamble regarding the exclusion of any interest in a retirement plan from the definition of “ownership or investment interest” in § 411.354(b)(3). According to the commenter, some physicians are using retirement plans to purchase DHS entities to which they refer patients for DHS. The commenter requested clarification of our position.

Response: We agree with the commenter that the purchase of ownership interests in DHS entities by physicians through their retirement funds is inconsistent with the statutory intent. In addition to the information provided by this commenter, we have

heard anecdotally that some physicians are purchasing ownership interests in DHS entities through their retirement plans. In the CY 2008 Physician Fee Schedule notice of proposed rulemaking (72 FR 38122), we proposed revisions to § 411.354(b)(3) to address the issue of ownership in a retirement plan. We may finalize that proposal, or a similar change to the regulation, in a future rulemaking. We caution that, depending on the facts, arrangements involving a DHS entity owned through a physician’s retirement plan may be part of an indirect compensation arrangement between the referring physician and the DHS entity (pursuant to § 411.354(c)) that would need to satisfy the requirements of the exception in § 411.357(p) for indirect compensation arrangements. In many cases, the referring physician would receive compensation from the retirement plan that takes into account the referrals to the DHS entity owned by the retirement plan. The arrangements described by the commenter are also problematic under the anti-kickback statute.

Comment: A commenter asked whether a guaranty of a loan constitutes an ownership interest in the debtor and, if so, what exception would be available.

Response: A guaranty does not create an ownership interest, but a guaranty usually creates a compensation arrangement between the guarantor and the debtor.

B. Compensation

Phase II discussed at some length the definition of an indirect compensation arrangement. Some commenters on the Phase II rule requested further clarification, particularly regarding—

- The treatment of an indirect compensation arrangement;
- The relationship between the definition of “indirect compensation arrangement” and the exception for indirect compensation arrangements; and

- The relationship between the exception for indirect compensation arrangements and other exceptions.

Many commenters sought clarification regarding the application of the indirect compensation arrangement definition in the context of financial arrangements in which a group practice was interposed between the entity furnishing DHS and the referring physician. According to some commenters, in most of these arrangements, there would not appear to be an indirect compensation arrangement within the meaning of the regulation, because the physician’s compensation from the group practice would likely be based on his or her

productivity in the group practice, and not tied to referrals to the DHS entity with which the group practice has a financial arrangement. Other commenters stated that they continued to find the definition difficult to understand and apply.

In Phase II, we specifically solicited comments with respect to whether we should permit physicians to “stand in the shoes” of their group practices for purposes of determining whether they have a direct or indirect compensation arrangement with a DHS entity (69 FR 16060). This Phase III final rule includes new provisions in § 411.351 and § 411.354 that address compensation arrangements in which a group practice (or other “physician organization,” as newly defined at § 411.351) is directly linked to the physician in a chain of financial relationships between the referring physician and a DHS entity. Under the Phase I and II regulations, such arrangements did not fit in the definition of a direct compensation arrangement (66 FR 868, 69 FR 16059–16060); rather such arrangements would have been analyzed under the as “indirect compensation arrangements” under § 411.354(c)(2). If an arrangement meets the definition of an “indirect compensation arrangement,” it must comply with the exception for indirect compensation arrangements at § 411.357(p) if the physician refers DHS to the entity.

This approach creates two issues. First, industry representatives have claimed that resorting to the indirect compensation arrangements definition and exception adds an unnecessary step when determining compliance with the physician self-referral prohibition. These parties believe that it would be easier, more efficient, and consistent with the purposes of the physician self-referral law to examine the relationship between the hospital and the group practice for compliance with a physician self-referral exception. They urge that a referring physician should “stand in the shoes” of his or her group practice, which acts on behalf of its physician members and contractors. This would, in turn, enable the parties to analyze the arrangement between the DHS entity and the group practice (for example, a lease of office space, personal service arrangement, or fair market value arrangement) under the various direct compensation arrangements exceptions, without using the indirect compensation arrangements definition or exception. We agree.

Second, we are concerned about reports that parties may be construing the definition of an indirect compensation arrangement too

narrowly, resulting in determinations that arrangements that involve financial incentives for referring physicians fall outside the ambit of the physician self-referral law. In particular, we are concerned that arrangements between DHS entities and group practices are often viewed as outside the application of the statute. The new “stand in the shoes” provisions should close this unintended loophole by treating compensation arrangements between DHS entities and group practices as if the arrangements are with the group’s referring physicians. This approach incorporates a commonsense understanding of the relationship between group practices and their physicians. Thus, if a DHS entity leases office space to a group practice, the lease will be deemed to be a direct compensation arrangement with each physician in the group practice, and the lease will need to fit in the exception for rental of office space in § 411.357(a) if the DHS entity wants to submit claims for DHS referrals from those physicians. For purposes of the “stand in the shoes” provision, we are including in the definition of “physician organizations,” in whose shoes the referring physician will stand, the referring physician’s professional corporation, physician practice, or group practice.

Specifically, under the new provision, a physician is deemed to have a direct compensation arrangement with an entity furnishing DHS if the only intervening entity between the physician and the DHS entity is his or her physician organization. In addition, for purposes of the definition of “indirect compensation arrangement,” a physician will be deemed to stand in the shoes of the physician organization with which he or she has a direct financial relationship (that is, the physician organization with which he or she is directly linked). When a physician stands in the shoes of his or her physician organization, he or she will be deemed to have the same compensation arrangement (with the same parties and on the same terms) as the physician organization has with the DHS entity. We have included language in the regulations in § 411.354(c)(3)(i) to make clear that “parties” refers to the physician organization and all of its physician members, employees, and independent contractors. In the preceding example, the arrangement for the rental of office space would need to satisfy all of the requirements of the exception in § 411.357(a), including, for example, the requirement that the rental charges not take into account the volume or value of referrals or other

business generated between the parties. The “parties” to the arrangement would be the hospital and the group practice, including all members, employees, and independent contractors of the group practice. Thus, if the lease arrangement takes into account referrals or other business generated by the group practice (or any of its physicians) the arrangement will not be protected.

We are mindful that many existing arrangements involving relationships with an interposed physician organization between the DHS entity and the referring physician, like the one discussed in the example above, may have been properly structured to comply with the indirect compensation arrangements exception in § 411.357(p). It is not our intent to require that those arrangements be reexamined and revised to comply with a direct compensation arrangements exception. Except as provided below, as of the effective date of this Phase III final rule, all compensation arrangements must be analyzed under the “stand in the shoes” provisions in § 411.354 to determine what type of compensation arrangement exists (direct or indirect) and what corresponding exceptions might be available. However, arrangements that were entered into prior to the *publication* date of this Phase III final rule and that satisfied the requirements of the indirect compensation arrangements exception in § 411.357(p) on the date of the *publication* of this Phase III final rule need not be amended during the original term of the arrangement or the current renewal term (that is, the renewal term the arrangement is in on the date of *publication* of this Phase III final rule) to comply with the requirements of another exception. Those arrangements may continue to use the exception in § 411.357(p) during the original or current renewal term of the agreement as if the “stand in the shoes” doctrine does not apply.

We are not making any changes at this time to the treatment of arrangements that, after application of the “stand in the shoes” provision, still do not meet the definition of a direct compensation arrangement. Those arrangements will continue to require analysis under the indirect compensation arrangements definition. In other words, arrangements involving an intervening entity other than a physician organization (for example, a chain that runs DHS entity to management company to referring physician) or involving more than one intervening entity (for example, a chain that runs DHS entity to management company to group practice to referring physician) would continue to be

analyzed under the Phase I and II rules for indirect compensation arrangements and the indirect compensation arrangements exception. Although we remain concerned that arrangements that interpose such entities are subject to abuse, we believe that we would benefit from additional public input on the best way to apply a “stand in the shoes” rule to these indirect relationships. We note that an arrangement that may not qualify as either a direct or an indirect compensation arrangement for purposes of the physician self-referral statute may still be suspect under the anti-kickback statute.

We believe that this new provision will address the concerns raised in the comments, including comments discussed below in section VI.B, as well as simplify compliance with the physician self-referral regulations generally. Our responses to specific comments are discussed below.

Comment: A number of commenters requested further clarification, for purposes of the indirect compensation arrangement definition, regarding the circumstances under which compensation received by a physician may “otherwise reflect” the volume or value of the physician’s referrals to an entity furnishing DHS. Specifically, these comments addressed situations in which the physician has a direct financial relationship with an “intervening entity” that, in turn, has a direct relationship with the DHS entity to which the physician refers patients for DHS. Several commenters believed that payments by a hospital to a group practice for the recruitment of a physician should not implicate the general prohibition with respect to referrals made by physicians in the group other than the recruited physician, provided that the physicians in the group are not compensated based on the volume or value of their referrals to the hospital making the recruitment payment. Another commenter stated that, if we interpret the “otherwise reflect” language to mean that a fixed payment may “reflect” the volume or value of referrals if that payment exceeds fair market value, we should state that clearly. However, the commenter noted that such an interpretation would be very problematic, because the volume and value standard is critical to many of the statutory and regulatory exceptions.

Response: First, in Phase II, we clearly stated that fixed compensation (that is, one lump payment or several individual payments aggregated together) can take into account or otherwise reflect the volume or value of referrals (for

example, if the payment exceeds the fair market value for the items or services provided) (69 FR 16059). Whether the compensation does, in fact, take into account or otherwise reflect the volume or value of referrals will require a case-by-case determination based on the facts and circumstances.

Many of the commenters’ concerns regarding indirect compensation arrangements involving payments to group practices will become moot, given our decision to adopt a “stand in the shoes” policy, as described above. Many arrangements will need to satisfy a direct exception, and the group practice’s method of compensating a physician will be irrelevant for purposes of determining compliance with an exception.

Comment: Several commenters described financial arrangements between DHS entities and group practices that did not meet the definition of an indirect compensation arrangement. The commenters requested confirmation that, if there is no direct or indirect financial relationship (as defined in the regulations) between a DHS entity and a physician, section 1877 of the Act is not implicated.

Response: Section 1877 of the Act prohibits only referrals from a physician to entities furnishing DHS with which the physician (or an immediate family member) has a financial relationship as defined at § 411.354.

We believe that the commenters’ inquiries are addressed by the modifications we are making in this Phase III final rule regarding the treatment of certain compensation arrangements between entities furnishing DHS, group practices, and physicians in those group practices. Specifically, as discussed above, we are adding new provisions in § 411.354 to treat a physician as “standing in the shoes” of his or her group practice or physician organization. Conceptually, this new provision has the effect of treating many compensation arrangements that previously would have been treated as indirect compensation arrangements as direct compensation arrangements and requiring them to satisfy the requirements of an exception for direct compensation arrangements. It also has the effect of treating some arrangements that may not previously have met the definition of either a “direct compensation arrangement” or an “indirect compensation arrangement” as a direct compensation arrangement for which an exception is needed. As many commenters to Phase II recognized, indirect compensation arrangements are

clearly subject to the physician self-referral prohibition.

Comment: One commenter sought clarification concerning the interplay between the use of the “volume or value” standard in the definition of an indirect compensation arrangement and the exception for indirect compensation arrangements. Specifically, the commenter asked how any indirect compensation arrangement could satisfy the exception’s requirement that the arrangement not take into account the volume or value of referrals “in any manner,” given that, by definition, the compensation must vary with, or otherwise reflect, the volume or value of referrals.

Response: In Phase II, we responded to a similar comment. In that rule (69 FR 16069), we stated:

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.

In short, the definition looks to the aggregate compensation (that is, compensation that combines each individual payment under the arrangement), whereas the exception looks at individual payments without aggregating them.

Comment: One commenter asked that we clarify that the conversion of a direct compensation arrangement that does not meet a direct compensation arrangements exception into an indirect compensation arrangement that meets the indirect compensation arrangements exception is not a prohibited circumvention scheme.

Response: We are unclear about the exact nature of the arrangements described by the commenter. If an

arrangement between a referring physician (or immediate family member) and a DHS entity meets the definition of an "indirect compensation arrangement" and, in fact, satisfies the requirements of the indirect compensation arrangements exception in § 411.357(p), referrals made between the referring physician (or immediate family member) and the DHS entity are not prohibited. The arrangement must satisfy the exception in operation, not just on the face of the documentation. Efforts to circumvent improperly the statute in any form may evidence improper intent for purposes of the physician self-referral statute, which may be relevant to enforcement actions for civil monetary penalties and false claims if the financial arrangement does not satisfy the requirements of an exception. Moreover, such efforts are also relevant in analyzing the intent of the arrangement for purposes of the anti-kickback statute. We note that the indirect compensation arrangements exception includes a condition that the arrangement not violate the anti-kickback statute. In addition, arrangements that interpose a leasing or other entity between the DHS entity and the referring physician may involve illegal kickbacks, even if they do not come within the definition of an indirect compensation arrangement.

Comment: A hospital association asserted that some hospitals collect information regarding physicians' financial relationships for purposes of monitoring conflicts of interest and suggested that we not use such information in determining whether a DHS entity satisfies the knowledge criteria in § 411.354(c)(2)(iii) for purposes of the indirect compensation arrangements definition.

Response: Any information in the possession of a hospital may be relevant in assessing whether the hospital knew or had reason to know of an indirect financial relationship involving a referring physician.

Comment: A commenter requested clarification of the example in Phase II regarding an indirect financial relationship involving a physician who has an ownership interest in a hospital that contracts for services with a clinical laboratory to which the physician refers (69 FR 16060). The commenter questioned our analysis, asserting that the hospital would not be receiving compensation that would vary with the volume or value of referrals, because the hospital would be paying for services furnished. The commenter requested further clarification.

Response: As we stated in Phase II, the arrangement referenced by the

commenter normally would not create an indirect compensation arrangement. Absent unusual circumstances, the hospital would not receive aggregate compensation that reflects the volume or value of referrals because the hospital would not be receiving any compensation from the clinical laboratory (assuming the contracted charges for the laboratory services are at fair market value) (69 FR 16060). However, if the laboratory charged the hospital less than fair market value for its services (resulting in remuneration to the hospital), the arrangement could meet the definition of an indirect compensation arrangement between the referring physician and the laboratory (depending on the facts and circumstances). The arrangement would not satisfy the requirements of the indirect compensation arrangements exception because payments for the laboratory services were not at fair market value.

C. Special Rules on Compensation

Section 411.354(d) sets forth rules regarding several key terms, including "set in advance," "the volume and value of referrals," and "other business generated between the parties." These terms are used in many of the compensation arrangements exceptions. In addition, § 411.354(d)(4) provides that, in certain circumstances, it is permissible for a physician's compensation from an employer, or under a managed care or other contract, to be conditioned on referrals to particular entities, notwithstanding the general ban in many exceptions on compensation that takes into account the volume or value of referrals.

In Phase I, we provided that compensation would be considered "set in advance" if the aggregate compensation or a time-based or per-unit of service-based amount is set in advance in the initial agreement in sufficient detail so that it can be effectively verified (66 FR 959). In Phase II, we modified the special rule to provide that compensation would also be considered "set in advance" if the specific formula for calculating the compensation is set out in an agreement between the parties before the furnishing of the items or services, and the formula is set forth in sufficient detail so that it can be effectively verified and is not changed during the course of the agreement in any manner that reflects (or takes into account) the volume or value of referrals or other business generated. The principal impetus for deeming formula-based compensation to be "set in advance" came from comments from associations

representing physicians that urged us to accommodate common percentage compensation arrangements. This Phase III final rule retains flexibility for utilizing unit-based and percentage-based compensation formulae for arrangements.

In Phase I, we stated that unit-based compensation would be deemed *not* to take into account "the volume or value of referrals" if the compensation is fair market value and does not vary during the course of the arrangement in any manner that takes into account DHS referrals (66 FR 876). Similarly, in Phase I, we stated that unit-based compensation would be deemed *not* to take into account "other business generated between the parties" if the compensation is fair market value and does not vary during the course of the arrangement in any manner that takes into account other business generated by the referring physician, including private pay health care services (66 FR 877). We made no changes in Phase II with respect to either the "volume or value" or "other business generated" deeming provisions.

The Phase I special rules on compensation permitted entities furnishing DHS to condition physician compensation in certain circumstances on the physician's compliance with referral restrictions, if certain conditions were satisfied. Phase II clarified that the required referral provision applies to employment, managed care, and personal service arrangements only, and set forth new requirements specifying that: (1) the required referrals must relate solely to the physician services covered by the arrangement; and (2) the referral requirement must be reasonably necessary to effectuate the legitimate purpose of the compensation arrangement (69 FR 16069). In this Phase III final rule, we are amending the regulatory text in § 411.354(d)(4) to include expressly contracts for personal services.

Comment: Two commenters sought clarification that percentage-based compensation arrangements, the methodologies of which were fixed at the outset of the contract and did not vary during the term of the agreement, would satisfy the "set in advance" standard in § 411.354(d)(1) and be deemed not to take into account the "volume or value" of referrals or "other business generated between the parties" pursuant to § 411.354(d)(2) and (d)(3), respectively. One commenter requested that the text of § 411.354(d)(2) and (d)(3) be revised to reference percentage-based compensation specifically. Another commenter asked if compensation based on a percentage of collections satisfied

the requirements of the regulation, and another commenter asked about compensation that includes a percentage of the net revenues of a business unit for which the physician is responsible.

Response: To satisfy the requirements of many compensation arrangements exceptions, compensation must be “set in advance,” consistent with fair market value, and not take into account the volume or value of referrals or other business generated by the referring physician.

The first two commenters are correct that, under the Phase II special rule in § 411.354(d), percentage-based compensation arrangements can be considered “set in advance” if the methodology is fixed at the outset of the contract with sufficient specificity and not changed during the course of the agreement in a manner that reflects referral volumes or other business generated.

With respect to the comments about percentage of collections and percentage of revenues compensation methodologies, such methodologies may be able to meet the “set in advance” test, depending on the facts. However, such compensation arrangements must also meet the other terms of a relevant exception, such as the terms excluding compensation that takes into account the volume or value of referrals or other business generated between the parties. This would involve, among other things, testing the arrangements against the deeming provisions in § 411.354(d)(2) and § 411.354(d)(3) related to “volume or value of referrals” and “other business generated between the parties”; these deeming provisions apply only to unit-based compensation and require that unit-based compensation be fair market value and unrelated to referrals. We cannot determine based on the facts provided whether the arrangements would comply with an exception. We are not persuaded that § 411.354(d)(2) and (d)(3) should be revised to reference specifically percentage-based compensation arrangements.

Comment: Three commenters objected to § 411.354(d)(4), which provides that a physician’s compensation from an employer or under a managed care or other contract may be conditioned on referrals to particular entities in certain circumstances. Two of the commenters also objected to our response to a comment in Phase II that stated that a hospital may require its employees to refer patients to its home health agency if the requirements in § 411.354(d)(4) are satisfied (69 FR 16089). According to all three commenters, § 411.354(d)(4)

conflicts with section 4321 of the Balanced Budget Act of 1997 (BBA 1997), which amended section 1861(ee)(2) of the Act, and which relates to hospitals’ obligations under the discharge planning process to patients in need of home health services. Section 1861(ee)(2) of the Act requires the Secretary to develop guidelines and standards for the discharge planning process in order to ensure a timely and smooth transition to the most appropriate type of setting for post-discharge care. Section 4321 of BBA 1997 amended section 1861(ee)(2) of the Act to require, among other things, that the discharge plan advise the patient of participating home health agencies that serve the area in which the patient resides and that it identify any home health agency to which the patient is referred in which the hospital has a disclosable financial interest.

One commenter stated that allowing an entity to condition employment on an agreement to refer patients to a particular provider may implicate the Federal anti-kickback statute, and may encourage a violation of Federal and State antitrust laws or State unfair trade practices laws. The commenter suggested that we delete § 411.354(d)(4).

Response: Section 411.354(d)(4) does not conflict with the requirements of section 1861(ee)(2) of the Act, as amended by section 4321 of BBA 1997. Under section 4321 of BBA 1997, as part of the discharge plan, a hospital is required to provide a patient needing home health services or skilled nursing facility services a list of local home health agencies or skilled nursing facilities, as appropriate. If, after being provided the list, the patient expresses a choice as to the particular provider from which he or she wishes to receive treatment, the hospital and the patient’s treating physician are required to honor that choice. Nothing in § 411.354(d)(4)(iv) permits a physician and the employing or contracting entity to override a patient’s choice of provider. To the contrary, § 411.354(d)(4)(iv) affirmatively requires that the arrangement between the physician and the entity honor a patient’s choice. Section 411.354(d)(4)(iv) requires that the arrangement must provide that the physician is not obligated to refer to a particular provider, practitioner, or supplier 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. Section 411.354(d)(4)(v) further

provides that the requirement to make referrals to a particular provider, practitioner, or supplier must relate solely to the physician’s services covered by the scope of his or her employment or contract.

Whether an arrangement implicates the anti-kickback statute is a matter for the Department of Justice (DOJ) and the OIG. Arrangements that include referral requirements may implicate the anti-kickback statute and should be closely scrutinized to ensure that no purpose of the compensation is to induce or reward referrals. An arrangement that fully complies with the requirements of § 411.354(d)(4), however, does not necessarily raise concerns under Federal and State antitrust or unfair trade practices statutes. Accordingly, we are not persuaded that the potential for implication of the anti-kickback statute or the Federal and State antitrust laws noted by the commenters warrants withdrawal of § 411.354(d)(4).

Comment: Commenters asked whether an agreement between an entity furnishing DHS and a referring physician could be amended during the first year of the agreement and still satisfy the “set in advance” requirement. According to one commenter, the definition of “set in advance” implies that an amendment is permissible, provided that the amendment is not related to the volume or value of referrals or other business generated between the parties. According to the commenter, the implication is that any number of amendments for other, *bona fide* reasons is permissible.

Response: The commenter is correct that amendments are permissible under the “set in advance” definition if they are made for *bona fide* reasons unrelated to the volume or value of referrals or other business generated between the parties. However, parties must still satisfy all requirements of an exception, including any requirements bearing on amendments of agreements. (See discussion in section IX.A below.)

VII. General Exceptions to the Referral Prohibition Related to Both Ownership and Compensation—§ 411.355

A. Physician Services

Section 1877(b)(1) of the Act specifies that the general prohibition does not apply to physician services (as defined in section 1861(q) of the Act) that are furnished: (1) Personally by another physician in the same group practice as the referring physician; or (2) under the supervision of another physician in the same group practice as the referring physician. In Phase I, we interpreted the

exception to apply to referrals to, or physician services supervised by, a "member of the group practice" or an independent contractor who qualifies as a "physician in the group practice" as defined at § 411.351 (69 FR 879). We made no changes to this exception in Phase II. In this Phase III final rule, we are making no substantive modifications to this exception; however, we are deleting § 411.355(a)(3), which incorrectly suggests that diagnostic tests are "incident to" services. As we clarified in the CY 2003 Physician Fee Schedule final rule published December 31, 2002, any diagnostic service that has its own benefit category cannot be billed as an "incident to" service (67 FR 79994). In addition, § 411.355(a)(3) is repetitive of § 411.355(a)(2) and, therefore, is unnecessary.

Comment: One commenter suggested that we amend the physician services exception by deleting from § 411.355(a) "physician in the same group practice" (as defined at § 411.351) from among the types of physicians who can be the "referring physician." According to the commenter, this change would clarify that referrals within a group practice to independent contractor pathologists who perform services for the group in off-site "pod labs" are impermissible under the physician services exception. According to the commenter, the development of the concept of "physician in the group practice" was not intended to allow group practices simply to refer to independent contractors for whose services the group could then bill on reassignment.

Response: The physician services exception in section 1877(b)(1) of the Act and § 411.355(a) enables group practice physicians to make referrals within their group practices for physician services that are DHS and that are performed or supervised by either a member of the group practice or by a "physician in the group practice." A "physician in the group practice" is considered to be in the group practice only when he or she is performing services in the group practice's facilities. Accordingly, although professional services performed by a member of the group practice may be provided on or off the group practice's site for purposes of this exception, professional services performed by an independent contractor physician must be performed in the group practice's facilities. Thus, the exception is not applicable to services provided by independent contractors in off-site locations that are not group facilities.

However, we do not believe that it is appropriate to ban group practices from referring to any independent contractor

physician. We appreciate the commenter's concerns regarding independent contractor pathologists who perform services for the group practice in off-site "pod labs" and continue to study the issue. At this time, we decline to make the change to the physician services exception requested by the commenter. We note that, in addition to physician self-referral considerations, the provision of off-site services by group practices raises significant concerns under the anti-kickback statute.

B. In-office Ancillary Services

The in-office ancillary services exception is one of the most important exceptions to the physician self-referral prohibition. Generally, it permits a physician or group practice to order and provide DHS, other than most durable medical equipment (DME), in the office of the physician or group practice, provided that the DHS is truly ancillary to the medical services furnished by the group practice. The statutory exception has four main components—

- The *nature* of the DHS;
- The *personnel* who perform or supervise the DHS;
- The *location* where the DHS are provided; and
- The *manner* in which the DHS are billed.

The Phase I rule interpreted the statutory provision by permitting great flexibility in the provision of ancillary services in the "same building" (as defined at § 411.351) where a physician or a group practice routinely provides the full range of their medical services, while limiting the availability of the "centralized building" (as defined at § 411.351) option to premises that are used on an exclusive and full-time basis. With respect to the other requirements, the Phase I rule clarified the types of DHS that could be provided under the exception and relaxed the supervision requirements by incorporating the Medicare coverage and payment supervision rules and permitting independent contractor physicians to provide supervision on a group practice's premises.

In response to public comments urging a more "bright-line" test, Phase II revised the criteria for determining when services are furnished in the "same building" where the physician or group furnishes the full range of their medical services. Under the revised location requirement, DHS qualify for the exception if they are furnished in the "same building" in which—

- The referring physician or his or her group practice has an office that is normally open to patients at least 35

hours per week, and the referring physician or one or more members of the referring physician's group practice regularly practices medicine and furnishes physician services to patients in that office at least 30 hours per week; or

- The referring physician or his or her group practice has an office that is normally open to patients at least 8 hour per week, the referring physician regularly practices medicine and furnishes physician services to patients in that office at least 6 hours per week, and the patient receiving the DHS usually receives physician services from the referring physician or members of the referring physician's group practice at this location; or

- The referring physician or his or her group practice has an office that is normally open to patients at least 8 hours per week, 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, and the referring physician is present and orders the DHS during a patient visit on the premises or a member of the referring physician's group practice is present while the DHS are furnished.

In each of the three alternative tests, the minimum hourly requirement for furnishing physician services 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.

We received numerous comments on aspects of the in-office ancillary services exception. We are making no substantive changes to the in-office ancillary services exception. We respond to issues of concern to the commenters below.

We also received a large number of comments from physical and occupational therapists and groups representing physical and occupational therapists objecting to the in-office ancillary services exception, asserting that the exception has a detrimental effect on their practice. The in-office ancillary exception is a statutory exception and we have no discretion to eliminate the exception as requested by these commenters. However, we may propose additional changes to the exception in a future rulemaking.

Comment: Several commenters requested further guidance regarding the amount of physician services that would be considered unrelated to the furnishing of DHS for purposes of satisfying the requirement that at least

“some” physician services furnished in the same “building” are unrelated to the furnishing of DHS.

Response: For the reasons previously set forth in Phase II, we decline to provide a quantitative measure of “some” non-DHS (69 FR 16073). The critical factor is that the premises are used for the regular provision of the group practice’s physician services, even if on a part-time basis, with respect to the requirements in § 411.355(b)(2)(i). In evaluating whether “some” physician services unrelated to DHS are performed in the building, we will take into account the nature of the group’s overall practice (for example, the specialties of the group’s physicians) and the referring physician’s full range of practice. Creating a satellite office that appears to satisfy the “same building” requirements, but in fact is merely a sham arrangement, will result in claims denial. For example, renting office space part-time in a freestanding imaging facility purportedly to provide physician services unrelated to DHS at the facility location would be considered a sham if few or no such services were actually contemplated or provided. In addition, a part-time arrangement cannot meet the centralized building test. As we have noted in other contexts, the operation of an arrangement, not its form on paper, is determinative. Thus, for purposes of the in-office ancillary services exception, all of the conditions related to supervision, location, and billing must be strictly satisfied with respect to each claim for DHS submitted to the Medicare program.

Comment: A physician professional association requested clarification regarding whether the requirements relating to the quantity and type of physician services necessary to satisfy the “same building” requirement can be met by including services provided to patients physically present in remote locations via telemedicine. Specifically, the commenter requested “additional guidance * * * for practitioners with offices in rural locations in which they may not be physically present but nonetheless provide the requisite amount and types of care.”

Response: We assume that the comment pertains to the situation in which a patient is present in one location and a physician, who is present in another location during an appointment with the patient, orders an item or service that he or she wishes to be furnished in the office in which the patient is located. We do not consider the ordering physician to be located in the rural office with the patient for purposes of satisfying any of the “same

building” tests in § 411.355(b)(2)(i). Rather, the physician’s time spent performing telemedicine services is counted for purposes of the “same building” requirement as time spent in the location where the physician is physically present. However, there are three alternate methods for meeting the “same building” test that provide considerable flexibility, even in situations where physicians provide some services via telemedicine. For example, in the case of a referring physician who is a member of a group practice, time spent by other physician members of the group at the patient’s location would count toward the “same building” requirement.

Comment: A commenter stated that it appreciated Phase II’s added flexibility of the three alternative tests for determining whether services furnished in the “same building” meet the requirements of the in-office ancillary services exception. The commenter stated, however, that it was concerned that requiring physician presence, either by the referring physician when ordering, or by a member of the group practice when furnished, may be too onerous for some group practices. According to the commenter, it may be difficult for a group practice to distinguish its operations as clearly meeting one test or another, as well as to track and document its compliance with the alternative tests.

Response: We believe that it should not be difficult for a group to distinguish and document the nature of the services furnished by the physicians at its various locations. To the extent that some additional complexity was added by Phase II, it is a necessary consequence of allowing additional flexibility through the three alternative tests.

Comment: One commenter asked for further guidance on physicians who provide DHS to their patients in a shared space in the same building. Specifically, the commenter asked whether the physicians could use simultaneously the facilities (for example, an imaging suite, clinical laboratory, or physical therapy office) and simply share the costs and administration of the DHS without having to separately lease the facilities for specific blocks of time determined in advance.

Response: A physician sharing a DHS facility in the same building must control the facility and the staffing (for example, the supervision of the services) at the time the designated health service is furnished to the patient. To satisfy the in-office ancillary services exception, an arrangement must

meet all of the requirements of § 411.355(b), not merely on paper, but in operation. As a practical matter, this likely necessitates a block lease arrangement for the space and equipment used to provide the designated health service. Shared facility arrangements must be carefully structured and operated (for example, with respect to billing and supervision of the staff members who provide DHS in the facility). We note that common per-use fee arrangements are unlikely to satisfy the supervision requirements of the in-office ancillary services exception and may implicate the anti-kickback statute.

Comment: Several commenters strongly criticized the centralized building prong of the in-office ancillary services exception. They requested that the rule be changed to require, in addition to full-time use of the facility, that the arrangement meet a “commercially reasonable” test. According to the commenters, the Phase II rule permits numerous abusive arrangements that are designed solely to permit group practices and physicians to refer and bill for DHS that section 1877 of the Act would otherwise prohibit. Commenters objected to group practices developing satellite DHS facilities, sometimes in different states, specifically to capture ancillary income. Several commenters identified “condominium” pathology laboratories that rent space to urology groups as the types of abusive arrangements that are proliferating. On the other hand, one commenter complained that the requirement that the centralized building be occupied exclusively by the group practice is too restrictive.

Response: Section 1877 of the Act permits group practices to furnish DHS in a centralized building. However, we recognize that part-time, shared, off-site facilities are readily subject to abuse. To address this obvious potential for abuse, the Phase I final rule included the requirement that a centralized building be used on an exclusive basis (66 FR 881). In the CY 2007 update to the physician fee schedule, we proposed additional requirements for the centralized building test (71 FR 49056–49057). We will address those proposals in a separate rulemaking. In the meantime, we caution parties to arrangements such as those described by the commenters that, as with shared facilities in the same building, off-site arrangements must fully comply with the in-office ancillary services exception in operation, not only on paper. In other words, compliance is required with respect to every DHS claim filed. “Condominium” arrangements are

particularly vulnerable to non-compliance, and staff and operations at the off-site facility should be closely monitored. For example, a supervising physician who is an independent contractor of a group practice must be in the group practice's specific premises at the specific time a designated health service is furnished (and supervised) for a group practice patient. Moreover, these arrangements raise substantial concerns under the anti-kickback statute.

Comment: Several commenters commended us for the flexibility provided by the in-office ancillary services exception. A number of other commenters complained that the exception effectively vitiated the prohibition on physician self-referral.

Response: The in-office ancillary services exception allows a physician to provide DHS to his or her own patients, which may appear to undercut the purpose of the physician self-referral prohibition. Nevertheless, the statutory exception evidences intent by the Congress to permit a physician to furnish DHS to his or her own patients if certain conditions are met. We are considering whether certain types of arrangements, such as those involving in-office pathology labs and sophisticated imaging equipment, should continue to be eligible for protection under the in-office ancillary services exception.

Comment: One commenter requested that we confirm that compliance with the in-office ancillary services exception is not necessary if an arrangement complies with the rural provider exception in § 411.356(c)(1).

Response: Compliance with the in-office ancillary services exception is not necessary with respect to referrals from owners or investors if an ownership or investment interest complies with the rural provider exception in § 411.356(c)(1). As a reminder, the rural provider exception protects ownership and investment interests only; it does not protect compensation arrangements. Thus, if the group practice submits claims for DHS referred by employed or contracted physicians, an exception, such as the in-office ancillary services exception, must apply.

Comment: A commenter suggested that, where group practices or physicians in the same building share DHS facilities, the in-office ancillary services exception should be restricted to clinical laboratory and imaging services that are necessary on an urgent basis.

Response: Without further review, we do not believe that it is appropriate or feasible to restrict the in-office ancillary

services exception as suggested by the commenter. We will continue to monitor the situation to determine whether to propose additional restrictions to safeguard against program or patient abuse.

Comment: One commenter requested that we confirm that a hospital-employed physician would be treated the same as any other sole practitioner for purposes of satisfying the in-office ancillary services exception (that is, whether any non-group practice physician meeting the same requirements of personal supervision or personal performance and location may fit within the exception). The commenter asserted that when the facts are the same (that is, supervision, location, and other requirements are satisfied), it should not matter whether the employer is a group practice or a hospital. The commenter believed that hospitals in States that prohibit the corporate practice of medicine are disadvantaged because they cannot set up a group practice to employ the physician (who, presumably, could utilize the in-office ancillary services exception).

Response: As set forth in section 1877(b)(2) of the Act, the in-office ancillary services exception applies only to certain DHS furnished by a physician or group practice; it does not apply to inpatient or outpatient hospital services billed by a hospital employer. In order to utilize the in-office ancillary services exception, a hospital-employed physician, such as the one described by the commenter, must meet all of the requirements set forth in § 411.355(b). If a hospital-employed physician's referred DHS are billed by the hospital employer, the in-office ancillary services exception would not apply. The hospital would be the entity furnishing the DHS (not the physician or a group practice), and the hospital-employed physician would not meet the billing requirement in § 411.355(b)(3). We are not persuaded to create a similar exception for hospital-employed physicians. We see no disadvantage as described by the commenter. Hospitals may use other exceptions, including the exception for *bona fide* employment relationships, to protect legitimate arrangements with referring physicians.

Comment: One commenter requested clarification that the in-office ancillary services exception did not override our policies on reassignment and purchased diagnostic tests. Another commenter requested clarification that the rules on purchased diagnostic tests and purchased test interpretations were not altered by our implementation of section 952 of the MMA.

Response: The physician self-referral rules do not supersede Medicare payment and billing rules and policies, including rules on reassignment, supervision, or purchased diagnostic tests; however, the physician self-referral rules do affect their application. For example, following enactment of section 952 of the MMA, we amended § 424.80 of our regulations to provide that an independent contractor physician may reassign to an entity his or her right to bill Medicare, regardless of whether the services were performed on the premises of the entity (as required prior to section 952 of the MMA) or off the premises of the entity. However, where the independent contractor physician who wishes to reassign to a DHS entity with which he or she has a financial relationship, it is not enough that the rules on reassignment are met. Rather, the rules on physician self-referral must also be satisfied. For example, where an independent contractor physician wishes to reassign his or her right to receive Medicare payment for DHS to a group practice to which he or she will refer DHS, an exception such as the physician services exception or the in-office ancillary services exception must be met. The services performed by the independent contractor in this example must be performed in the group practice's facilities (see the definition of "physician in the group" at § 411.351).

Conversely, the fact that an arrangement complies with the physician self-referral rules does not negate the relevancy of other rules, such as the rules on reassignment and purchased diagnostic tests. For example, where an independent contractor physician furnishes DHS in a centralized building of a group practice and the other requirements of the in-office ancillary services exception are satisfied, the anti-markup rules would nonetheless apply if the service at issue is a diagnostic test of the type that is covered under the provision at § 414.50 and the physician and the group have effected a valid reassignment (including completing the 855-R).

We are amending § 411.350 to state clearly that nothing in the physician self-referral rules alters a party's obligation to comply with—

- The rules regarding reassignment of claims (§ 424.80);
- The rules regarding purchased diagnostic tests (§ 414.50);
- The rules regarding payment for services and supplies "incident to" a physician's professional services (§ 410.26); or
- Any other applicable Medicare laws, rules, or regulations.

We note that § 424.80 states that nothing in that section alters a party's obligation to comply with the physician self-referral statute and other authorities.

Comment: Commenters asked whether, in order to satisfy the requirements of the in-office ancillary services exception, a physician who is an independent contractor with a group practice must perform DHS supervision services *on the premises* of the group practice, regardless of coverage policies.

Response: For purposes of compliance with the physician self-referral rules, independent contractor physicians are "physicians in the group practice" only when performing services on the group practice's premises, regardless of whether reassignment or coverage rules would allow an independent contractor physician to perform services off the premises of the billing entity. Therefore, in order to satisfy the requirements of the exception, an independent contractor must supervise services *on the premises* of the group practice.

Comment: Section 1877(b)(2)(B) of the Act and § 411.355(b)(3) require that, in order for the in-office ancillary services exception to apply, the services must be billed by one of the following: The physician performing or supervising the service; the group practice of which the performing or supervising physician is a member under a billing number assigned to the group practice; the group practice if the supervising physician is a "physician in the group practice" under a billing number assigned to the group practice; or by an entity that is wholly-owned by the physician or the group practice under the entity's own billing number or under a billing number assigned to the physician or group practice. Two commenters asked for clarification that the billing requirement in the in-office ancillary services exception in § 411.355(b)(3) can be satisfied by an entity (that is, a billing entity) that is wholly-owned by the group members in their individual capacities (as opposed to being owned by the group practice), but structured to mirror the group practice (for example, ownership of the billing entity is contingent on membership in the group practice). According to the commenters, the separate structure is common to avoid tax liability.

Response: We disagree with the commenters. Section 1877(b)(2)(B) of the Act and the corresponding regulations in § 411.355(b)(3)(iv) require that the supervising physician, the referring physician, or the group practice must wholly own the billing entity. The arrangement described by the commenters would not satisfy this

requirement. The regulations make clear that claims submitted by a wholly-owned entity must be submitted under a billing number assigned to the entity or under a billing number assigned to the physician or group practice. Moreover, the arrangement may not comply with our rules on reassignment. Under our longstanding policy, only *individuals* may reassign benefits. If the commenter is, in effect, asking whether a physician member or a "physician in the group practice" is allowed to reassign benefits to the group, which would then reassign benefits to the billing entity, we do not believe that the arrangement would comply with our rules on reassignment. Nothing in the regulations prohibits the use of an independent billing company in an administrative capacity to process and submit claims on behalf of billing physicians or group practices under billing numbers assigned to them.

C. Services Furnished by an Organization (or Its Contractors or Subcontractors) to Enrollees

Section 1877(b)(3) of the Act creates an exception for services provided pursuant to certain Medicare managed care arrangements. In Phase I, we interpreted the provision broadly and updated the references to covered managed care plans in light of changes to the Medicare program. In Phase II, we again expanded the exception, which appears at § 411.355(c), to include Medicaid managed care plans. This Phase III final rule makes no changes to Phase II.

Comment: Comments submitted on behalf of Alaskan tribal health organizations requested that we create an exception for referrals made by physicians under compensation arrangements with tribal health care providers. According to the commenter, the native tribal organizations have assumed much of the responsibility for carrying out the programs of the Indian Health Service. In discharging that responsibility, the tribes have developed a comprehensive, integrated health care system that utilizes primary, secondary, and tertiary caregivers and clinics staffed by employees, independent contracting practitioners, Federal employees, and commissioned officers. The commenter asserted that, because of limited funds, utilization of services is carefully monitored and strictly controlled, giving them many characteristics of managed care organizations. According to the commenter, services are prioritized so that only certain services are covered, and firm policies exist requiring prior authorization for non-emergent care and

notice for emergency care at non-tribal or Indian Health Service facilities. The commenter stated that the tribal health care providers have three principal types of compensation arrangements. First, and most frequently, the providers have physician employees. Second, the providers have personal service arrangements with physicians. Third, the providers enter into agreements with the Indian Health Service under which Federal employees are assigned to work for a specific tribal health program, and under which the providers are responsible for the costs of such employees. The commenter asserts that monitoring and reviewing the myriad compensation arrangements with physicians in the Alaska tribal health network consumes scarce time and financial resources. In light of the system's integration and strong elements of managed care, the commenter urged that referrals in the network be protected.

Response: We agree that many of the arrangements between the Indian Health Service and various Indian nations have many of the characteristics of managed care. However, when Medicare services are furnished, the exception in § 411.355(c) for services furnished to enrollees of a prepaid health plan would not apply. We decline to create an exception at this time to address the commenter's concerns for two reasons. First, we question whether we have the legal authority to expand the exception in § 411.355(c) or to create a new exception without first proposing such an expansion or new exception through a notice of proposed rulemaking. Second, the commenter has not supplied us with an adequate explanation thus far as to why existing exceptions such as those for *bona fide* employment relationships (§ 411.357(c)) or personal service arrangements (§ 411.357(d)) would be insufficient to protect the arrangements at issue. The commenter appears to recognize that these exceptions are available, but states that monitoring and reviewing the compensation arrangements consumes scarce time and financial resources. We believe, however, that the parties should be able to design model structures for the compensation arrangements, which would be applicable for existing and newly hired physicians. Monitoring and reviewing for compliance is necessary and prudent to ensure compliance with the physician self-referral law, other fraud and abuse laws, and other Medicare rules and regulations.

D. Reserved

There is no regulation at § 411.355(d). Section 411.355(d) continues to be “reserved” in this Phase III final rule.

E. Academic Medical Centers

In Phase I, we created a new exception for payments to faculty of academic medical centers that meet certain conditions that ensure that the arrangements pose no risk of fraud or abuse (66 FR 916). The exception required that the referring physician: (1) Is a *bona fide* employee of a component of an academic medical center on a full-time or substantial part-time basis; (2) is licensed to practice medicine in the State(s) in which he or she practices medicine; (3) has a *bona fide* faculty appointment at the affiliated medical school; and (4) provides either substantial academic or substantial clinical teaching services for which the referring physician receives compensation as part of his or her employment relationship with the academic medical center. In addition, the exception required the total compensation paid to the referring physician for the previous 12-month period from all academic medical center components to be set in advance, in the aggregate not exceed fair market value for the services provided, and not be determined in a manner that takes into account the volume or value of any referrals or other business generated within the academic medical center.

Phase II made several changes to broaden the applicability of the academic medical centers exception. We expanded the definition of an academic medical center to allow hospitals or health systems that sponsor four or more medical education programs to qualify as a component of an academic medical center. We revised the exception to include not-for-profit supporting organizations (whose primary purpose is supporting the teaching mission of the academic medical center) as a potential component of an academic medical center. We revised the regulatory text to make clear that the majority of physicians on the medical staff must be on the faculty of an affiliated medical school and that the aggregation of faculty from any affiliated medical school is permitted. We expanded the exception modestly to cover DHS referrals within an academic medical center if the money the academic medical center pays to the referring physician for research is used for teaching services in addition to *bona fide* research (if consistent with the terms and conditions of the grant). To

guard against fraud and abuse, we declined to extend the protection of the exception to DHS referrals to an academic medical center if the academic medical center pays the referring physician for research and the research funds are used for indigent care or community service. Finally, we modified the requirement that the relationship among the components of the academic medical center be set out in a written agreement; the revised provision allows the relationship to be memorialized in multiple writings.

In Phase II, we also added a “safe harbor” provision that deems 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 to be compliant with the requirement in § 411.355(e)(1)(i)(D) that the physician provide “substantial academic services or clinical teaching services.” We also deleted the requirement, formerly in § 411.355(e)(2)(ii), that the faculty practice plan (or plans) be organized as a tax-exempt organization under either section 501(c)(3) or (c)(4) of the Internal Revenue Code.

In Phase II, we made clarifications to the academic medical centers exception, including: (1) that the referring physician may be on the faculty of the affiliated medical school or the accredited academic hospital; (2) that an academic medical center may have more than one affiliated faculty practice plan (and that the faculty practice plans may be affiliated with other components such as the teaching hospital, the medical school, or the accredited academic hospital); (3) that a hospital or health system under § 411.355(e)(2)(i) may be the same hospital that meets the “affiliated hospital” requirement in § 411.355(e)(2)(iii); and (4) that the substantial services test may be met through either academic services or clinical teaching services, or a combination of both. We declined to extend the protection of the exception to services referred by a physician who is not an employee of a component of an academic medical center, where the referring physician does not provide substantial academic services or clinical teaching services (as may be the case with volunteer and primary care physicians), or where the referring physician does not meet the other requirements in § 411.355(e)(1)(i).

This Phase III final rule adopts the Phase II rule with minor clarifications. For example, for purposes of determining whether the majority of physicians on the medical staff consists of faculty members, the affiliated

hospital must include or exclude all physicians holding the same class of privileges at the affiliated hospital.

Comment: One commenter asked us to clarify that the academic medical centers exception protects payments to physicians for the provision of indigent care or community service. The commenter sought an explanation of our statement in Phase II that payments to referring physicians for indigent care or community service may be structured to fit other exceptions. (69 FR 16110–16111.)

Response: Nothing in § 411.355(e) prohibits academic medical centers from compensating faculty members for the provision of indigent care or community service, provided that the funds do not derive from research funding (see § 411.355(e)(1)(iii)(C)); the total compensation paid to the referring physician is fair market value and satisfies the other requirements of § 411.355(e)(1)(ii); and the physician also performs the requisite clinical teaching or academic services under § 411.355(e)(1)(i)(D). The Phase II language referenced by the commenter was in response to a suggestion that we revise the definition of “academic medical center” at § 411.355(e)(1)(iii). Section 411.355(e)(1)(iii) provided that, to qualify as an academic medical center for purposes of the exception, all research grant money paid to a referring physician must be used solely to support *bona fide* research. The Phase II comment suggested that we revise the provision to include the use of *research* money for teaching, indigent care, and community service (as opposed to for *bona fide* research only). (69 FR 16110–16111.) We agreed in part with the commenter and revised the provision in § 411.355(e)(1)(iii) to require that any money paid to a referring physician for research must be used solely to support *bona fide* research or teaching, which are core academic medical center functions. However, we declined to extend the provision to cover the use of research money for indigent care and community service, explaining that research grants can be subject to potential abuse. (66 FR 917.) We note that the academic medical center exception is available for DHS furnished by academic medical centers that pay physicians to provide indigent care and community service, provided that all other provisions of the exception are met and the money used for the payments does not come from research grant funds. If an academic medical center pays a physician using research funds and the payments are used for purposes other than *bona fide* research or teaching, the academic medical

center would not satisfy the conditions of § 411.355(e)(1)(iii), and the exception would be unavailable for any DHS furnished by the academic medical center.

Comment: A commenter stated that the requirement in § 411.355(e)(1)(ii) that the total compensation paid by all components of an academic medical center to the referring physician be “set in advance” was unnecessary. According to the commenter, the flows of money within an academic medical center support the missions of patient care, education, and research, which are the core of any academic medical center. The commenter asserted that the other criteria for meeting the exception provide adequate assurances that abuses will not occur. Because the exception is available only to *bona fide* employees of an academic medical center component, the criteria for compensation should mirror those for the exception for *bona fide* employment arrangements, which does not require that compensation be set in advance.

Response: The commenter misunderstands the purpose of the academic medical centers exception. It is designed to protect compensation received by the physician from *all* components of the center, not only the component with which he or she has an employment relationship. Therefore, although the employment exception may protect the compensation the physician receives from the component that employs the physician, it does not protect the physician’s aggregate compensation. We disagree with the commenter that the “set in advance” requirement for *aggregate* compensation from *all* components of the academic medical center is unnecessary. We believe that it is appropriate to treat physician compensation under the academic medical center exception the same as compensation for independent contractor physicians under the exception for personal service arrangements. (69 FR 16066.)

Comment: One commenter asked that we clarify that the condition in § 411.355(e)(1)(ii), which requires that the total compensation to referring physicians be set in advance, does not require that the actual amount of the compensation be set in advance. The commenter also asked that we confirm its understanding that our use of “total” compensation was intended to reflect that faculty physicians in an academic medical center setting may be paid by more than one component of the academic medical center and that each such payment arrangement must meet each of the requirements of the exception, namely that the

compensation be set in advance, not exceed fair market value for the services provided, and that it not take into account the volume or value of referrals or other business generated by the referring physician within the academic medical center.

Response: The commenter is correct that the actual dollar amount of the referring faculty physician’s compensation need not be set in advance. It is sufficient if the contribution of *each* component of the academic medical center to the aggregate compensation uses a methodology that qualifies under § 411.354(d). The commenter is also correct that, where a physician is paid by more than one component of the academic medical center, *each* such payment arrangement must not take into account the volume or value of referrals or other business generated by the referring physician within the academic medical center. The commenter is incorrect, however, that the exception requires that compensation paid by each component must satisfy a fair market value test. Rather, § 411.355(e)(1)(ii) states that the aggregate (that is, the total from all components) compensation cannot exceed fair market value for the services provided. We have clarified the language of § 411.355(e)(1)(ii).

Comment: An association of medical schools asserted that, due to the numerous and complex criteria of the academic medical center exception, we should provide advisory opinions to entities that submit a request for a definitive opinion as to whether they meet those criteria.

Response: We believe that the criteria set forth in the academic medical centers exception are clear and that most entities should be able to determine whether they qualify as an academic medical center. We believe that an advisory opinion, although appropriate in some circumstances, would normally not be needed. In addition, institutions that do not satisfy the definition of an academic medical center may be able to comply with one or more of the other physician compensation arrangements exceptions.

Comment: A commenter asked for clarification regarding § 411.355(e)(2)(iii), which defines an academic medical center to include an affiliated hospital in which, among other things, “a majority of the physicians on the medical staff consists of physicians who are faculty members.” The regulation provides that any faculty member “may” be counted for purposes of this requirement, including courtesy and volunteer faculty. The commenter sought

confirmation that an affiliated hospital may exclude courtesy staff when determining whether the majority of the physicians on its medical staff are faculty members of the affiliated medical school.

Response: An affiliated hospital may exclude courtesy staff when determining whether the majority of the physicians on its medical staff are faculty members of the affiliated medical school or on the faculty of the educational programs at the accredited affiliated hospital. We are modifying § 411.355(e)(2)(iii) to clarify that, if a hospital elects to include or exclude a physician holding a particular class of privileges (for example physicians holding courtesy privileges), the hospital must include or exclude, respectively, all individual physicians with the same class of privileges at the affiliated hospital when determining whether the majority of the physicians on its medical staff are faculty members of the affiliated medical school or are on the faculty of the educational programs at the accredited academic hospital.

Comment: One commenter stated that the requirement in § 411.355(e)(2)(iii) that faculty members order the majority of hospital admissions is difficult for many accredited hospitals to control and, effectively, renders most community hospitals ineligible for the academic medical center exception. According to the commenter, community hospitals that sponsor four or more approved education programs (and which potentially could constitute an academic medical center) frequently provide substantial services unrelated to those training programs, particularly if there are few other hospitals serving that area.

Response: We believe that the requirement that faculty members order the majority of admissions is a good measurement of a hospital being sufficiently integrated into an academic medical center. As we noted in Phase II, it is important to ensure that the relationship between the components is sufficiently focused on the academic medical center’s core mission (69 FR 16109). The tests for affiliated hospital faculty and admissions set forth in § 411.355(e)(2)(iii) are strong indicators of that core relationship. The academic medical centers exception is designed to supplement—not supplant—other exceptions, such as the exception for *bona fide* employment relationships in § 411.357(c) and the exception for personal service arrangements in § 411.357(d). To the extent that a hospital or other entity cannot take advantage of the academic medical centers exception, it should be able to

structure its legitimate compensation arrangements with physicians to meet another exception.

Comment: One commenter stated that a newly-affiliated hospital might not qualify as an academic medical center because it fails to meet “the two majority tests” in § 411.355(e)(2)(iii) (that is, the majority of physicians on the medical staff are faculty members and the majority of admissions are made by faculty members). According to the commenter, the hospital may execute an academic affiliation agreement under which it increases the number of physicians on its medical staff who are faculty members so that it meets the requirement that a majority of its medical staff are faculty members, but the hospital would not immediately meet the requirement that a majority of admissions are made by the faculty (as the new faculty will begin admitting only upon execution of the agreement). The commenter requested guidance that would clarify when a hospital could rely on the academic medical centers exception in such circumstances.

Response: We disagree that the regulation is unclear as to when a compensation arrangement between a physician and a newly-affiliated hospital will satisfy the academic medical centers exception. We believe that the regulation is clear that all conditions must be met at the time the referral is made. To the extent that the commenter is suggesting that we allow a transition period during which the two majority tests would not apply or would be relaxed, we decline to do so. If an arrangement does not meet the academic medical centers exception, another exception may be available.

Comment: Two commenters asked for clarification regarding the applicability of § 411.357(p), the indirect compensation arrangements exception, in the academic medical center setting. One of the commenters asserted that many academic medical centers have organizational structures that enable them to satisfy the requirements of the exception for indirect compensation arrangements, citing the situation where a referring physician does not have a direct financial relationship with an affiliated hospital. For example, a hospital component of an academic medical center could be an organization separate and distinct from the university that operates the faculty practice plan as a wholly-owned division of the university in connection with the university’s school of medicine. According to the commenter, any financial arrangements between the hospital and the university with respect to the physicians in the faculty practice

plan would be indirect. Moreover, if the physicians were salaried employees of the university, with no compensation paid from the hospital to the physicians, there would be no direct or indirect compensation arrangement within the meaning of the definition at § 411.354(c)(2) if the physician’s compensation did not vary with or otherwise reflect the physician’s referrals to the hospital. According to the commenter, even if this arrangement were construed as being an “indirect compensation arrangement” (which the commenter did not believe was the case), it would qualify for the exception for indirect compensation arrangements in § 411.357(p) if the physician’s compensation were fair market value and not determined in any manner that takes into account the volume or value of referrals or other business generated by the physician for the hospital. The second commenter simply asked that we confirm that the exception for indirect compensation arrangements applies in the academic medical center setting.

Response: The definition of “indirect compensation arrangement” at § 411.354(c)(2) and the exception for indirect compensation arrangements in § 411.357(p) are potentially applicable to arrangements involving academic medical centers and physicians. As we have stated previously and in this Phase III final rule, parties generally may utilize any exception that the arrangement between them satisfies. If the academic medical centers exception applies to the DHS referrals at issue, it would not be necessary for another exception to apply. With respect to the situation described by the commenter, as discussed above, we have revised § 411.354 to clarify the application of the indirect compensation definition at § 411.354(c)(2) and the indirect compensation arrangements exception in § 411.357(p).

F. Implants Furnished by an Ambulatory Surgical Center

In Phase I, we established a new exception in § 411.355(f) for implants furnished by an ambulatory surgical center (ASC) when acting as an entity furnishing DHS. The new exception was intended to allow a physician-owner of an ASC that is not in a rural area (and thus not covered by the rural provider exception) to order and perform surgeries that implant DME, prosthetics, or prosthetic devices that are not reimbursed as part of the composite ASC payment rate. The new exception was necessary because many implantable items are DHS but are not bundled in the ASC composite rate. Without the exception, an ASC (which

is often owned by one or more physicians) would become a DHS entity when it furnishes the implant. We did not make any changes to § 411.355(f) in Phase II, nor are we making any in this Phase III final rule.

Comment: One commenter referenced the discussion in Phase II where we noted that the exception in § 411.355(f) applies only when the implant is billed by the ASC and that, when the physician submits the claim for the implant, the physician is the entity furnishing DHS (69 FR16111). The commenter asked whether the exception in § 411.355(f) applies if the ASC furnishes and submits the claim for the implant procedure, but the physician furnishes and submits the claim for the device.

Response: The exception does not apply in the situation described by the commenter. Under Medicare payment policy (section 10.3–10.4 of the CMS Internet-only Manual, publication 100–04, Claims Processing Manual, Chapter 14 (ambulatory surgical centers)), whenever an implant is performed during an ASC procedure, the provider/supplier (that is, the ASC) must bill for the implanted item. We did not mean to imply that any individual or entity other than the ASC may bill for an item implanted during an ASC procedure.

G. EPO and Other Dialysis-Related Drugs Furnished in or by an End-Stage Renal Disease Facility

Phase I created a new exception in § 411.355(g) for epoetin (EPO) and certain other dialysis-related outpatient prescription drugs furnished in or by an end-stage renal dialysis (ESRD) facility. The drugs that may qualify for this exception were initially identified by CPT and HCPCS codes in Phase I (66 FR963–964), and updates to that list appear on our Web site and in annual updates published in the **Federal Register**. There were no changes to § 411.355(g) in Phase II, nor are we making any in this Phase III final rule.

Comment: A commenter wrote that the list of ESRD drugs in § 411.355(g) was incomplete. The commenter asked that the exception be expanded to include all drugs furnished as part of a dialysis treatment, whether in a home or at a facility. Alternatively, the commenter asked that the exception include by reference our Single Drug Pricer file. [The Single Drug Pricer file is a drug-pricing file used prior to January 1, 2004 that contains the allowable price for each drug covered “incident to” a physician’s service. This includes the allowable price for drugs furnished by independent dialysis facilities that are separately billable

from the composite rate and for clotting factors to inpatients.] The commenter voiced concern that a dialysis center with physician-owners or other financial relationships with physicians would not be able to deliver the same convenient, quality care that could be provided by a center without these relationships.

Response: We believe that the list of ESRD drugs, as updated annually, is complete and that we are acting within the constraints of the statute. Section 1877(h)(6) of the Act specifically includes outpatient prescription drugs as DHS. However, we established a broad exception in § 411.355(g) using our authority under section 1877(b)(4) of the Act, which allows the Secretary to establish an exception if there is no risk of program or patient abuse. We intend for the exception to include drugs that have to be administered at the time of dialysis “that are required for the efficacy of dialysis.” (69 FR 16117.) For the reasons stated in Phase II, we believe that we cannot further expand the list as suggested by the commenter without creating a risk of program or patient abuse (69 FR 16117–16118). Although we do not want to burden Medicare beneficiaries unnecessarily by making them go elsewhere for intravenous drugs, the Congress prohibited physician self-referrals for outpatient prescription drugs, and we are concerned that expanding the list of drugs subject to this exception may lead physicians to order intravenous administration of a drug when oral administration is as effective, or to not choose the most cost-effective drug.

To the extent that individuals or organizations believe that specific drugs should qualify for the exception because they are required for the efficacy of dialysis and must be administered at the time of dialysis, they may contact us. We also note that the list of drugs that qualify for this exception is updated annually in the Physician Fee Schedule, and comments on the list are accepted upon publication of the proposed rule for the Physician Fee Schedule. We note that the Single Drug Pricer file is no longer in use.

H. Preventive Screening Tests, Immunizations, and Vaccines

In Phase I, we created a new regulatory exception for certain preventive screening tests, immunizations and vaccines furnished under circumstances that do not pose a risk of abuse (66 FR 923). The exception requires that: (1) The preventive screening tests, immunizations, and vaccines are subject to CMS-mandated

frequency limits; (2) the arrangement does not violate the anti-kickback statute; (3) the arrangement does not violate any Federal or State law or regulation governing billing or claims submission; and (4) the preventive screening tests, immunizations, and vaccines are covered by Medicare and listed as eligible for this exception on the list of CPT/HCPCS codes. Phase I included a listing of the CPT and HCPCS codes for screening tests that qualify for the exception if all of the other requirements of the exception are satisfied.

In Phase II, we made no major changes to the exception (69 FR 16116). We did, however, decline to expand the exception to protect referrals for diagnostic Pap smears or mammography tests, as we were unpersuaded that these types of referrals would not pose a risk of program or patient abuse. We clarified in Phase II that we recognized that some of the vaccines covered under the exception may be paid by Medicare using a different reimbursement system than the fee schedule required under the exception. To avoid confusion we deleted the requirement that the preventive screening tests, immunizations, or vaccines be reimbursed by Medicare under a fee schedule.

We received no comments to Phase II regarding § 411.355(h) and are making no changes in this Phase III final rule.

I. Eyeglasses and Contact Lenses Following Cataract Surgery

In Phase I, we created a new regulatory exception for eyeglasses and contact lenses following cataract surgery (66 FR 923). The exception requires that: (1) The eyeglasses or contact lenses are provided in accordance with Medicare coverage and payment policies (§ 410.36(a)(2)(ii) and § 414.228, respectively); (2) the arrangement does not violate the anti-kickback statute; and (3) the arrangement does not violate any Federal or State law or regulation governing billing or claims submission.

Phase II made no changes to § 411.355(i) (nor were any comments received on Phase I). We received no comments to Phase II regarding this exception. We are not making any changes to § 411.355(i) in this Phase III final rule.

J. Intra-Family Rural Referrals

Phase II created a new exception in § 411.355(j) for certain referrals from a referring physician to his or her immediate family member or to a DHS entity with which the physician's immediate family member has a financial relationship. The exception

requires that the patient being referred reside in a rural area and that there is no other person or entity available to furnish the referred DHS in a timely manner, in light of the patient's condition, either: (1) At the patient's residence (in the case of home health services or other DHS required to be furnished in the patient's home); or (2) within 25 miles of the patient's residence (in the case of services furnished outside the patient's home). In addition, the exception requires that the referring physician make reasonable inquiries as to the availability of other persons or entities and that the financial relationship does not violate the anti-kickback statute or any other Federal or State law or regulation governing billing and claims submission. We are making one modification to § 411.355(j) in this Phase III final rule. Specifically, we are modifying the exception to include an alternative distance test based on transportation time from the beneficiary's residence.

Comment: One commenter stated that, notwithstanding the exception in § 411.355(j), the prohibition on intra-family referrals leads to unfair results, especially where one of the family members is a general practitioner or surgeon and the other is a pathologist or a radiologist, and the pathologist or radiologist is part of a group of physicians that provides services for local hospital inpatients and outpatients. The commenter asserted that, in these circumstances, the general practitioner or surgeon is unable to refer hospital patients for pathology or radiology services to the family member's group practice. In addition, the commenter stated that a physician should not be prohibited from referring patients to a member of his or her immediate family (for example, a brother or sister) if the referring physician receives no economic benefit from the referral. The commenter suggested that we accept an attestation from the referring physician that he or she receives no economic benefit from referrals to the family member.

Another commenter asserted that CMS should revise the intra-family rural referral exception (or modify the definition of “referral”) to allow a physician to make referrals to an immediate family member (or his or her employer) provided that the immediate family member has an excepted financial arrangement under which the family member does not receive remuneration that takes into account the volume or value or referrals or other business generated by the family member.

Response: Section 1877(a) of the Act prohibits referrals for DHS to entities in cases in which a physician “or an immediate family member of such physician” has a financial relationship with the entity, unless an exception applies. The law does not authorize a case-by-case inquiry into whether the referring physician actually benefits from referrals to entities with which an immediate family member has a financial relationship.

We recognize the commenters’ concerns, but section 1877(b)(4) of the Act allows us to create an exception only if there is no risk of program or patient abuse. We are not expanding the exception in § 411.355(j) in the manner recommended by the commenters because we do not believe that it would be consistent with congressional intent, nor do we believe that we could do so without creating a risk of program or patient abuse.

Comment: One commenter asked that we modify § 411.355(j) to include patients in any medically underserved area or Healthcare Professional Shortage Area (HPSA). The commenter also requested that we modify the exception to permit a referring physician to refer to an immediate family member (or to an entity furnishing DHS with which the immediate family member has a financial relationship) after the referring physician determined, following reasonable inquiry, that there was no other available person or entity to furnish the referred DHS.

Response: The definition of rural is sufficiently broad to encompass many HPSAs and medically underserved areas, and we do not believe that the change suggested by the commenter regarding HPSAs and medically underserved areas is necessary. With respect to the commenter’s second inquiry, we have reconsidered § 411.355(j) as it pertains to the availability of services in a rural area. We believe that a test that takes into account distance, posted speed limits, and weather conditions would be an appropriate alternative to a test that considers only whether a provider is a specific distance from a patient’s home. Therefore, we are modifying § 411.355(j) to permit parties to utilize an alternative test that allows a physician to refer a patient to an immediate family member (or to a DHS entity with which the immediate family member has a financial relationship) for DHS if the DHS cannot be provided otherwise within 45 minutes transportation time from the patient’s home at the time the referral for the DHS is made. We are making no changes to the 25-mile rule in § 411.355(j). Referring physicians are

free to choose either of the tests (that is, 25 miles from the beneficiary’s residence or 45 minutes transportation time from the beneficiary’s residence) when determining whether a DHS referral may be made to an immediate family member under § 411.355(j). However, whichever test the physician chooses must be applied both for purposes of § 411.355 (j)(1)(ii) (determining distance or transportation time from available services) and § 411.355(j)(2) (the physician’s reasonable inquiry as to the availability of persons or entities to provide the needed DHS).

The new alternative test requires a case-by-case analysis of the conditions that exist at the time of the referral for the DHS. Although a bright-line test may be preferred by many physicians, we do not believe that such a test always provides sufficient flexibility to ensure that our beneficiaries receive needed DHS in a timely manner and in a location that is convenient to the beneficiary. The modification to § 411.355(j) would permit some intra-family referrals when the distance to the closest non-family member physician (or entity) is less than 25 miles from the beneficiary’s residence.

We note that, when the new alternative test is utilized, because compliance will be determined on a case-by-case basis, an intra-family referral that is permitted at one time (for example, in the winter months when snow covers mountain roads and limits access) may not be permitted at a different time (for example, in the summer months when roads are clear and a non-family member physician (or entity) is available to provide the needed DHS within 45 minutes transportation time from the beneficiary’s residence). Physicians utilizing the 45 minutes transportation time test should maintain documentation of the information used in determining the transportation time. Resources including websites that provide detailed mileage and drive time (such as Mapquest or MapBlast) and published weather reports (either online or in print, for example, in the newspaper) should be consulted when determining a beneficiary’s transportation time from his or her residence to the location of the available DHS.

Comment: One commenter noted that we stated in Phase II that the exception “does not take into account the quality of other available DHS entities” and that other laws exist to address quality issues. The commenter asserted that this statement suggests that the physician would not be able to refer to an

immediate family member if there is another entity furnishing DHS within 25 miles of the patient’s residence, even if that entity does not participate in the patient’s health plan or has lesser qualifications (for example, no board certification). The commenter requested that we clarify what we meant by this statement.

Response: For the reasons noted in Phase II, we do not believe that it is feasible to craft an objective, qualitative measure in the exception for intra-family rural referrals as suggested by the commenter. As we stated in Phase II, this exception “looks to timely availability of DHS, [but] it does not take into account the quality of other available DHS entities” (69 FR 16084). However, in a situation such as that described by the commenter in which the only entity that can furnish the DHS needed by a beneficiary within 25 miles of or 45 minutes transportation time from the beneficiary’s home does not participate in Medicare, the entity should be treated as if it does not exist. In other words, the beneficiary constructively cannot obtain needed DHS within 25 miles of or 45 minutes transportation time from his or her home.

Comment: We received two comments concerning *urban* hospitals that have exclusive arrangements with a radiology group practice for performing the professional component of radiology services. The commenters were concerned that a physician in the community would not be able to refer patients *to the hospital* for radiology services when the physician’s immediate family member is a member of the group practice with the exclusive arrangement.

The first commenter asserted that the prohibition on referring Medicare patients to immediate family members is a severe hardship for the patients of physicians with immediate family members who are radiologists, radiation therapists, or pathologists, and that many such family situations exist. The commenter noted that a physician could refer a patient to an immediate family member for other types of physician services without implicating the physician self-referral rules and, therefore, it is difficult to understand why radiologists, radiation therapists, and pathologists are treated differently. This commenter recommended that we either not consider the professional component of a service to be a designated health service, or allow referrals if the physician’s immediate family member personally performs the DHS.

The second commenter suggested that we modify the definition of “radiology and certain other imaging services” to permit referrals in the situation described above, or that we modify the definition of “referral” so that the referral in this situation would be deemed a referral to the hospital rather than to the group practice in which the immediate family member practices. The commenter offered what it considered to be program safeguards that could be included in a new exception or a modification of an existing exception or definition.

Response: We note that the comments pertained to situations in which the patient would not be located in a rural area and, thus, the exception in § 411.355(j) for intra-family referrals would not be applicable. We decline to adopt either of the suggestions offered by the first commenter.

We do not believe that it would be consistent with congressional intent to include as DHS only the technical component, and not the professional component, of radiology, radiation therapy, or pathology services. The physician self-referral rules treat radiology, radiation therapy, and pathology services differently than other physician services because section 1877(h)(6) of the Act specifically includes these services, which have a significant professional component, as DHS, whereas other physician services specifically are not subject to the physician self-referral prohibition.

We are not modifying the exception for intra-family rural referrals because we are authorized under section 1877(b)(4) of the Act to create regulatory exceptions only where doing so would pose no risk of program or patient abuse, and we do not believe that the fact that the family member would personally perform the services, by itself, would remove all risk of abuse. For the same reasons, we do not believe that it is appropriate to modify the definition of “referral” as requested by the commenter. Where the requirements of the exception for intra-family rural referrals cannot be satisfied, the parties to the arrangement can take certain actions to avoid any potential problems arising from intra-family referrals. For example, where the referral to the group practice comes from a physician whose immediate family member is a physician in the group practice, the group practice could forward the referral to a physician outside the group to perform the service and bill for it. Alternatively, the group practice could have one of the physicians in the group practice (other than the family member) perform the service and bill for it

directly (instead of reassigning his or her right to bill to the group practice).

VIII. Exceptions to the Referral Prohibition Related to Ownership or Investment Interests—§ 411.356

A. Publicly-Traded Securities and Mutual Funds

Section 1877(c) of the Act creates an exception for ownership in certain publicly-traded securities and mutual funds that may own DHS entities to which the physician may refer patients. As we explained in the 1998 proposed rule, “we believe that the purpose of this exception is to allow physicians or family members to acquire stock in large companies if the transaction does not particularly favor the physicians over other purchasers” (63 FR 1698). 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 (i) 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 (ii) be foreign securities listed on a recognized foreign, national, or regional exchange, or (iii) be traded under the automated inter-dealer quotation system operated by the National Association of Securities Dealers; and

(3) The securities 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.

In Phase II, we interpreted the statutory provision in section 1877(c)(1) of the Act, which requires that the investment securities be those that “may be purchased on terms generally available to the public,” to mean that the ownership interest must be in securities that are generally available to the public at the time of the DHS referral (69 FR 16081). We are making no changes in this Phase III final rule to § 411.356(a) (regarding publicly-traded securities) or § 411.356(b) (regarding mutual funds).

Comment: One commenter supported our clarification that the investment interest must be available to the public

at the time the referral is made and not at the time the interest is acquired. However, the commenter was concerned that it will be difficult for either the physician or the entity furnishing DHS to determine if the entity is in compliance.

Response: We disagree. The inquiry turns on objective facts that are readily ascertainable to the physician or the entity furnishing DHS.

B. Hospitals Located in Puerto Rico

Section 1877(d)(1) of the Act provides that an ownership or investment interest in a hospital located in Puerto Rico is not considered a financial relationship within the meaning of section 1877 of the Act. In the January 1998 proposed rule, we proposed to incorporate this exception into our regulations at § 411.356(c)(2) (63 FR 1667). We received no comments to § 411.356(c)(2) and made no changes in Phase I to the exception. Phase II similarly made no changes to the exception (69 FR 16082). We received no comments on Phase II regarding § 411.356(c)(2) and are making no changes to the exception in this Phase III final rule.

C. Rural Providers

Section 1877(d)(2) of the Act provides an exception for ownership or investment interests in entities 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 MMA amended section 1877(d)(2) of the Act to specify that, for the 18-month period beginning on December 8, 2003, the rural provider exception was not available for specialty hospitals. Section 507 of the MMA defined the term “specialty hospital” in new section 1877(h)(7) of the Act. The moratorium expired on June 7, 2005.

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, the proposed rule provided that, although the DHS entity (that is, the “rural provider”) need not be located in a rural area, the exception applied only in the case of DHS furnished in a rural area. The proposed rule would have defined rural area as an area that is not considered to be an urban area pursuant to § 412.62(f)(1)(ii) (that is, an area outside of a Metropolitan Statistical Area (MSA)).

Phase II adopted the January 1998 proposed rule without change. This Phase III final rule makes no substantive changes to § 411.356(c)(1).

Comment: One commenter asked for confirmation that, if an entity furnishing DHS qualified for the rural ownership exception in § 411.356(c), the arrangement did not also have to meet the in-office ancillary services exception in § 411.355(b).

Response: The commenter is correct with respect to the referring physician's ownership or investment interest. Any compensation arrangement would have to meet a compensation arrangements exception, such as the in-office ancillary services exception in § 411.355(b). We address this issue more fully in section VI.B of this preamble.

Comment: A commenter complained that it was difficult to determine if a specific location qualified as "rural" for purposes of the exception. The commenter suggested that we provide a list of rural zip codes on our Web site. Another commenter asked that we clarify the definition of "rural." The commenter recommended that we provide our own definition of "rural" rather than cross-referencing to other statutes. The commenter also requested confirmation that the definition of rural does not include Micropolitan Statistical Areas.

Response: We decline to create a list of all zip codes in counties that are considered rural for physician self-referral purposes because the amount of resources that would be required to create and update a list of zip codes is significantly greater than the effort required for health care entities with physician ownership to determine whether they are furnishing DHS in a rural area to patients who reside in a rural area. However, we explain below how a health care entity would determine whether a particular location is in a rural area.

For physician self-referral purposes, a location is in a rural area if it is not located in a MSA. This test differs from the rural/urban test that a hospital uses for wage index purposes. To determine whether an entity is furnishing DHS in a rural area for physician self-referral purposes, see the current list of MSAs on the Web site of the Office of Management and Budget (OMB). This list, which includes the constituent cities and counties of each MSA, currently may be accessed at (www.whitehouse.gov/omb) by typing in "update of statistical area definitions," and by then locating the list entitled "Metropolitan Statistical Areas." We also will provide a link to the OMB Web site on our physician self-referral Web site.

A Micropolitan Statistical Area is an area containing a single urbanized core population of at least 10,000 but less

than 50,000. (65 FR 82230, 82233.) Micropolitan Statistical Areas are not within MSAs; thus, for purposes of the physician self-referral rules, Micropolitan Statistical Areas are not considered urban and are, therefore, rural areas.

The rural provider exception in section 1877(d)(2) of the Act applies to rural areas as defined in section 1886(d)(2)(D) of the Act (regarding the computation of urban and rural standardized amounts under the inpatient hospital prospective payment system). The non-codified material following section 1886(d)(2)(D) of the Act states that "the term 'urban area' means an area within a [MSA] (as defined by [OMB]) or within such similar area as the Secretary has recognized under subsection (a) by regulation * * *." In Phase II, 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 MSA (69 FR 16082–16083). Although we no longer use MSAs to determine urban areas for purposes of the inpatient hospital prospective payment system, we decline to adopt a categorization other than MSAs for physician self-referral purposes.

Comment: A commenter stated that DHS entities serving patients located in rural areas that subsequently are classified as urban should continue to receive some protection. The commenter related a situation in which an existing hospital/physician joint venture owned a MRI machine. The county in which the joint venture served patients previously was not a constituent county in a MSA and thus was considered to be located in a rural area for physician self-referral purposes. However, the county was later reclassified as a constituent county of a MSA and physician-investor referrals to the joint venture would now violate the physician self-referral provisions. The commenter stated that it was no longer able to satisfy the rural provider ownership exception, despite the fact that the area was designated as medically underserved and the only other MRI machine was located 30 miles away. The commenter requested that we adopt alternative criteria for the exception in § 411.356(c)(1) that would address the situation, such as location in a medically underserved area in which the nearest DHS entity (except for the one owned by the physician) is at least 30 miles away.

Response: The rural provider ownership exception is statutory. A physician who invests in an entity furnishing DHS in a rural area takes a

risk that the area will subsequently be classified as an urban area.

Section 1877(b)(4) of the Act allows us to create an exception only if there is no risk of program or patient abuse. We do not believe that an across-the-board exception for a medically underserved area in which the nearest DHS entity (except for the one owned by the physician) is at least 30 miles away is appropriate because we cannot determine that, even with this restriction, there would be no risk of program or patient abuse. Physician ownership of DHS entities is at the heart of the physician self-referral law and is precisely the conduct at which the statute is aimed. The Congress provided limited exceptions for ownership of DHS entities, expressly carving out a rural provider exception with a very specific definition of "rural."

D. Ownership Interest in a Whole Hospital

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 in 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 the MMA amended section 1877(d)(3) of the Act to provide that, effective for the 18-month period beginning on December 8, 2003, the ownership or investment interest must not be in a specialty hospital. Section 507 defined the term "specialty hospital" in a new subsection 1877(h)(7) of the Act. The moratorium expired on June 7, 2005.

The January 1998 proposed rule 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 (63 FR 1698). We stated that the exception protects only 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. In addition, the interest must be in the whole hospital, not in a part or department of the hospital. 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 that includes the particular hospital, because the statute does not require the

physician to have a direct ownership or investment interest in the hospital. (63 FR 1713.)

The Phase I final rule adopted the proposed rule with incidental conforming changes. Phase II made no changes other than conforming amendments to incorporate the provisions of section 507 of the MMA. This Phase III final rule makes no changes to § 411.356(c)(3). We discuss issues related to the moratorium in section XI, below.

Comment: Two commenters objected to our decision to limit the protection of § 411.356(c)(3) to referrals to the hospital, rather than extending the protection to separately-licensed subsidiary providers or suppliers, such as a hospital's wholly-owned home health agency, skilled nursing facility, or durable medical equipment supplier. According to one commenter, the requirement that services be provided directly by the hospital is not found in the language of the statute and does not serve a public policy purpose. The second commenter stated that, if a physician owns an interest in the whole hospital, the exception should apply to referrals for all services provided by the hospital and its affiliates or subsidiaries because the nexus between a physician's referrals and his or her return on investment is extremely limited or non-existent, thereby causing little or no risk of program or patient abuse.

Response: For the reasons stated in Phase II, we believe that our interpretation of the statute is faithful to its language and purpose (69 FR 16084–81605). As we explained in Phase II, we believe that the better reading of the statute is that the Congress intended to protect ownership and investment interests in a hospital with respect to services furnished by the hospital. Therefore, we decline to modify the exception. Further, we do not believe that the Congress intended to create a blanket exemption for physician ownership in for-profit hospital conglomerates, which would, in our view, intensify rather than diminish the incentive to refer due to increased profit opportunities.

Comment: One commenter stated that, whereas CMS has some legitimate concerns that expanding the exception in § 411.356(c)(3) to cover all services provided by a hospital and its affiliates or subsidiaries could result in an overbroad exception, we should consider that the definition of an ownership interest is very broad and includes a security interest. Thus, a physician's security interest "in a hospital," even if extremely attenuated,

could result in a prohibition on referrals to other entities owned by the hospital. Therefore, if we decline to expand the exception to cover ownership in providers owned by a hospital, we should consider allowing the exception to cover ownership in providers owned by a hospital where such ownership derives only from a security interest in the hospital.

Response: It is unclear whether the commenter is referring to a security interest in equipment sold to a hospital or a security interest in the hospital itself. As noted in section VI.A of this Phase III final rule, we are clarifying that a security interest in equipment sold to a hospital by a physician and financed through a loan to the hospital by the physician is not an ownership interest in the hospital, but rather a compensation arrangement. A security interest in the hospital itself is an ownership interest in the hospital (and an indirect ownership interest in any subsidiary owned by the hospital). We decline to expand the exception to protect the referrals of a physician who has, by virtue of a security interest in the hospital, an ownership interest in DHS entities owned by a hospital.

IX. Exceptions to the Referral Prohibition Related to Compensation Arrangements—§ 411.357

A. Rental of Office Space and Equipment

Sections 1877(e)(1)(A) and (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 (except that space leases may include appropriately prorated payments for common areas), and, when used by the lessee, is done so exclusively;
- (iii) The rental or lease term is at least 1 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 forth by the Secretary

to protect against program or patient abuse.

"Fair market value" is defined at 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 established § 411.357(a) and (b) (exceptions for the rental of office space and rental of equipment, respectively), which tracked the statutory language, including the definition of "fair market value."

In the January 1998 proposed rule, we proposed several clarifications to the statutory provisions. Leases could be terminated for cause within the initial 1-year period, provided that the parties did not enter into another lease until after the expiration of the original term (63 FR 1713). Any renewal of a lease would have to be for at least 1 year, thereby precluding holdover month-to-month leases (63 FR 1713). Subleases would be prohibited unless the sublease itself satisfied the conditions of the exception (63 FR 1714). Capital leases would not qualify for the exceptions (63 FR 1714). "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).

Phase II adopted the provisions of the January 1998 proposed rule, with several changes (69 FR 16085). Specifically—

- Leases or rental agreements may be terminated with or without cause during the term of the agreement as long as no further agreement is entered into between the parties within the first year of the original lease term. (Any new lease would need to satisfy the requirements of an exception on its own terms (§ 411.357(a)(2) for space leases or § 411.357(b)(3) for equipment leases.)
- Month-to-month holdover leases for up to 6 months, immediately following the expiration of an agreement of at least 1 year that met the conditions of a rental exception, will continue to satisfy the requirements of the exception if the holdover is on the same terms and conditions as the immediately preceding lease (§ 411.357(a)(7) for space leases or § 411.357(b)(6) for equipment leases).

• All leases or rental agreements, whether operating or capital, are eligible for the lease exceptions if they meet the applicable criteria.

• A lease (or sublease) is considered to satisfy the “exclusive use test” provided that 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) (§ 411.357(a)(3) for space leases or § 411.357(b)(2) for equipment leases). (We note that a subleasing arrangement could create a separate indirect compensation arrangement between the lessor and a 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 provided that 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 at § 411.351 and § 411.354.

We are making no substantive changes to § 411.357(a) or (b).

Comment: Two commenters sought clarification as to whether lease agreements between physicians and entities furnishing DHS may be amended prior to the stated termination of the agreement. The commenters asked about several different scenarios involving amendments to lease agreements prior to their expiration, specifically:

(1) Whether the parties to an agreement may amend an agreement during or after the first year of a multi-year agreement if the amendment is not related to the volume or value of referrals or other business generated between the parties;

(2) Whether an amended agreement must continue for an additional term of at least 1 year following the amendment even if the termination date of the original agreement would occur in less than 1 year;

(3) Whether a “without cause” termination clause in a multi-year agreement is permissible and whether the parties could simply amend an agreement they wish to change, rather than go through the formality of terminating the original agreement and entering into a new agreement; and

(4) Whether there is a limit on the number of amendments that may be made in the first year of an agreement.

Response: In order to satisfy the requirements of § 411.357(a) and (b), rental charges for the rental of office space and equipment 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 between the parties. In addition to these and other requirements, the written agreement must provide for at least a 1-year term. An amended lease agreement must comply with these four criteria, as well as the remaining conditions of the exception. Changes to the rental charges (including changes to the methodology for calculating the rental charges) and changes to certain other terms that are material to the rental charges (for example, a change to the amount of space rented) may jeopardize compliance with one or more of these four criteria, and thus, § 411.357(a) or (b).

Because rental charges, including the methodology used to calculate rental charges, must be “set in advance,” as defined at § 411.354(d)(1), parties may not change the rental charges at any time during the term of the agreement. Parties wishing to change the rental charges must terminate the agreement and enter into a new agreement with different rental charges and/or other terms; however, the new agreement may be entered into only after the first year of the original lease term (regardless of the length of the original term). In addition, the new lease must be for a term of at least 1 year and must comply with all other criteria in the relevant rental exception. As we stated in Phase II (69 FR 16085), leases or rental agreements may provide for termination with or without cause.

Parties may amend a lease agreement multiple times during or after the first year of its term, provided that the rental charges are not changed and all other requirements of the exception are satisfied. However, changes to terms that are material to the rental charges, such as the amount of space leased, may cause the rental charges to fall out of compliance with the fair market value and “volume and value of referrals” requirements. For example, if the original rental charges were \$5,000 per month for 200 square feet of space and the amended lease added 100 square feet of space but did not require additional payment beyond the original monthly payment of \$5,000, the rental charges under the new agreement likely would not be consistent with fair market value and may take into account the volume or value of referrals or other business generated between the parties.

An amended agreement need not continue for an additional 1 year following its amendment if the original termination date of the agreement would occur sooner. Rather, because the exceptions in § 411.357(a) and (b)

require a term of 1 year from the inception of the lease or rental agreement, the amended agreement may terminate upon the original expiration date, provided that the original term of the agreement is at least 1 year. As we noted above, rental charges may not be amended.

If the parties merely wish to end an arrangement prior to the original termination of the written agreement, as we stated in Phase II, they may terminate without cause at any time (subject to the terms of the agreement, of course), provided that the parties do not enter into a new lease agreement within the first year of the original term and any new agreement complies with an exception (69 FR 16085–16086). As we also stated (69 FR 16085), leases and rental agreements may provide for termination with or without cause.

Comment: One commenter asked for clarification regarding the termination of a lease. The commenter wanted confirmation that the prohibition on entering into a new lease agreement in § 411.357(a)(2) applied only to a new lease for the same office space. According to the commenter, the parties should not be prohibited from entering into a personal service arrangement or even a lease agreement for different office space.

Response: The commenter is correct that the prohibition on entering into a new lease applies to only a new lease for all or part of the same office space. The parties are not prohibited from entering into a personal service arrangement or a lease agreement for completely different office space.

Comment: One commenter described a “time-share” leasing arrangement under which a physician or group practice pays the lessor for the right to use office space exclusively on a turn-key basis, including support personnel, waiting area, furnishings, and equipment, during a schedule of time intervals for a fair market value rate per interval of time or in the aggregate. The commenter suggested that, although this arrangement may qualify under the exceptions for the rental of space and equipment, it would be addressed more appropriately in the fair market value exception (§ 411.357(l)) or payments by a physician exception (§ 411.357(i)). The commenter urged us to clarify that such “time-share” arrangements may qualify under § 411.357(l) or (i).

Response: We disagree with the commenter. As we stated in Phase II, we decline to permit space leases to be eligible for the fair market value exception in § 411.357(l) (69 FR 16086). Similarly, we are not persuaded that

§ 411.357(i) should protect space leases (69 FR 16099).

Comment: A number of commenters sought clarification regarding the application of § 411.357(a)(3) and (b)(2) to office-sharing arrangements in which several physicians and/or groups share facilities and some limited equipment without exclusivity. According to these commenters, sharing of facilities is extremely common for physicians and may not readily fit into the leasing exceptions.

Response: Irrespective of whether the office-sharing arrangements described by the commenters are common, both the statute and our regulations require that the lessee have *exclusive* use of the leased space or equipment when the lessee uses the space or equipment. In effect, § 411.357(a)(3) and (b)(4) require that space and equipment leases be for established blocks of time.

Comment: One commenter asked that we clarify that a sublessor and sublessee may share common areas. Another commenter requested guidance with respect to what is meant by “common areas” for the purposes of the exception. One commenter questioned whether the ability to share “common space” permitted parties to share actual *office space* (for example, exam rooms) if the arrangement is at fair market value.

Response: As we stated in Phase II, common areas may be shared if the rent is appropriately prorated (69 FR 16086). By common areas, we mean foyers, central waiting rooms, break rooms, vending areas, etc., to the extent that the areas are, in fact, used by the sublessee. (That is, the sublessee cannot pay rent for a break room that it will never use). Common areas do not include exam rooms. Common areas that contain certain limited equipment may be shared, such as hallways used by non-physician staff to weigh patients or draw fluid samples. Permissible equipment in shared common areas is limited to the type that is not usually separately leased (for example, scales). Non-exclusive arrangements, other than for common space (as described above), do not satisfy the requirements of § 411.357(a)(3) and (b)(2).

Comment: Several commenters expressed concern about the language in § 411.357(a)(3) and (b)(2) prohibiting a lessee from sharing space or equipment with a lessor or any person or entity related to the lessor. The commenters requested guidance on specific shared leasing arrangements, including whether the physician self-referral law prohibits the subleasing of space or equipment by a physician from a physician employed by or a group owned by a hospital.

Response: To prevent parties from circumventing the exclusive use requirement, we modified the space and equipment rental exceptions in Phase II (69 FR 16086) to preclude the sharing of rented office space or equipment with the lessor or any person or entity related to the lessor, including group practices, group practice physicians, or other entities owned or operated by the lessor. Determining whether a lessee is sharing space or equipment with a person or entity related to the lessor will require a case-by-case review of the facts. Nothing in § 411.357(a)(3) or (b)(2) prohibits physicians from subleasing space or equipment from a hospital, a hospital-owned group, or physicians employed by a hospital, provided that the sublessee has exclusive use of the space or equipment that is the subject of the sublease and all other requirements of the exception(s) are satisfied.

Comment: One commenter asked how tenant improvements should be addressed for purposes of compliance with the exception for the rental of office space. Specifically, the commenter asked whether the costs of any capital improvements should be allocated over the useful life of the improvements or be passed on in their entirety to the physician lessee who requested the improvements during the term of his or her lease.

Response: For accounting purposes, tenant improvements should be accounted for in accordance with generally accepted accounting practices. For purposes of determining the fair market value for rental charges, whether the costs of capital improvements should be allocated over the useful life of the improvements or be passed on in their entirety to the physician lessee who requested them will depend upon the facts and circumstances of the particular case. Specifically, if a lessor provides improvements for the benefit of a physician lessee that are unlikely to be chargeable to a subsequent tenant, the lessor should allocate the entire cost of these improvements to the lessee for whose unique benefit they are made. Improvements that the lessor reasonably expects would be chargeable to subsequent lessees may be allocated over their expected useful life.

Comment: A number of commenters welcomed the flexibility provided by § 411.357(a)(7) and (b)(6) with regard to lessees who hold over upon the expiration of space and equipment leases. The commenters requested confirmation that lessors could enforce leases that imposed higher fees during holdover tenancies, provided that the provisions were contained in the written lease at the time of initial or

renewal execution of the lease. One commenter asked that the holdover grace period be extended indefinitely, provided that, during the holdover period, the lessor continually was taking steps to evict the lessee.

Response: We agree that lessors can charge a holdover rental premium, provided that the amount of the premium was set in advance in the lease agreement (or in any subsequent renewal) at the time of its execution and the rental rate (including the premium) remains consistent with fair market value and does not take into account the volume or value of referrals or other business generated between the parties. We decline to permit the holdover grace period to last for the length of time that the landlord is taking steps to evict the tenant as suggested by the commenter. We believe that the 6-month holdover period permitted in the regulations is sufficient.

B. Rental of Equipment

The exception in § 411.357(b) and the comments we received in response to Phase II are discussed above in section IX.A in conjunction with the exception in § 411.357(a) for the rental of office space.

C. Bona Fide Employment Relationships

Section 1877(e)(2) of the Act sets forth an exception for payments made by an employer to a physician (or immediate family member of the physician) with whom the employer has a *bona fide* employment relationship, if certain conditions are met. The August 1995 final rule incorporated the provisions of section 1877(e)(2) of the Act into our regulations in § 411.357(c) without change (60 FR 41975, 41981). The January 1998 proposed rule proposed to prohibit productivity bonuses paid to employed physicians based on DHS personally performed by the referring physician.

Phase II adopted the January 1998 proposed rule without the limitation on productivity bonuses given the Phase I determination that personally performed DHS are not referrals for purposes of section 1877 of the Act (69 FR 16087). We also declined to expand the definition of employee at § 411.351 in Phase II to include leased employees as defined by State law (69 FR 16087).

We received no comments concerning the exception in § 411.357(c) for *bona fide* employment relationships and we are making no changes.

D. Personal Service Arrangements

Section 1877(e)(3) of the Act establishes an exception for personal service arrangements that satisfy certain

requirements. The August 1995 final rule incorporated the personal service arrangements exception into the regulations in § 411.357(d). The January 1998 proposed rule would have retained the exception and proposed technical corrections and some additional interpretations (63 FR 1701).

Phase II adopted the January 1998 proposed rule with several modifications. In Phase II, we qualified the requirement in § 411.357(d)(1)(iv) that the term of an arrangement must be for at least 1 year to permit an arrangement to be terminated during the initial term with or without cause, provided that the parties do not enter into the same or substantially the same arrangement during the first year of the original term of the agreement (69 FR 16090). In Phase II, we modified the regulation to allow cross-referencing to a master list of contracts, in addition to the existing option of incorporation of multiple agreements by reference. We also added a requirement that a master list (or lists) be made available for inspection by the Secretary upon request (69 FR 16091). In Phase II, we declined to extend the exception beyond contracts between DHS entities and physicians or group practices. In addition, we declined to modify the exception to allow physicians to hire independent contractors or use wholly-owned companies to perform services they have contracted to provide, due to the potential for abuse (69 FR 16090).

Phase II also made minor changes to the physician incentive plan exception but did not expand significantly the exception. We clarified that the exception applies to downstream subcontractor arrangements related to health plan enrollees (69 FR 16090).

This Phase III final rule makes minor modifications to the personal service arrangements exception, including the addition of a provision in § 411.357(d)(1)(vii) to permit a holdover personal service arrangement similar to the holdover provisions in the exceptions for the rental of office space and equipment. We modified § 411.352(d)(2) to refer consistently to “downstream contractor,” a term for which we added a definition at § 411.351, as noted above.

Comment: One commenter asked how long the master list kept by an entity must include a record of a personal service agreement between the DHS entity and a referring physician. At some point, an expired agreement becomes irrelevant, according to the commenter. The commenter suggested 5 years after termination or expiration as the appropriate retention period. Another commenter asked for

clarification as to whether the master list needs to include personal service agreements between the DHS entity and the physician that involved “similar or related” transactions, as opposed to *all* compensation and ownership arrangements between the parties. The commenter also asserted that the master list should have to include arrangements between the identical parties only, and not, for instance, contracts with the physician’s family members.

Response: We note that the exception permits, but does not require, the use of a master list. Parties seeking protection under this exception must have a written agreement that covers all of the services to be furnished to the entity by the physician (or an immediate family member of the physician) or group practice. A master list may be used to meet this requirement. The master list must include all personal service arrangements with any physician, family member, or group practice. The condition in the exception requiring that the arrangement cover all services is not limited to “similar or related” services between the entity and the physician, but covers *all* services. This requirement is a bright-line rule that promotes transparency and is not dependent on subjective determinations of similarity or relatedness. Moreover, personal service arrangements with a physician’s immediate family members must be included on the master list because section 1877(d) of the Act treats a financial relationship with an immediate family member of a physician the same as a financial relationship with the physician.

Comment: Two comments involved physician incentive payments referenced in § 411.357(d)(2). One commenter asked that we define a “downstream contractor” as used in § 411.357(d). A second commenter asked that the physician incentive plan exception be expanded to permit hospitals to pay physicians on a capitated or risk-sharing basis for services to hospital patients who are not enrolled in a managed care plan.

Response: We are revising the definition of “physician incentive plan” at § 411.351 to reference newly defined “downstream contractor.” As defined at § 411.351, and for purposes of § 411.357(d)(2), a “downstream contractor” means both a “first tier contractor” as defined at § 1001.952(t)(2)(iii) and a “downstream contractor” as defined at § 1001.952(t)(2)(i). Therefore, for physician self-referral purposes, a downstream contractor includes both an individual or entity that has a contract

directly with an eligible managed care organization to provide or arrange for items and services (that is, a first tier contractor) and an individual or entity that has a subcontract directly or indirectly with a first tier contractor for the provision of or arrangement for items or services that are covered by an agreement between an eligible managed care organization and the first tier contractor. We also note that, in § 411.357(d)(2), we used the terms “downstream contractor” and “downstream subcontractor” interchangeably. We have revised § 411.357(d)(2) to use only the term “downstream contractor”.

The commenter wants DHS entities to be allowed to provide incentives to physicians for their services in connection with fee-for-service patients provided that the incentives “fit the general structure of the [personal service arrangements] exception (for example, no payment to reduce medically necessary services).” We are not persuaded to make such a change. In the exception for personal service arrangements, the Congress included a statutory provision permitting certain physician incentive plan payments (structured to protect patient care) that would otherwise run afoul of the general restriction on compensation determined in a manner that takes into account the volume or value of referrals or other business generated between parties. This provision facilitates certain managed care arrangements that conceptually compensate physicians based on limiting the volume of care provided or ordered by a “gatekeeper” physician. The exception proposed by the commenter, for similar payments related to fee-for-service patients, would pose a risk of program or patient abuse. (For example, see section 1128A(b)(1) of the Act, which authorizes civil monetary penalties for payments made by hospitals to physicians to reduce or limit services to hospital patients.) However, as we discussed in Phase II, compensation related to patient satisfaction goals or other quality measures unrelated to the volume or value of business generated by the referring physician and unrelated to reducing or limiting services would be permitted under the personal service arrangements exception, provided that all requirements of the exception are satisfied (for example, compensation to reward physicians for providing appropriate preventive care services where the arrangement is structured to satisfy the requirements of the exception) (69 FR 16091).

CMS is working on two demonstration projects that concern

hospital incentives paid to physicians in connection with the provision of high quality care, as authorized under section 646 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and section 5007 of the Deficit Reduction Act of 2005 (DRA). In addition, section 5001(b) of the DRA requires CMS to propose a demonstration for FY 2009 that would provide incentives to hospitals for the provision of high quality care. This will be a "rewards sharing" demonstration under which hospitals will share money with physicians based on quality of care rather than on reducing or limiting medically necessary services.

Comment: Several commenters raised issues regarding the exceptions for personal service arrangements and indirect compensation arrangements as they are applied to relationships involving a DHS entity, a group practice, and the physicians employed by the group practice who refer patients to the DHS entity. One commenter requested confirmation that, if a hospital contracts with a group practice for the provision of services, the relevant analysis is whether the arrangement meets the indirect compensation arrangements exception in order to ensure that referrals from individual physician-employees in the group practice are protected. One commenter asked for clarification that the personal service arrangements exception does not apply to most medical foundations because they typically contract with a group practice which, in turn, employs or contracts with physicians. Another commenter asserted that, if the personal service arrangements exception would protect an arrangement directly between a DHS entity and a physician, it should also be applicable to and protect an arrangement pursuant to which the physician has an indirect relationship with the DHS entity. Finally, one commenter asked for clarification that compliance with either the personal service arrangements or indirect compensation arrangements exception is sufficient to protect a compensation arrangement.

Response: As discussed in section VI.B, we now consider a physician to "stand in the shoes" of his or her group practice or physician organization. In the hypothetical situations posed by the first two commenters, the referring physician would stand in the shoes of the group practice that employs the physician and be considered to have a direct relationship with the hospital or the medical foundation, respectively, on the same terms as the hospital's or medical foundation's arrangement with

the group practice. Thus, in the first hypothetical situation, the financial relationship between the hospital and the physician (who is standing in the shoes of the group practice) must meet an exception in order for the physician to be able to refer patients to the hospital. However, if the hospital contracts with a medical foundation which, in turn, contracts with the group practice which employs the physician (who stands in the shoes of the group practice), compliance with the indirect compensation arrangements exception would still be necessary for the physician to refer patients to the hospital (assuming that the arrangement meets the definition of an indirect compensation arrangement at § 411.354(c)(2)). The chain of financial relationships would be hospital—foundation—group practice—physician. However, if the physician makes a referral to the medical foundation's clinic (as opposed to a hospital with which the medical foundation contracts) for DHS furnished by the clinic, then the relationship between the physician (standing in the shoes of his or her group practice) and the medical foundation's clinic would be deemed to be a direct relationship (that is, medical foundation clinic—physician standing in the shoes of his or her group).

As we noted in Phase II, the exception for personal service arrangements would apply to payments made by a nonprofit medical foundation under a contract with an individual physician to provide health care services (69 FR 16077, citing H. R. Conf. Report No. 103–213 at 814 (1993)). Upon the effective date of this final rule, when the group practice physician stands in the shoes of the group practice with which the medical foundation has contracted, the medical foundation may apply the personal service arrangements exception to the arrangement between it and the group practice in order to protect referrals from the physician.

Finally, as we discussed in Phase I, where more than one exception can apply to a financial relationship, the relationship needs to satisfy the requirements of only one of the applicable exceptions (66 FR 916).

Comment: One commenter asked that we revise the exception in § 411.357(d)(1) to permit a holdover personal service arrangement on terms similar to those specified in the equipment and space lease context.

Response: We agree and have modified the regulation accordingly by adding a new provision in § 411.357(d)(1)(vii).

Comment: One commenter asked for clarification regarding when and on

what terms a contract for personal services can be amended.

Response: A personal service contract can be amended in the same manner as an office space or equipment lease as noted above in section IX.A.

E. Physician Recruitment

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 for the protection of the exception, the following requirements must be satisfied—

- The physician is not required to refer patients to the hospital;
- The amount of remuneration under the arrangement is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician; and
- 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 in § 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. The January 1998 proposed rule would have made minor editorial changes.

Based on public comments, Phase II substantially modified the rule (69 FR 16094–16095) in the following respects—

- A physician must relocate his or her practice, rather than his or her residence. To be eligible for the exception, a physician must be new to the hospital's medical staff and relocate to the geographic area served by the hospital (defined as the lowest number of contiguous postal zip codes from which the hospital draws at least 75 percent of its inpatients).

- Relocation of a physician's practice to the geographic area served by the hospital must involve either: (1) Relocating the physician's office a minimum of 25 miles; or (2) establishing that 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 1 year will not be considered to have an established practice and will, therefore,

be eligible for compensation under the physician recruitment exception regardless of whether the physician actually moves his or her practice location.

- Federally qualified health centers may make recruitment payments to physicians on the same basis as hospitals.
- Recruitment payments made through existing group practices (rather than directly to the recruited physician) are permitted under certain conditions. (These conditions are designed to ensure that any remuneration in connection with recruiting a new physician that flows from the hospital through an existing group is remuneration for the benefit of the recruited physician and does not inure to the benefit of the group.)

We received a substantial number of comments regarding the physician recruitment exception. We are making several changes to the exception in response to the comments, and are clarifying our interpretation of certain provisions as requested by commenters. Because the exception in § 411.357(e) applies to federally qualified health centers and (now) rural health clinics in the same manner as it applies to hospitals, references to “hospital” below also implicitly include federally qualified health centers and rural health clinics.

Amendments to the text of § 411.357(e) include—

- Permitting rural health clinics to utilize the exception;
- Deeming the geographic area served by a hospital to be the area comprised of all of the contiguous zip codes from which the hospital’s inpatients are drawn when the hospital draws fewer than 75 percent of its inpatients from contiguous zip codes;
- Permitting a hospital located in a rural area to determine the “geographic area served by the hospital” using an alternative test that encompasses the lowest number of contiguous (or in some cases, noncontiguous) zip codes from which the hospital draws at least 90 percent of its inpatients;
- Permitting a more generous income guarantee under certain circumstances in the case of a physician who is recruited to replace a deceased, retiring or relocating physician;
- Permitting group practices to impose certain practice restrictions;
- Permitting rural hospitals to recruit physicians into an area outside of the hospital’s geographic service area if it is determined through a CMS advisory opinion that the area has a demonstrated need for the recruited physician;

- Exempting from the relocation requirement a physician who, for the 2 years immediately prior to the recruitment arrangement, was employed on a full-time basis by a Federal or State bureau of prisons (or similar entity operating correctional facilities), the Department of Defense or Department of Veterans Affairs, or facilities of the Indian Health Service, provided that the physician did not maintain a separate private practice in addition to such full-time employment;

- Exempting from the relocation requirement those physicians whom the Secretary has deemed in an advisory opinion not to have an established medical practice comprised of a significant number of patients who are or could become patients of the recruiting hospital;

- Clarifying that a physician must relocate his or her practice from outside the geographic service area to a location inside the service area and either: (1) Move his or her medical practice at least 25 miles; or (2) have a new medical practice that 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); and

- Clarifying that § 411.357(e)(4)(iii) pertains to any type of income guarantee.

Comment: Many commenters requested clarification as to the effect of Phase II on pre-existing recruitment arrangements that did not meet the Phase II requirements. Commenters urged us to grandfather any pre-existing recruitment arrangements.

Response: We posted guidance regarding pre-existing physician recruitment agreements on July 14, 2004 on the physician self-referral website in the form of a question and answer (www.cms.hhs.gov/physicianselfreferral). We are still not persuaded that we should grandfather pre-existing arrangements. Thus, any arrangement that was in effect as of July 26, 2004, should have been amended to comply with Phase II, whether the arrangement was in a payout period or in a forgiveness period.

Comment: Two commenters questioned the need for the requirement in § 411.357(e)(1) that the recruited physician not already be on the medical staff. One commenter said it was unnecessary in light of the relocation requirement. The other commenter stated that the requirement should not apply to physicians who are not active

or who are on the hospital’s courtesy staff only.

Response: We disagree with the first commenter. Section 1877(e)(5) of the Act states that the recruited physician must “relocate * * * in order to be a member of the medical staff of the hospital.” This language makes clear that the recruited physician cannot already be a member of the hospital’s medical staff. We believe that the relocation requirement is insufficient to establish that a physician who is already a member of the hospital’s active staff needs an incentive to move his or her practice. We are not persuaded that permitting recruitment of physicians who are not on a hospital’s “active” medical staff, but who hold some type of medical staff privileges (for example, courtesy privileges), poses no risk of program or patient abuse. Moreover, defining “active” privileges is difficult, as many hospitals use different terminology to refer to different types of medical staff privileges.

Comment: One commenter objected to the conditions in § 411.357(e)(1)(iii) and (e)(4)(v) that the remuneration not directly or indirectly take into account the volume or value of actual or anticipated referrals or other business generated by the recruit or the physician practice, if it received any payments. According to the commenter, hospital recruitment arrangements always anticipate referrals to the hospital.

Response: We recognize that parties to a physician recruitment arrangement may anticipate some referrals by the recruited physician. In this context, the “volume and value” condition prohibits the amount of assistance payable to the physician or the group practice from taking into account, in any manner, the volume or value of past or anticipated referrals to the hospital. The unconditional payment of actual moving expenses, for example, would not take into account the volume or value of referrals.

Comment: One commenter asserted that a Mississippi statute prohibits physician employees of county- or city-owned hospitals from having any contractual relationship with the hospital other than an employment contract. Because of this restriction, these hospitals that recruit physicians as employees are unable to enter into a recruitment agreement that is separate and distinct from the employment agreement between the hospital and the recruit. The commenter requested that, in order to avoid placing community hospitals in a position where they have to choose between obeying State law or our physician self-referral regulations, we delete the word “separate” from the

phrase “except as referrals may be restricted under a separate employment or services contract” in § 411.357(e)(1)(iv).

Response: The commenter misunderstands the purpose of the quoted language in § 411.357(e)(1)(iv). This language appears in, and pertains to, the physician recruitment exception, not the employment exception (which would apply if the hospital was to employ the recruited physician directly and all requirements of the exception were satisfied). The purpose of the physician recruitment exception is to allow hospitals, subject to certain conditions, to provide remuneration directly or indirectly to physicians in order to induce them to relocate their medical practices to the hospital’s geographic service area. The exception contemplates that recruited physicians will either practice on their own or as part of a physician practice. The exception does not contemplate that the recruited physicians will be employees of the recruiting hospitals, although nothing in the exception specifically precludes this result if all requirements of the exception are satisfied. Section 411.357(e)(1)(iv) provides that, as a condition of compliance with the recruitment exception, the recruited physician must be allowed to establish staff privileges at any other hospital(s) and to refer business to any other entities, except to the extent that referrals may be restricted under a separate employment, managed care, or services contract that complies with § 411.354(d)(4). The “separate employment contract” contemplated in the regulation would be between the recruited physician and, for example, a group practice that employs the physician recruited by a hospital. Where a hospital wishes to recruit a physician as an employee, it need comply only with the requirements of the exception in § 411.357(c) for *bona fide* employment relationships, and, if it wishes to restrict the ability of the physician-employee to refer patients to other entities, with the requirements in § 411.354(d)(4) (special rule on compensation). Neither the employment exception nor the special rule on compensation requires the employing hospital to set forth referral restrictions in an agreement separate and distinct from the underlying employment contract.

Comment: Several commenters objected to the explanatory language in the Phase II preamble that appeared to condone credentialing restrictions aimed at restricting a recruited physician from competing with the recruiting hospital (69 FR 16095). Two

commenters were concerned that such language lends itself to “economic credentialing” and objected to what they characterized as an inconsistent interpretation of what would be considered an inappropriate practice restriction on physicians. One commenter asked for examples of what we mean by “reasonable credentialing restrictions.”

Response: The preamble discussion referenced by the commenters was primarily concerned with clarifying that recruited physicians cannot be prohibited from establishing staff privileges at other hospitals and from referring to other hospitals, even if such hospitals are competitors of the hospital that recruits the physician. We also intended to convey that the exception does not prevent hospitals from imposing reasonable credentialing restrictions on physicians when they compete with the recruiting hospital. Such restrictions must not take into account the volume or value of referrals. We take no position as to the application of any other State or Federal law or regulation pertaining to such credentialing restrictions. We merely intended to clarify that the physician self-referral law and our regulations do not prohibit reasonable credentialing restrictions that do not take into account in any way the volume or value of referrals or other business generated by the physician.

Comment: Some commenters asked that § 411.357(e) be expanded to protect recruitment of mid-level non-physician practitioners into a hospital’s service area, including into an existing group practice. Other commenters asked that § 411.357(e)(5) be expanded to protect rural health clinics.

Response: Section 1877(e)(5) of the Act limits the recruitment exception to physicians, and, under section 1877(b)(4) of the Act, we cannot create a new exception unless there is no risk of program or patient abuse.

The physician recruitment exception in § 411.357(e) applies only to payments made directly (or, in some circumstances, passed through) to a recruited physician. Recruitment payments made by a hospital directly to a non-physician practitioner would not implicate the physician self-referral law, unless the non-physician practitioner serves as a conduit for physician referrals or is an immediate family member of a referring physician. Payments made by a hospital to subsidize a physician practice’s costs of recruiting and employing non-physician practitioners would create a compensation arrangement between the hospital and the physician practice for

which no exception would apply. These kinds of subsidy arrangements pose a substantial risk of fraud and abuse.

We are, however, persuaded to modify the exception to include rural health clinics, subject to the same conditions that apply to recruiting hospitals. We do not believe that such an expansion poses a risk of program or patient abuse. We have amended the regulation text accordingly.

Comment: A number of commenters objected to the condition in § 411.357(e)(1) that a hospital may recruit physicians only into the “geographic area served by the hospital,” which is defined at § 411.357(e)(2) as the lowest number of contiguous zip codes from which the hospital draws at least 75 percent of its inpatients. Commenters noted that this condition prevents hospitals from recruiting physicians into outlying parts of their service areas where there is likely to be greater need. Some commenters asserted that this condition hurts rural hospitals, and that it is very difficult for federally qualified health centers to satisfy the condition. Still other commenters stated that the restriction was unnecessary in light of the requirement that the physician relocate at least 25 miles or establish a practice with 75 percent of revenues derived from professional services provided to patients not seen or treated by the physician within the preceding 3 years. Although most of these commenters requested that we eliminate this condition, some commenters suggested that, in the event the geographic restriction is retained, we should revise the regulation. Suggested revisions included: expanding the geographic area served by the hospital to 90 percent of zip codes from which the recruiting hospital draws its inpatients; making the 75 percent of inpatients/least number of zip codes requirement a *minimum* service area; permitting case-by-case determinations for good cause; and allowing a hospital to use any methodology permitted by the State in which it is located to determine the hospital’s service area.

Response: We are not persuaded to eliminate the requirement that a recruited physician establish his or her medical practice within the geographic area served by the hospital; however, we are persuaded by some of the commenters that suggested an expansion of the definition of “geographic area served by the hospital.” With respect to a hospital located in a rural area, the “geographic area served by the hospital” may be the area composed of the lowest number of contiguous zip codes from which the

hospital draws at least 90 percent of its inpatients. If the hospital draws fewer than 90 percent of its inpatients from all of the contiguous zip codes from which it draws inpatients, the “geographic area served by the hospital” may include noncontiguous zip codes, beginning with the noncontiguous zip code in which the highest percentage of the hospital’s inpatients resides, and continuing to add noncontiguous zip codes in decreasing order of percentage of inpatients. A rural hospital will continue to have the option of determining the “geographic area served by the hospital” using the methodologies applicable to all hospitals. We believe that this expansion will address much of the concern that Phase II did not permit recruiting into outlying portions of a rural hospital’s service area. We are also modifying the regulation by adding a new provision in § 411.357(e)(5) to permit rural health clinics, rural hospitals, and federally qualified health centers located in rural areas to recruit a physician into an area outside the entity’s geographic service area if it is determined by the Secretary in an advisory opinion issued under section 1877(g)(6) of the Act that the area has a demonstrated need for the recruited physician.

Comment: Some commenters asked for clarification regarding what they perceive as an inconsistency between the regulation text and the preamble language in Phase II regarding whether a recruited physician must relocate his or her practice from *outside* the geographic area served by the hospital (as defined in the regulation) *into* the area, or whether the physician may simply relocate his or her practice within the geographic service area as long as the physician either: (1) Moves the site of his or her practice a minimum of 25 miles; or (2) derives at least 75 percent of the relocated practice’s revenues from services provided by the physician to new patients.

Response: With respect to the commenters’ concern regarding what they perceive as an inconsistency between the regulation text and the preamble language in Phase II, we confirm that the final regulation requires that the recruited physician relocate his or her medical practice from outside the “geographic area served by the hospital” (as defined in the regulation) into the area, and that the recruited physician must also either: (1) move the site of his or her practice a minimum of 25 miles; or (2) derive at least 75 percent of his or her practice’s revenues from services provided by the

physician to new patients. To the extent that the Phase II preamble discussion inadvertently suggested a different interpretation, we are clarifying our intent here. Our interpretation here is consistent with the regulatory text in Phase II. We are making additional conforming changes in the regulatory text in § 411.357(e)(2)(iv) for greater clarity.

Comment: Commenters raised a number of specific questions concerning the use of zip codes for purposes of determining the geographic area served by a hospital, including:

(1) What is the appropriate geographic service area if the zip codes contiguous to the hospital account for only 69 percent of the hospital’s inpatients? Specifically, the commenter asked what a hospital should consider to be its geographic service area if the contiguous zip codes proximate to the hospital account for only 69 percent of the hospital’s inpatients and, due to the national reputation of the hospital and its medical staff, the remainder of the hospital’s inpatients are drawn from distant, noncontiguous zip codes.

(2) What if there is a zip code “hole” in the contiguous area (with the geographic service area resembling a donut)? May a hospital recruit a physician to establish his or her medical practice location in the zip code that forms the hole?

(3) What if multiple configurations of zip codes will satisfy the 75 percent requirement?

(4) How often can a hospital determine its service area and what, if anything, must a hospital do if the service area changes after a physician is recruited by the hospital?

(5) If a health system has two hospitals, is the geographic service area determined at the hospital or system level?

Response: Phase II defined “geographic area served by the hospital” at § 411.357(e)(2) as the area composed of the lowest number of contiguous zip codes from which the hospital draws at least 75 percent of its inpatients. As noted above, in this Phase III final rule, we are amending § 411.357(e) to permit a hospital located in a rural area to determine its geographic service area using noncontiguous zip codes if the hospital draws fewer than 90 percent of its inpatients from all of the contiguous zip codes from which it draws inpatients. Other than as determined using our new rule for hospitals located in rural areas, the geographic area served by the hospital must be comprised of contiguous zip codes. We are clarifying that “contiguous zip codes” does not mean only zip codes

that are contiguous to the zip code in which the hospital is located. It is our intention that “contiguous zip codes” means zip codes that are next to (or contiguous to) each other. A hospital should look at its inpatient data to determine where patients live and then calculate the lowest number of zip codes that touch at least one other zip code in which the inpatients reside. Our specific responses are as follows.

(1) We do not expect that many hospitals would be in the situation described by the commenter. However, to the extent that this situation exists, the hospital would be prohibited from relying on the recruitment exception because, under the Phase II definition of “geographic area served by the hospital,” the contiguous zip codes from which the hospital draws inpatients would not meet either the “at least 75 percent of inpatients” test (applicable to all hospitals) or, under this Phase III final rule, the “at least 90 percent of inpatients” test (the optional test for hospitals located in rural areas). In order to avoid this result, we are modifying § 411.357(e) to deem a hospital’s geographic service area as comprising *all* of the contiguous zip codes from which the hospital’s inpatients are drawn when the hospital draws fewer than 75 percent of its inpatients from those contiguous zip codes (or 90 percent in the case of the new optional test for hospitals located in rural areas). Using the commenter’s example, the hospital would be permitted to recruit into the zip codes from which it draws the 69 percent of its inpatients.

(2) Provided that the “hole” zip code is surrounded by contiguous zip codes as described by the commenter, if no people reside in the “hole” zip code, the hospital may recruit a physician to establish a practice into the “hole” zip code. For example, a “hole” zip code might be one assigned to a large office building or commercial district. We have modified the regulation accordingly.

(3) If multiple configurations containing the same number of zip codes permit the hospital to meet the applicable percent of inpatients threshold (that is, 75 percent for all hospitals or 90 percent for hospitals located in rural areas), the hospital is free to use any of the configurations.

(4) A hospital may use any configuration that satisfies the lowest number of zip codes/applicable percent of inpatients test on the date it enters into the recruitment arrangement (that is, the date on which all parties have signed the written recruitment agreement). In some cases, this may result in the use of a different

geographic service area for different recruitment arrangements.

(5) The determination of the geographic area served by a hospital is applied at the *hospital* level rather than at the *hospital system* level. Therefore, the service area is hospital-specific, not system-specific.

Comment: One commenter asked whether, for purposes of § 411.357(e)(3), a “residency” includes all training, including post-residency fellowships.

Response: For purposes of § 411.357(e)(3), a residency includes all training, including post-residency fellowships.

Comment: Section 411.357(e)(3) specifies that the relocation requirement does not apply to residents and physicians who have been in practice 1 year or less, provided that the resident or physician establishes his practice in the geographic area served by the hospital. One commenter requested that we expand this provision to include other physicians who do not have a private medical practice, such as physicians on active military duty who are ending their military careers; physicians who live in, but have never practiced medicine in, the geographic area served by the hospital; and physicians who are employed by the Department of Veterans Affairs, Native American Hospital System, or a staff model HMO. According to the commenter, such physicians do not have an established medical practice that is capable of being relocated because virtually none of their patients could be treated by the recruited physician (or another physician) in the recruited physician’s new medical practice and virtually none of the patients could become patients of the recruiting hospital.

Response: The recruitment exception in § 411.357(e) excepts certain remuneration that is intended to induce a physician “to relocate his or her medical practice” to the geographic area served by the hospital. In Phase II, we stated that residents and physicians who have been in practice 1 year or less would not be considered to have an established medical practice to relocate and that recruitment arrangements involving such physicians could qualify for the recruitment exception regardless of whether or not the physician actually moves his or her practice location, provided that all other conditions of the exception are satisfied (69 FR 16094–16095). We agree that some of the physicians identified by the commenter have practices that are incapable of being relocated due to unique restrictions that effectively prevent the recruited physician’s patients from

receiving medical care furnished by either the recruiting hospital or the recruited physician’s new medical practice. Thus, we are expanding § 411.357(e)(3) to provide that, as long as the recruited physician establishes his or her medical practice in the geographic area served by the hospital, the relocation requirement will not apply if, for at least 2 years immediately prior to the recruitment arrangement, the recruited physician was employed on a full-time basis by one of the following—

- A Federal or State bureau of prisons or similar entity (operating correctional facilities) to serve exclusively a prison population;
- The Department of Defense or Department of Veterans Affairs to serve active or veteran military personnel and their families; or
- Facilities of the Indian Health Service to serve patients who receive medical care exclusively through the Indian Health Service.

Also, the physician must not have maintained an independent private practice in addition to his or her full-time employment with one of the above entities. We believe that the 2-year employment restriction is necessary to prevent program abuse. Because physicians often see patients less than once a year, we believe that an experienced physician may have an established medical practice that is capable of being relocated even when the physician has not practiced in that location for a period of time. Thus, for example, we believe that the exception’s relocation requirement should apply in the case of a physician who left private practice in the hospital’s geographic service area to become a full-time employee of the Indian Health Service for 1 year only.

In addition, to accommodate those rare instances in which a hospital should be permitted to provide recruitment assistance to a physician whose practice cannot be relocated for reasons other than those stated above, we are modifying the exception to provide that the relocation requirement will not apply if the Secretary has deemed in an advisory opinion issued under section 1877(g)(6) of the Act that the physician does not have an established medical practice that serves or could serve a significant number of patients who are or could become patients of the recruiting hospital.

Comment: One commenter asked for clarification with respect to the signatories to the recruitment contract. The commenter was concerned that § 411.357(e)(4)(i), which requires that the recruitment agreement be signed

also by the party to whom the payments are directly made, could be interpreted to require that the hospital, the physician practice, and the recruited physician all had to sign one document. The commenter asserted that this would be unnecessary and would add unnecessarily to the transaction costs. The commenter suggested that we require a written agreement between the hospital and either: (1) The recruit; or (2) the physician practice to which the payments will be made. The commenter suggested, alternatively, that it should be acceptable to limit the contracting parties to the hospital and the physician practice receiving the recruitment assistance and require the recruited physician to sign a one-page acknowledgement agreeing to be bound by the terms and conditions set forth in the recruitment agreement signed by the hospital and the physician practice.

Response: The exception requires a written agreement signed by all parties, including the recruiting hospital, the recruited physician, and the physician practice that the physician will be joining, if any. Nothing in the regulations precludes execution of the agreement in counterparts. This requirement is necessary to safeguard against program and patient abuse, and we are not persuaded that it creates any undue burden.

Comment: Two commenters asked whether a hospital could require a group practice that was receiving recruitment assistance to guarantee repayment of any monies advanced to the group on behalf of the recruited physician if the physician did not fulfill his or her community service requirement.

Response: Nothing in this rule precludes a hospital from requiring a physician practice to repay any monies advanced to the group on behalf of the recruited physician if the physician does not fulfill his or her community service requirement. However, if requiring the physician practice to guarantee repayment on behalf of the recruited physician is used to shield the recruited physician from any real liability for failure to fulfill his or her community service obligation under a recruitment agreement, the parties would be at significant risk of noncompliance with the fraud and abuse laws, particularly if the recruiting hospital failed to collect amounts owed by the physician practice making the guarantee. Any such arrangement should be carefully scrutinized under the fraud and abuse laws (including the physician self-referral law and the anti-kickback statute) for other implications, such as problematic relationships

between the group practice and the recruited physician or additional, unexcepted remuneration from the hospital to the group practice or the recruited physician.

Section 411.357(e)(4) excepts remuneration provided by a hospital to a physician: (1) Indirectly through payments to a physician practice; or (2) directly to a physician who joins a physician practice. To the extent that a physician practice guarantees the obligations of the recruited physician, and indemnifies the recruited physician against repayment of those obligations, the indemnification would create a remunerative relationship between the physician practice and the recruited physician (and potentially between the physician practice and the hospital) that could implicate the fraud and abuse laws, including the physician self-referral law and the anti-kickback statute.

Comment: A number of commenters requested clarification regarding the applicability of § 411.357(e)(4)(ii) to situations in which a group practice, through which a hospital makes indirect recruitment payments to a recruited physician, employs the recruited physician. The commenters requested clarification that the group practice could deduct from the amount passed through to the physician in salary, the group practice's actual costs attributable to recruiting the physician. Examples of such costs include headhunter fees, travel expenses and moving expenses associated with the recruitment, and employee benefits, taxes and professional fees attributable to hiring the recruited physician. The commenters pointed out that § 411.357(e)(4)(iii) specifically permitted such adjustments in the case of an income guarantee.

Response: Under § 411.357(e)(4)(iii), the costs allocated by a group practice that employs the recruited physician under an income guarantee may include the group's actual additional incremental costs attributable to the recruited physician. Depending on the circumstances, these costs may include those noted by the commenters. This provision was included in § 411.357(e)(4)(iii) in Phase II (69 FR 16096–16097).

Comment: A commenter requested clarification regarding the types of expenses that qualify as recruiting expenses. The commenter suggested that the following should qualify as covered expenses: Headhunter fees; air fare, hotel, meals, and other costs associated with visits by the recruited physician and his or her family to the relevant geographic area; moving

expenses; telephone calls; and the cost of tail malpractice insurance covering the physician's prior practice. Another commenter asked whether a hospital could pay a physician or a group practice for time spent recruiting a physician into the hospital's service area, and whether our answer depends on if the recruited physician joined the recruiting physician's or group's practice or an unrelated medical practice.

Response: We understand the first commenter to be asking about the language in § 411.357(e)(4)(ii) that refers to "actual costs incurred by the * * * physician practice in recruiting the new physician * * *." This language describes only costs incurred in the recruiting of the physician and does not include costs incurred after the physician is recruited and has joined the group. Depending on the circumstances, these costs incurred in recruiting could include the actual costs of headhunter fees; air fare, hotel, meals, and other costs associated with visits by the recruited physician and his or her family to the relevant geographic area; moving expenses; telephone calls; and tail malpractice insurance covering the physician's prior practice.

With respect to the second commenter's questions, if a hospital pays a physician or group for time spent recruiting a physician, as opposed to the expenses discussed above, such compensation would have to meet all of the requirements of a compensation exception (other than the recruitment exception). It would not matter whether the recruited physician actually joined the compensated physician's practice.

Comment: Several commenters requested clarification regarding what types of income guarantees trigger the application of § 411.357(e)(4)(iii). Several commenters claimed that *revenue* guarantees are not considered income guarantees.

Response: Any income guarantee, whether gross income, net income, revenues, or some variation, involves a potential cost to the guarantor hospital and a benefit to the recipient physician. Any such guarantee triggers the application of § 411.357(e)(4)(iii). We have modified the provision to clarify that § 411.357(e)(4)(iii) applies to any type of income guarantee.

Comment: Many commenters objected to the condition in § 411.357(e)(4)(iii) that a group practice cannot allocate more than its actual, additional incremental costs attributable to the recruited physician under an income guarantee. According to the commenters, the limitation will prevent groups from recruiting new physicians

using hospital funding, and is unreasonable. The commenters requested that we revise the regulation to permit other reasonable methods of allocating overhead costs, such as *pro rata* or *per capita*. The commenters noted that § 411.352 permits group practices to use such allocation methods for distributing certain group practice revenues. A number of commenters stated that the rule was particularly unfair when the new physician was merely replacing a deceased, retiring, or relocating group physician, because there was no real benefit to the remaining physicians from a replacement physician who merely "takes over" the overhead costs of the deceased, retired, or relocated physician.

Response: We agree that, in the limited situation in which the recruited physician is replacing a deceased, retiring, or relocating physician in an underserved area, a physician practice may, for purposes of an income guarantee, allocate to the recruited physician a *per capita* allocation of the practice's aggregate overhead and other expenses, not to exceed 20 percent of the practice's aggregate costs. In the alternative, the practice may allocate the actual additional incremental costs attributable to the recruited physician as provided for in Phase II (69 FR 16096–16097). This additional flexibility should assist hospitals that seek to replace needed physicians in their communities. In all other cases, the group may allocate to the recruited physician only the actual additional incremental expenses attributable to the recruited physician.

Contrary to the commenter, we perceive no unfairness. Physician practices that use their own funds to recruit physicians to join them are free to use any cost allocation method when compensating the recruited physicians (subject to any conditions necessary to satisfy the requirements of an applicable physician self-referral exception, such as the exception for *bona fide* employment relationships or the in-office ancillary services exception). In the case of a hospital-subsidized income guarantee, a restriction on the allocation of costs becomes necessary to prevent physician practices from inappropriately shifting overhead costs to the hospital to which the physician practice refers. If a hospital were to subsidize costs that are not genuinely attributable to the recruited physician, the hospital would confer remuneration on the physician practice for which no exception would apply and which could reflect referrals. This would pose a substantial risk of program abuse under

the physician self-referral law, as well as under the anti-kickback statute. We believe that permitting broader overhead allocation in the limited way described above will provide appropriate assistance in underserved areas, where a deceased, retired, or relocated physician might create a deficit in available care for patients, without the risk of increased program or patient abuse. We are modifying the regulation in § 411.357(e)(4)(iii) accordingly.

Comment: One commenter asked whether the income guarantee requirements in § 411.357(e)(4)(iii) with respect to “actual additional incremental costs” apply to a recruited physician who leases space and equipment from and is co-located with (rather than a member of or a physician in) a group practice.

Response: The requirements of § 411.357(e)(4)(iii) apply only in the case of income guarantees provided by a hospital when a physician joins a physician practice. For purposes of the recruitment exception, a physician has not “joined” a physician practice unless he or she has become a “physician in the group practice” or a “member of the group” (or the equivalent, in the case of a physician who joins a practice that is not a “group practice” as defined at § 411.352). In the case of a physician who joins a physician practice, except as provided in new § 411.357(e)(4)(iii), the physician practice may not allocate costs under the income guarantee that exceed the actual additional incremental costs attributable to the recruited physician. In the case of a physician who merely co-locates with a physician practice (for example, by leasing office space from a group practice), none of the provisions of § 411.357(e)(4) would apply. Rather, the arrangement must satisfy the requirements of the recruitment exception without reference to § 411.357(e)(4), or satisfy the requirements of another exception. The recruitment exception would not protect any remuneration provided by the hospital to the physician practice indirectly through payments made to the recruited physician. For example, the exception would not protect an arrangement in which a recruited physician uses funds from a hospital (including amounts pursuant to an income guarantee) to pay inflated rental payments to a group practice. Nor, for example, would it protect any arrangement in which a hospital uses a recruitment arrangement with a recruited physician who co-locates with a physician practice to provide remuneration indirectly to the physician

practice (for example, by arranging for the recruited physician to co-locate with, but not join, the existing physician practice and to pay that practice inflated amounts for rent or services). We are aware of no circumstances in which it would be appropriate for a physician practice to be a party to an income guarantee made by a hospital to a recruited physician who is not joining the practice.

We caution that the physician practice and the physician may not improperly shift costs to the hospital making the income guarantee. We note that any lease or contract between the recruited physician and the physician practice would create a financial relationship that would require an exception, such as the exception for the rental of office space in § 411.357(a), if the recruited physician refers DHS to the physician practice. Moreover, such lease would potentially create an indirect compensation arrangement between the hospital and the physician practice’s physicians who refer DHS to the hospital (the chain links the hospital to the recruited physician (via the income guarantee) to the physician practice (via the lease) to the referring physicians (via ownership or employment)). Such arrangement would need to satisfy the requirements of the indirect compensation arrangements exception in § 411.357(p), and should also be closely scrutinized under the anti-kickback statute.

Comment: One commenter asked for confirmation that § 411.357(e)(4)(iv) requires that the physician practice keep records of its actual costs and the amount passed through to the recruited physician, and that a physician practice’s failure to keep the records would not, by itself, subject the hospital to sanction.

Response: Section 411.357(e)(4)(iv) requires that records of costs be maintained for at least 5 years and made available to the Secretary upon request. Because the recruiting hospital is the DHS entity seeking payment from Medicare in the scenario presented, it is the hospital’s responsibility to maintain the necessary records. The commenter is correct that the physician practice’s failure to keep records would not subject the hospital to sanction under the physician self-referral provisions. However, the hospital’s failure to keep full, complete and accurate records of the actual costs it has subsidized and the amounts passed through to the physician it has recruited would preclude protection under the physician recruitment exception. Hospitals should take appropriate steps to ensure that their funds, intended for the benefit of

recruited physicians, are appropriately handled by the physician practices that receive them.

Comment: We received many comments concerning the requirement in § 411.357(e)(4)(vi) that a physician practice may not impose additional practice restrictions on the recruited physician other than conditions related to quality of care. Commenters (including hospital associations) that addressed the issue of the allowability of non-compete agreements were uniformly opposed to prohibitions on them. They also stated that the restriction limited the utility of the exception and was contrary to State laws permitting such restrictions. Several commenters suggested that § 411.357(e)(4)(vi) be revised to prohibit only restrictions that prohibit the physician from practicing in the hospital’s geographic service area. The commenters asserted that non-compete agreements are a standard business practice between physician groups and physicians. They stated that, without the ability to enter into non-compete agreements, physician practices would be less likely to take on new physicians and, as a result, hospitals may be unable to attract new physicians, and certain health care needs of the surrounding communities could go unmet. Other commenters questioned whether the following were permitted—

- Restrictions on moonlighting;
- Prohibitions on soliciting patients and/or employees of the physician practice;
- Requiring that the recruited physician treat Medicaid and indigent patients;
- Requiring that a recruited physician not use confidential or proprietary information of the physician practice;
- Requiring the recruited physician to repay losses of his or her practice that are absorbed by the physician practice in excess of any hospital recruitment payments; and
- Requiring the recruited physician to pay a predetermined amount of reasonable damages (that is, liquidated damages) if the physician leaves the physician practice and remains in the community.

Response: We indicated in Phase II that we considered a non-compete clause to be a practice restriction and not a condition related to quality of care (69 FR 16096–16097). Although we did not list other examples of such practice restrictions, we intended to include only such restrictions placed on the recruited physician by a physician practice that would have a substantial effect on the recruited physician’s ability to remain and practice medicine

in the hospital's geographic service area after leaving the physician practice or group practice. We do not consider the restrictions, prohibitions, and requirements that are specifically mentioned in the bulleted points above as falling into the category of having a substantial effect on the recruited physician's ability to remain in the hospital's geographic service area. (We note that we may consider a liquidated damages clause requiring a *significant or unreasonable* payment by the physician leaving the physician practice to have a substantial effect on the recruited physician's ability to remain in the recruiting hospital's geographic service area.) Our purpose in prohibiting practice restrictions such as non-compete clauses was to avoid frustrating the purpose of the exception. That is, we intended to discourage physician practices that recruit physicians using hospital funding from making it difficult for a recruited physician to remain in the community and fulfill his or her commitments under the recruitment agreement with the hospital. Allowing a physician to remain in the community not only furthers the health care needs of the community, but also obviates the need for the hospital to enter into a new recruitment agreement to replace the physician.

Upon review of the comments, however, we are persuaded that categorically prohibiting physician practices from imposing non-compete provisions may have the unintended effect of making it more difficult for hospitals to recruit physicians. We are concerned that physician practices and individual physicians may be unable or reluctant to hire additional physicians, regardless of the receipt of financial assistance from hospitals, unless they are able to impose a limited, reasonable non-compete clause. Therefore, we are amending § 411.357(e)(4)(vi) to state that physicians and physician practices, may not impose on the recruited physician any practice restrictions that unreasonably restrict the recruited physician's ability to practice medicine in the geographic area served by the hospital. Although we are not *per se* conditioning payment for DHS on compliance with State and local laws regarding non-compete agreements, we believe that any practice restrictions or conditions that do not comply with applicable State and local law run a significant risk of being considered unreasonable. (Nothing in § 411.357(e)(4)(vi) should be construed, however, as prohibiting a hospital that provides financial assistance to the

hiring physician practice from entering into an agreement with the practice that prohibits the hiring physician practice from imposing a non-compete agreement or other practice restriction.)

Comment: Several commenters asked whether money paid to a group practice under a physician recruitment arrangement constitutes indirect compensation within the meaning of § 411.354(c)(2). Other commenters asked why physician recruitment arrangements could not qualify for the fair market value exception in § 411.357(l).

Response: With respect to the first comment, as discussed in Phase II (69 FR 16097), the provisions of § 411.357(e)(4) related to pass-through hospital recruitment payments establish an exception applicable to the compensation arrangement created between the hospital and the recruited physician (and to the compensation arrangement between the hospital and the existing physician practice) (69 FR 16097). With respect to the second comment, physician recruitment arrangements cannot qualify for the fair market value compensation exception for the reasons explained in Phase II (69 FR 16096). Our position with respect to the application of the fair market value compensation exception to recruitment arrangements has not changed.

Comment: A commenter requested that we amend the physician recruitment exception to provide that the requirements in § 411.357(e)(4) do not apply in the case of remuneration involving the recruitment of a faculty physician to a nonprofit faculty practice plan affiliated with the hospital. The commenter stated that the Phase II preamble was clear that physician recruitment activities conducted in compliance with the academic medical centers exception do not need to comply with the physician recruitment exception. The commenter also stated, however, that an academic medical center may choose not to structure its compensation arrangements to fit within the academic medical centers exception, either because the indirect compensation rules apply or because another exception or exceptions are available for the compensation arrangements. The commenter theorized that our concerns with hospital payments for the recruitment of a physician who joins an existing physician practice arise from the potential incidental benefit that such arrangements may confer on the existing physician practice and its owner-physicians (who may have existing referral relationships with the hospital). However, the commenter asserted that,

where a nonprofit hospital provides remuneration to recruit a needed faculty physician to an affiliated nonprofit faculty practice plan, it is unlikely that any improper incidental benefit would be conferred on any physician group.

Response: To the extent that a hospital, including one affiliated with an academic medical center, wishes to provide remuneration to a physician for recruitment purposes, the arrangement, depending on the facts and circumstances, may be structured to satisfy one or more exceptions, such as the exception for *bona fide* employment relationships in § 411.357(c), the academic medical centers exception in § 411.355(e), or the physician recruitment exception in § 411.357(e). Where the only exception potentially applicable is the physician recruitment exception (because some remuneration would be paid to another physician or to a physician practice), the arrangement must satisfy all of the requirements of § 411.357(e)(4). We are not persuaded that any additional protection under the physician self-referral statute for a nonprofit hospital's recruitment of faculty physicians is necessary or appropriate. We believe that the potential for program and patient abuse in the form of anti-competitive behavior or over-utilization exists whether the DHS entity is a for-profit or nonprofit entity.

F. Isolated Transactions

Section 1877(e)(6) of the Act provides that an isolated transaction, such as a one-time sale of property or a medical 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; and
- The transaction meets any other requirements that the Secretary may impose by regulation as needed to protect against program or patient abuse.

Phase II incorporated the provisions of section 1877(e)(6) of the Act into our regulations in § 411.357(f), with a requirement that there be no additional transactions between the parties for 6 months after the isolated transaction, except for transactions that are specifically permitted under another

exception (69 FR 16098). Phase II set forth definitions of “transaction” and “isolated transaction” at § 411.351. Phase II provided that installment payments could qualify as isolated transactions, as long as the total aggregate payment is: (1) set before the first payment is made; and (2) does not take into account, directly or indirectly, referrals or other business generated by the referring physician (69 FR 16098). Additionally, the payments must be immediately negotiable or guaranteed by a third party, secured by a negotiable promissory note, or subject to a similar mechanism to ensure payment even in the event of default by the purchaser or obligated party. Phase II also clarified that 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 (69 FR 16098). We are making no changes to the isolated transactions exception in this Phase III final rule.

Comment: Two commenters raised questions regarding the requirement in the definition of isolated transaction at § 411.351 that the payments be immediately negotiable or secured by a negotiable promissory note, among other options. According to one commenter, a promissory note is immediately negotiable if the note so states, although as a practical matter, there may not be a market for the note. The other commenter claimed that promissory notes are typically immediately negotiable only in the event of default, and that requiring immediate negotiability is inconsistent with installment payments. One of the commenters also pointed out that a promissory note does not necessarily secure the underlying debt; rather, it can serve as security for a different obligation. Both commenters sought clarification of the “immediately negotiable” note requirement.

Response: We have carefully considered the commenters’ questions and assertions. The critical element with respect to installment payments is that a mechanism is in place to ensure payment (even in the event of default by the purchaser or obligated party). The regulation provides for several options to accomplish this: (1) Immediately negotiable payments or payments that are guaranteed by a third party; (2) payments that are secured by a negotiable promissory note; or (3) payments that are subject to a mechanism similar to (1) and (2) that ensures payment in the event of default. The regulation at § 411.351 does not

require that a *promissory note* be *immediately* negotiable. Installment payments need only be secured by a *negotiable* promissory note if that is the mechanism chosen by the parties to ensure payment in the event of default. The parties are free to choose one of the other options to satisfy the requirements for installment loans in isolated transactions. Whether a promissory note is negotiable is governed by the State’s version of the Uniform Commercial Code or other applicable State law.

Comment: One commenter asked for clarification concerning separate transactions involving related parties, such as a hospital’s purchase of a group practice and the purchase of an office building that is owned by some of the group practice physicians through a separate limited liability company. The commenter believed that such transactions are not unusual but would not appear to qualify for the exception.

Response: The commenter’s example appears to describe two isolated transactions between different parties that would each need to satisfy the requirements of the isolated transactions exception: a transaction between the hospital and the group practice, and a transaction between the hospital and the limited liability company. These arrangements could qualify for the exception, provided that they are structured with separate payments for each transaction and all other conditions of the exception are satisfied.

Comment: Two commenters asked for clarification regarding post-closing adjustments. One commenter stated that the 6-month limit on post-closing adjustments is too brief. The commenter asserted that, as a practical matter, it would encourage recalcitrant parties to “hold out” to increase their bargaining leverage. The commenter interpreted the exception as not precluding post-closing adjustments after 6 months, but precluding only other isolated transactions. The commenter suggested that the commercial reasonableness test provided sufficient protections. The commenter also requested clarification that an adjustment based on a breach of a warranty will not be considered a post-closing adjustment. The second commenter asked that post-closing adjustments be permitted for 24 months. According to the commenter, many purchase and sale agreements provide for warranties, representations, and indemnities to continue in effect for at least one complete audit cycle (that is, 1 fiscal year plus additional months, as needed, to complete the audit) to enable the buyer’s auditors to fully examine financial statements.

Response: The exception for isolated transactions permits commercially reasonable post-closing adjustments within the first 6 months following an isolated transaction, provided that the adjustments do not take into account (directly or indirectly) the volume or value of referrals or other business generated by the referring physician(s). After 6 months, any post-closing adjustment would be treated as a separate, additional transaction that would need to satisfy the requirements of an exception. Claims based on breach of warranty are not considered post-closing adjustments or new transactions; rather, they are considered part of the original transaction and, therefore, may occur at any time without jeopardizing compliance with the exception in § 411.357(f).

Comment: Several commenters were concerned with the interplay between the definition of “ownership,” which includes, for example, a security interest in property sold to an entity furnishing DHS, and the definition of the term “isolated transaction” at § 411.351, which permits installment payments only if the instruments are secured or guaranteed by a third party. According to the commenter, as a practical matter, the result is that a hospital has few options if it wants to purchase a physician’s equipment or practice using installment payments. Another commenter asked whether a guarantee from an entity furnishing DHS made to a physician would create an ownership interest in the entity. The commenters sought clarification as to how the exception would apply to these transactions.

Response: Hospitals and physicians can use other arrangements and methods (that is, other than installment payments made from the hospital to the physician) to secure legal obligations arising from transactions between them. However, we note that, as discussed in section VI.A, we do not consider a security interest in equipment sold by a physician to a hospital and financed through a loan from the physician to the hospital to be an ownership interest in the hospital or a portion of the hospital. Where a physician extends a loan to an entity and is granted a security interest by the entity in the equipment sold by the physician to the entity, the arrangement creates a compensation arrangement (subject to a contrary provision in the security instrument or agreement of the parties). In response to the second comment, a guarantee does not create an ownership interest in the entity providing the guarantee.

G. Remuneration Unrelated to Designated Health Services

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, nor does it apply to remuneration from entities other than hospitals.

Under Phase II, the exception is available only if the remuneration is wholly unrelated to the provision of DHS (69 FR 16093). Phase II provided that, for purposes of the exception, any item, service, or cost that could be allocated in whole or in part to Medicare or Medicaid under applicable cost reporting principles is considered to be related directly or indirectly to the provision of DHS. In addition, remuneration is 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 does not apply to any other remuneration that is related in any manner to the provision of DHS. This Phase III final rule makes no changes to Phase II.

Comment: Numerous commenters, including several hospital trade associations, strongly objected to § 411.357(g) as set forth in Phase II. According to the commenters, the regulation is inconsistent with the statutory language and congressional intent. Some of the commenters argued that the Congress intended that hospitals could provide any amount of remuneration to physicians provided that it was not directly related to the provision of DHS services. The commenters uniformly urged us to reconsider the position we took in Phase II in this regard.

Response: As we discussed in Phase II, § 411.357(g) is consistent with the statutory scheme and congressional intent (69 FR 16093–16094). We do not believe that the Congress intended that a hospital could provide any remuneration it chooses to physicians provided that the amount of remuneration is not directly related to the provision of DHS services. *Bona fide* compensation relationships related in any way to the furnishing of DHS should be structured to fit in another exception.

Comment: Two commenters asked us to provide additional examples of

arrangements that would qualify under the exception in § 411.357(g). Another commenter asked for clarification regarding what would constitute an improper targeted, preferential, or selective process for distributing a benefit. The commenter asked, for example, if a hospital could waive the entry fee for its charity golf tournament for the entire medical staff and still qualify for the exception.

Response: The determination of whether an arrangement is unrelated to the furnishing of DHS will require a detailed review of the facts and circumstances surrounding the arrangement. The examples provided in Phase II are suitably illustrative (69 FR 16093–16094). Parties seeking guidance on particular transactions may submit a request for an advisory opinion. Waiving an entry fee would be a targeted benefit if applied to the medical staff and not to all other participants. However, the arrangement between the hospital and a particular physician could fit into the exception in § 411.357(k) if the value of the total nonmonetary compensation to the physician during a calendar year is not greater than \$300 (as adjusted by the CPI–U).

Comment: One commenter requested confirmation that, where there are no explicit cost reporting guidelines or requirements with respect to the allowability of an item, it is sufficient to apply a good faith reading of general Medicare cost principles.

Response: We understand the commenter's concern to be situations in which a hospital does not know and could not reasonably be expected to know whether a particular item, service, or cost could be allocated in whole or part to Medicare or Medicaid under cost reporting principles, as required by § 411.357(g)(1). In such a situation, we would not consider the item, service, or cost to relate to the furnishing of DHS under § 411.357(g)(1). However, it is not sufficient to satisfy § 411.357(g)(1) alone in order to qualify for protection under the exception. Sections 411.357(g)(2) and (g)(3) set forth additional grounds for determining that remuneration relates to the furnishing of DHS. Specifically, remuneration also relates to the furnishing of DHS if either: (1) It is furnished directly or indirectly, explicitly or implicitly, in a selective, targeted, preferential, or conditional manner to medical staff or other persons in a position to make or influence referrals; or (2) otherwise takes into account the volume or value of referrals or other business generated by the referring physician.

Comment: One commenter expressed concern that the exception in § 411.357(g) was narrowed so much under Phase II that it does not allow hospitals to provide assistance with malpractice insurance premiums.

Response: As discussed below in section IX.R, assistance with malpractice insurance premiums may be structured to satisfy the requirements of other exceptions, such as the fair market value compensation exception (§ 411.357(l)), the exception for *bona fide* employment relationships (§ 411.357(c)), the exception for personal service arrangements (§ 411.357(d)), or the exception for obstetrical malpractice insurance subsidies (§ 411.357(r)). We note that the January 1998 proposed rule clearly stated that this exception would not protect malpractice insurance premium subsidies (63 FR 1702).

H. Group Practice Arrangements With a Hospital

Section 1877(e)(7) of the Act provides that an arrangement between a hospital and a group practice under which DHS are furnished by the group practice but are billed by the hospital does not constitute a compensation arrangement for purposes of the prohibition on referrals if certain conditions are met. The August 1995 final rule incorporated the provisions of section 1877(e)(7) of the Act into our regulations in § 411.357(h) (60 FR 41920, 41975). In the January 1998 proposed rule, we proposed revising § 411.357(h) to make several minor changes and to apply the provision to all DHS, not just clinical laboratory services (63 FR 1669–1670, 1702–1703). The changes included clarifying that the exception protects only arrangements that have continued in effect, without interruption, since December 19, 1989; interpreting the regulatory language to allow changes to the arrangement over time with respect to the services covered by the arrangement or the physicians providing those services; and clarifying that at least 75 percent of the DHS covered under the arrangement must be furnished to patients of the hospital by the group practice under the arrangement (63 FR 1702–1703).

Phase II adopted § 411.357(h) as proposed (69 FR 16099). We received no comments on this exception and are making no changes in this Phase III final rule.

I. Payments by a Physician

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 that are furnished at a price that is consistent with fair market value.

Phase II implemented section 1877(e)(8) of the Act in § 411.357(i) by making two clarifications (69 FR 16099). The first made the exception applicable to payments by a physician's immediate family members, as well as to payments by a physician. The second clarified that the exception does not apply to items or services for which there is another potentially applicable exception in § 411.355 through § 411.357. This Phase III final rule makes no change to this exception. However, we are amending the exception for fair market value compensation in § 411.357(l) to provide that that exception covers compensation from a physician, provided that all other conditions of the exception are satisfied. We note that the fair market value compensation exception does not protect office space lease arrangements; arrangements for the rental of office space must satisfy the requirements of the exception in § 411.357(a).

Comment: Two commenters objected to the provision in § 411.357(i)(2) that the exception applies only to items and services that are not specifically excepted by another exception in § 411.355 through § 411.357. According to the commenters, the restriction leaves many legitimate purchases of items or services by a physician from a DHS entity without an available exception. The first commenter gave the example of the lease of space on a non-exclusive basis to a physician. The commenters also noted that the statement in Phase II that the fair market value compensation exception was available is incorrect because that exception only protects payments to a physician from a DHS entity (69 FR 16099). The second commenter suggested that we either delete language in § 411.357(i) that indicates that the fair market value compensation exception is available, or that we allow the payments by a physician exception in § 411.357(i) to be generally available (rather than available only when another potential exception does not apply), except with respect to space rental arrangements.

Response: We continue to believe, as we stated in Phase II, that our policy of not allowing items and services addressed by another exception to be covered in this exception is consistent with the overall statutory scheme and purpose, and is necessary to prevent the exception from negating the statute (69 FR 16099). To that end, we are amending the text of the exception for fair market value compensation in § 411.357(l) to permit application of that

exception to arrangements involving fair market value compensation to physicians from DHS entities, as well as to arrangements involving fair market value compensation to DHS entities from physicians. We believe that this approach is consistent with the statutory scheme and intent.

The expansion of the applicability of the fair market value compensation exception to compensation paid to DHS entities by physicians will require parties to use the exception in § 411.357(l), rather than the exception in § 411.357(i), when payments by a physician to a hospital are, for example, for equipment leases of less than 1 year. Upon further consideration, we believe that the required application of the fair market value compensation exception, which contains conditions not found in the less transparent exception for payments by a physician to a hospital, further reduces the risk of program abuse. As discussed below in section IX.L, we have amended the text of the exception for fair market value compensation in § 411.357(l) to exclude arrangements for the rental of office space. The only exception applicable to arrangements for the rental of office space is § 411.357(a).

J. Charitable Donations by a Physician

Using our authority under section 1877(b)(4) of the Act, in Phase II, we established an exception in § 411.357(j) for *bona fide* charitable donations made by a physician (or his or her immediate family member) to an entity furnishing DHS. To qualify for the exception, donations must be made to an organization exempt from taxation under the Internal Revenue Code (or to an exempt supporting organization, such as a hospital foundation). The exception provided that the donation may not be solicited or made in any manner that reflects the volume or value of referrals or other business generated between the parties. As with all regulatory exceptions promulgated under section 1877(b)(4) of the Act, a protected arrangement must not violate the anti-kickback statute or billing or claims submission rules. This Phase III final rule clarifies that the donation may not be solicited or offered in any manner that reflects the volume or value of referrals.

Comment: A hospital association objected to the requirement in § 411.357(j)(2) that the donation cannot be made in a manner that takes into account referrals or other business generated between the physician and the entity furnishing DHS. According to the commenter, a hospital cannot control how the donor makes the

payment. The commenter asked that the exception be conditioned only upon the manner in which the charitable donations are solicited, rather than the manner in which they are both solicited and made.

Response: We disagree that only the manner of the solicitation should be relevant for this exception. We agree, however, that the phrase "nor made, in any manner" might be interpreted as implying that, irrespective of whether the entity had knowledge of an improper purpose of the donation, the donation is outside the protection of the exception simply if the physician intended that the donation was in exchange for future or past referrals or other business generated between the parties. Accordingly, we have amended § 411.357(j) to provide that the entity may not solicit the donation, nor may the physician offer the donation, in any manner that takes into account the volume or value of referrals or other business generated between the physician and the entity.

Comment: Two commenters asked for further guidance regarding acceptable fundraising efforts directed at medical staff. One of the commenters emphasized that such efforts are very important to hospitals.

Response: We recognize the importance of fundraising to nonprofit health care entities and the crucial role often played by medical staff in fundraising. The regulation is sufficiently clear that it permits solicitations of the medical staff provided that neither the solicitation nor the offer of a contribution from the physician takes into account the volume or value of referrals or other business generated between the physician and the hospital.

Comment: Two commenters asserted that the purpose of the law is to regulate payments to physicians from entities furnishing DHS, not contributions from the physicians to the entities. One of the commenters suggested that we define remuneration to exclude charitable donations from physicians.

Response: We disagree with the commenters. All financial relationships between a DHS entity and a physician who refers Medicare patients to the entity for DHS must comply with the physician self-referral provisions. Contributions from a physician to a hospital are remuneration and must comply with an exception. Moreover, some ostensible charitable donations have been abusive. The current regulation adequately protects legitimate fundraising while imposing minimal restrictions.

K. Nonmonetary Compensation

In Phase I, using our authority under section 1877(b)(4) of the Act, we established a new regulatory exception to protect nonmonetary compensation provided to physicians up to \$300 per year. Phase II provided that nonmonetary compensation that does not exceed \$300 per year does not create a compensation arrangement if—

- 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;
- The compensation is not solicited by the physician or the physician's practice; and

- The compensation arrangement does not violate the anti-kickback statute or other Federal or State law.

In addition, Phase II provided that the limit on the nonmonetary compensation would be adjusted for inflation to the nearest whole dollar effective January 1 of each calendar 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. The nonmonetary compensation limit increased to \$308 for CY-2005, \$322 for CY-2006, and \$329 for CY-2007. We display the increase in the CPI-U and these new limits on the physician self-referral Web site at http://www.cms.hhs.gov/PhysicianSelfReferral/10_CPI-U_Updates.asp.

This Phase III final rule makes two substantive changes to § 411.357(k): (1) The revised exception allows physicians to repay certain excess nonmonetary compensation within the same calendar year to preserve compliance with the exception; and (2) the revised exception allows entities, without regard to the dollar limitation in § 411.357(k)(1), to provide one medical staff appreciation function (such as a holiday party) for the entire medical staff per year. We are also clarifying that the aggregate limit in § 411.357(k)(1) is to be calculated on a calendar year basis.

Comment: Several commenters asked for clarification regarding the treatment under § 411.357(k) of specific activities. Two commenters believed that meals and reimbursement to physicians on a DHS entity's board should not count against the monetary limit, provided that the compensation is consistent with that provided to other non-physician board members. Other commenters asked that meals or other remuneration given to staff members for activities in connection with hospital business should not be subject to the limit. Examples provided by commenters

included off-site meetings of the medical staff due to space constraints, assistance in recruiting, hospital leadership meetings, and other business meetings.

Response: We previously addressed the issues raised by these commenters in Phase II (69 FR 16113-16114). There, we said that, "[w]hether 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 nonmonetary compensation [in] § 411.357(k) or the exception for fair market value compensation [in] § 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" (69 FR 16114). We also noted 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 (69 FR 16114).

Comment: One commenter sought clarification as to whether the dollar limit on nonmonetary compensation applied to the legal entity providing the compensation (such as a parent health system) or to the DHS entity. The commenter noted that some large systems could be hurt if the agency imposed aggregate limits, and suggested that the limit should be on each DHS provider.

Response: The limit applies to each DHS entity, and not to a parent health system. Remuneration provided by a parent health system to a referring physician could create an indirect compensation arrangement between the referring physician and the entity furnishing the DHS (for example, if the referring physician has a compensation relationship with the parent health system, which has an ownership interest in the DHS entity).

Comment: Two commenters asked that the cap be raised. One suggested \$500 and the other \$600.

Response: We believe that the limit (\$329 in CY-2007) is appropriate. As explained above and in Phase II, we have indexed the amount so that it will increase to account for inflation (69 FR 16112).

Comment: One commenter stated that inadvertently exceeding the yearly dollar limit on nonmonetary compensation could lead to disastrous and uncertain results. The commenter asserted that the harsh result should be mitigated by permitting the excessive payment to be cured by the physician's repayment of the excess. The commenter stated that errors can occur through, among other things, erroneously valuing a benefit, not properly accounting for a benefit, or not being aware of a family relationship between a physician and another person (including another physician). Another commenter asserted that, by their nature, gifts of nonmonetary compensation are very difficult to account for in traditional accounting systems. Tracking of such benefits is usually a manual process, based on the submission of reports from department heads and other members of hospital management. In addition, once the hospital becomes aware of a benefit provided to physicians, it is sometimes faced with difficult questions of how to value the benefit and allocate it among the physicians.

Response: Hospitals and other DHS entities that wish to use the exception for nonmonetary compensation should take steps to ensure the implementation of effective compliance systems, including appropriate tracking and valuation mechanisms. DHS entities should not provide benefits to physicians about which the entities are unaware or for which they are unable to account. However, we are persuaded to mitigate the potentially serious consequences of exceeding the nonmonetary compensation limits where the violation is inadvertent and the value of the overage is limited. Therefore, we are adding new subparagraph (3) to § 411.357(k) to provide some protection against inadvertent violations. Under this new provision, nonmonetary compensation will be deemed to be within the limit set forth in § 411.357(k)(1) if the entity has inadvertently exceeded the limit by no more than 50 percent during a calendar year and the physician repays the excess compensation within the earlier of: (1) The end of the calendar year in which the excess nonmonetary compensation was received; or (2) 180 days from the date the excess nonmonetary compensation was received. For example, if an entity gave nonmonetary

compensation with a value of \$250 to a physician on April 15 and then inadvertently made another gift, this time valued at \$200, to the physician on August 15, the total nonmonetary compensation to the physician is \$450, which is less than 150 percent of the amount allowed ($\$329 \times 150 \text{ percent} = \493.50). If the physician repays the excess of \$121 ($\$450 - \$329 = \121) by December 31, the entity continues to satisfy the requirements of the exception. An entity will not be allowed to use this new provision more than once every 3 calendar years with respect to the same physician. With respect to DHS referrals made by a physician after his or her receipt of excess nonmonetary compensation, any billing or claims submission by the entity for such referrals will not violate the prohibition in section 1877(a)(1)(B) of the Act, provided that the deeming provision set forth in § 411.357(k)(3) and the remaining conditions of the nonmonetary compensation exception are satisfied. Once a DHS entity becomes aware that it has provided to a physician excess nonmonetary compensation that could qualify for the deeming provision, it would be prudent for the DHS entity to delay any billing and claims submission for the physician's DHS referrals until after the physician has returned the nonmonetary compensation in accordance with § 411.357(k)(3).

Comment: One commenter stated that its physician relations department had routinely arranged occasional small services for physicians as tokens of appreciation. Events included free haircuts, manicures, massages, golf tournaments, and tickets to plays and sporting events. The commenter requested clarification concerning whether the cap on nonmonetary compensation applied to the hospital's cost of the item or the fair market value of the item to the physician. The commenter suggested that the exception exclude one-time annual events provided that the event is open to the entire medical staff or a specialty, the fair market value of the event is less than \$200 per attendee, and that there are no more than three such events per year. In addition, the commenter believed that hospitals should be permitted to give any staff member a token of appreciation annually if the fair market value does not exceed \$100 and the provision of the gift is not tied to referrals or other business generated between the parties.

Response: We believe that the limit on nonmonetary compensation per calendar year period is sufficient to provide for tokens of appreciation. We

note that we do not agree that all of the items listed by the commenter are "small." The cap under the nonmonetary compensation exception applies to the fair market value of the item, which is the amount the physician would have paid if he or she had purchased the item or service in a fair market value transaction. However, we believe that allowing one annual, local social event for the entire medical staff would not create a risk of program or patient abuse. (This is in addition to the nonmonetary compensation permitted under § 411.357(k).) Accordingly, we are modifying the exception in § 411.357(k) to permit hospitals and other entities with formal medical staffs to provide one local medical staff appreciation event per year open generally to all medical staff (that is, all physicians and other medical practitioners who order hospital services for patients). The entity's cost per medical staff member for such event will not be counted against the limit set forth in § 411.357(k)(1) (as adjusted under § 411.357(k)(2)). However, any gifts or gratuities provided in connection with the medical staff appreciation event (such as door prizes) would be subject to the limit in § 411.357(k)(1) (as adjusted under § 411.357(k)(2)).

L. Fair Market Value Compensation

In Phase I, we finalized an exception for fair market value compensation arrangements that was originally proposed in the January 1998 proposed rule (66 FR 917–919). The exception, which was promulgated using our authority under section 1877(b)(4) of the Act, protects compensation from a DHS entity to a physician, an immediate family member of a physician, or a group of physicians for the provision of items or services by the physician or group to the DHS entity, provided that, generally—

- The arrangement is set out in a writing that is signed by the parties and describes the items or services;
- The writing sets out the timeframe for the arrangement, subject to some restrictions;
- The writing specifies the compensation, which 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 any referrals or other business generated by the referring physician;
- The arrangement is commercially reasonable and furthers the legitimate business purposes of the parties; and
- The arrangement does not violate the anti-kickback statute or involve the counseling or promotion of any business arrangement that violates Federal or

State law. Phase II made no substantive changes to § 411.357(l). This Phase III final rule makes one substantive and one clarifying change to § 411.357(l). Specifically, and as discussed at section IX.I, we are amending the exception to provide that it may apply to compensation provided to a physician from an entity and to compensation provided to an entity from a physician. We are also clarifying that the exception is not applicable to leases for office space; rather, such lease arrangements must comply with § 411.357(a).

Comment: One commenter objected to our position that physician recruitment is not a service to the hospital and, therefore, cannot qualify under § 411.357(l), the fair market value compensation exception.

Response: We disagree with the commenter for the reasons stated in Phase II (69 FR 16096). There, we said 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." Money spent on recruitment of physicians who will not be employed by the hospital offering the recruitment incentives is essentially a contribution made for the benefit of the community and not a payment for services provided to the hospital. Therefore, recruitment incentives offered by hospitals must be structured to satisfy the requirements of the recruitment exception or another exception, such as the exception for *bona fide* employment relationships or obstetrical malpractice insurance subsidies.

Comment: One commenter objected to our position that a lease of office space cannot qualify for the fair market value compensation exception in § 411.357(l) because it is not an "item." The commenter noted that elsewhere in Phase II, we stated that a space lease is an item or service when a physician is the lessee (69 FR 16111).

Response: In Phase II, we explained that we could not expand the exception to be as comprehensive as the commenters advocated without posing a risk of fraud or abuse (69 FR 16111–16112). We do not believe that the lease of office space is an "item or service." Moreover, because space leases have been subject to abuse, we believe that the use of the fair market value compensation exception for space leases may pose a risk of program or patient abuse. Therefore, a space lease must qualify under the exception for the rental of office space in § 411.357(a), which contains more restrictive conditions. We have modified the

regulatory text in § 411.357(l) accordingly.

Comment: The same commenter asked us to provide bright-line guidance as to what is fair market value. The commenter recommended that there be a rebuttable presumption that a transaction is fair market value.

Response: The statute and regulations provide a definition of fair market value for purposes of section 1877 of the Act. The parties to a transaction or an arrangement are in the best position to ensure that the remuneration is at fair market value and to document it contemporaneously. If questioned by the government, the burden would be on the parties to explain how the transaction meets the fair market value compensation requirements. We are not adopting the suggestion that a transaction be presumed to be fair market value.

M. Medical Staff Incidental Benefits

In Phase I, we established a new exception in § 411.357(m) for medical staff incidental benefits (66 FR 920–922). This exception is limited to benefits, such as parking, cafeteria meals, and lab coats, that are customarily provided by a hospital to members of its medical staff and that are incidental to services being provided by the medical staff at the hospital.

In Phase II, we clarified that the exception is 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 in § 411.357(k) (69 FR 16112–16113). We also made other clarifications in § 411.357(m)(1) and (m)(2), and stated in § 411.357(m)(8) that certain institutional entities (such as long-term care facilities), federally qualified health centers, and other health care clinics, that have *bona fide* medical staffs are permitted to provide incidental benefits to those staffs on the same terms and conditions that apply to hospitals under the exception (69 FR 16112–16114). Phase II also provided that the \$25 limit on the value of each medical staff incidental benefit would be adjusted in the same manner as the limit on nonmonetary compensation in § 411.357(k). The limit for each medical staff incidental benefit for purposes of § 411.357(m) increased to \$26 for CY 2005, \$27 for CY 2006, and \$28 for CY 2007.

We are making no substantive changes to this exception in this Phase III final rule.

Comment: One commenter requested the elimination of the “on campus” requirement in § 411.357(m). According

to the commenter, the limitation is not necessary because the exception already requires the physician to be on rounds or otherwise engaged in services or activities that benefit the hospital or its patients. Alternatively, the commenter suggested that we define campus as a hospital and all facilities owned or operated by the hospital.

Response: We disagree with the commenter. The “on campus” limitation is integral to the exception and an important safeguard against program and patient abuse. A hospital’s campus includes all facilities operated by a hospital except for facilities that have been leased for non-hospital purposes and are not used exclusively by the hospital.

Comment: One commenter requested clarification as to whether a hospital may provide a physician with a device that is used to access patients who are at home or at work or personnel who are in locations other than the hospital campus.

Response: A hospital may not provide a device used to access patients who are at home or at work or personnel who are in locations other than the hospital campus under this exception. A hospital can provide a physician with a device that is used to access patients and personnel on the hospital’s campus, even if the physician is not on the campus. In Phase II, we indicated that the exception (as revised in that rulemaking) covers 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 (69 FR 16113). A physician may use the dedicated pager or two-way radio: (1) to contact the physician’s patients (who are hospital patients) only when the patients are on the hospital’s campus; or (2) to contact personnel only when the personnel are on the hospital campus. We note that some arrangements involving health information technology used for patients or personnel who are not on the hospital campus may qualify under the exception in § 411.357(u) for community-wide health information systems or the exceptions in § 411.357(v) and (w) for arrangements involving the provision of electronic prescribing technology and electronic health records technology, respectively.

Comment: One commenter noted that, whereas § 411.357(m) specifically provides that mere identification of medical staff on a hospital website or in hospital advertising is covered by the exception, the preamble to Phase II states that advertising or promoting a physician’s private practice would not

satisfy the requirements of the exception (69 FR 16113). The commenter asserted that it is unclear whether hospital physician referral services would be considered advertising or promotion of the physician. The commenter requested clarification that a hospital’s physician referral service could qualify for the exception in § 411.357(m).

Response: A hospital’s physician referral service may be considered a medical staff incidental benefit and qualify for the exception if all of the requirements of § 411.357(m) are satisfied. Whether a hospital’s physician referral service would constitute advertising or promotion of a physician or his or her private practice would depend on the nature of the particular referral service; however, many typical referral services constitute advertising or promotional activity. We note that hospital referral services sometimes involve payments by physicians to the hospital that operates the referral service. These payments, which are often assessed based on the costs of operating the referral service, would need to satisfy the requirements of an exception. Moreover, these payments also potentially implicate the anti-kickback statute. The payments could be structured to satisfy the exception in § 411.357(q) for referral services, which protects remuneration that satisfies all of the conditions of the safe harbor for referral services in § 1001.952(f).

N. Risk-Sharing Arrangements

In Phase I, we created a new exception for remuneration made pursuant to a *bona fide* “risk-sharing arrangement,” out of concern about the impact of the January 1998 proposed rule on commercial and employer-provided managed care arrangements (66 FR 912). The risk-sharing arrangements exception in § 411.357(n) applies to compensation (including, but not limited to, withholds, bonuses, and risk pools) between a managed care organization or an independent physician 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 or any laws or regulations governing billing or claims submission. In Phase II, we responded to several comments on the new risk-sharing arrangements exception in § 411.357(n) but made no changes to the exception (69 FR 16114). We received no comments on this exception and are making no changes to § 411.357(n) in this Phase III final rule.

O. Compliance Training

In the Phase I rulemaking, we exercised our authority under section 1877(b)(4) of the Act to create an exception for compliance training provided by a hospital to physicians who practice in the hospital's local community or service area (66 FR 915, 921). In Phase II, we modified the exception to include compliance training provided to a physician or a physician's office staff by any DHS entity and explicitly included training addressing the requirements of any Federal, State or local law governing the activities of the party receiving the training (69 FR 16114–16115). The Phase II exception excludes any programs for which continuing medical education (CME) credit is available.

This Phase III final rule amends § 411.357(o) to permit compliance training programs that involve CME credit, provided that compliance training predominates.

Comment: Several commenters objected that, under Phase II, § 411.357(o) does not protect any compliance training that also qualifies for CME credit. According to the commenters, provided that the compliance training program qualifies under the exception, it should not matter whether a physician receives CME credit.

Response: We agree that, if a program offers CME credit for compliance training, such compliance training should nonetheless be able to satisfy the requirements of § 411.357(o). However, we are concerned that the exception not be used to protect CME programs that are only incidentally about or related to compliance training. For the reasons set forth in Phase I and Phase II, we are not prepared to except generally from the physician self-referral law CME programs funded by DHS entities. Programs offering CME credit, when provided to a referring physician, have substantial value to the physician, who is required to obtain such CME credit for State licensure purposes. We are also not prepared to except CME programs merely because they contain a compliance training component. Instead, we are revising the exception in § 411.357(o) to cover all training programs of which compliance training is the primary purpose, including any genuine compliance training program that happens to qualify for CME credit. The revised exception does not protect traditional CME content under the guise of "compliance training." The exception may not be used for other programs that are not compliance training programs,

regardless of whether such programs may also provide CME.

Comment: A commenter requested clarification that internet-based compliance training can qualify as local training. The commenter also noted that many small- and medium-sized communities lack the resources to provide specialized compliance training and should be permitted to provide reimbursement for a physician's reasonable out-of-pocket expenses to obtain training outside of the local community.

Response: Section 411.357(o) protects 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 that the training is held in the local community or service area. With respect to on-line compliance training, if the physician (or the physician's immediate family member or office staff) accesses the on-line training while in a location that is in the entity's local community or service area, the compliance training would qualify for the exception in § 411.357(o), provided that all other requirements of the exception are satisfied. We disagree that an entity should be permitted to reimburse out-of-pocket expenses (such as travel expenses) for physicians to obtain training outside of the entity's local community or service area. We are not persuaded that permitting payment of such expenses does not create a risk of program or patient abuse.

P. Indirect Compensation Arrangements

In Phase I, we established a new exception for indirect compensation arrangements using our authority under section 1877(b)(4) of the Act (66 FR 865). Indirect compensation arrangements qualify for the exception if the following conditions are satisfied:

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

services covered by the arrangement (in the case of a *bona fide* employment relationship, the arrangement need not be set out in a written contract, but it must be for identifiable services and be commercially reasonable even if no referrals are made to the employer); and

- The compensation arrangement does not violate the anti-kickback statute or any laws or regulations governing billing or claims submission. (66 FR 867.)

Phase II made no substantive changes to the indirect compensation arrangements exception. This Phase III final rule similarly makes no changes to the exception.

We received a number of comments regarding § 411.357(p), the indirect compensation arrangements exception. Some commenters questioned how the indirect compensation arrangements exception applies in circumstances involving a compensation arrangement between a DHS entity and a group practice that employs or contracts with referring physicians. As discussed in section VI.B, we have revised § 411.354(c), which specifically addresses direct and indirect compensation arrangements between DHS entities and physicians. Under the revised rule, the relationship between the physician and his or her physician organization (as defined in this Phase III final rule at § 411.351) is disregarded and the physician "stands in the shoes" of his or her physician organization. The effect of this new provision is that many arrangements that would have constituted indirect compensation arrangements if analyzed under Phase I and Phase II are now deemed to be direct compensation arrangements, and the indirect compensation arrangements exception cannot be used. Moreover, under this Phase III final rule, many arrangements that may not have met the definition of an "indirect compensation arrangement" under the Phase I and Phase II analysis will constitute direct compensation arrangements that must satisfy the requirements of an exception in order for the physician to make DHS referrals to the entity furnishing DHS. As discussed above in section VI, the "stand in the shoes" provisions in § 411.354(c) are applicable as of the effective date of this Phase III final rule. However, arrangements that satisfied the Phase II definition of "indirect compensation arrangement" and the requirements of § 411.357(p) as of the *publication* date of this final rule need not be amended during the original or current renewal term of the arrangement to comply with the Phase III final regulations.

Comment: One commenter stated that the indirect compensation arrangements exception was difficult to apply because the DHS entity had no ready ability to monitor or assess the basis of payment being made by the intervening entity to the physician. The commenter suggested that we expand the exception by adding an alternative whereby the arrangement would be protected if: (1) The direct payment made by the DHS entity to the intervening entity complies with an exception; (2) the physician provides a written representation that his or her compensation from the intervening entity is not based on referrals; and (3) the DHS entity has no actual knowledge of the falsity of the representation. Another commenter stated that the exception was unfair to hospitals and other DHS entities because compliance turns on the physician's compensation arrangement with the intervening entity, and hospitals have no control over those compensation arrangements.

Response: We believe that the new "stand in the shoes" provision will substantially address the commenters' concerns. Under that provision, many arrangements will use direct compensation arrangements exceptions (for example, personal service arrangements, fair market value compensation, office space rental, or equipment rental) rather than the indirect compensation arrangements exception in § 411.357(p). We perceive no unfairness to DHS entities, because the definition of an "indirect compensation arrangement" includes a knowledge element.

Comment: Several commenters requested confirmation that, if there exists an indirect compensation arrangement involving a hospital and a physician in the group practice and the arrangement qualifies for the indirect compensation arrangements exception, the direct compensation arrangement between the hospital and the group practice would not also have to satisfy the requirements of a direct compensation arrangements exception, such as those for the rental of office space or personal service arrangements. The commenters noted that the indirect compensation arrangements exception was considerably more flexible because, for example, the arrangement could be amended at any time.

Other commenters wanted clarification that, in an identical situation (that is, a chain of financial relationships involving a hospital and a group practice and the group practice's physicians), referrals by the physicians to the hospital would be protected, provided that the financial relationship

between the hospital and the group practice complied with one of the direct compensation arrangements exceptions. One commenter requested confirmation that, whenever a direct or indirect compensation arrangements exception is applicable, the parties would be protected from the referral prohibition provided that they complied with any one of the potentially applicable exceptions.

Response: As noted above, the new "stand in the shoes" provision should address many of these commenters' concerns. Under this final rule, physicians "stand in the shoes" of physician organizations, including group practices. This means that, in the case of a chain of financial relationships involving a hospital, a group practice, and the group practice's physicians, the physicians "stand in the shoes" of their group and the financial relationship at issue is the direct relationship between the hospital and the group practice. The direct relationship could satisfy the requirements of any applicable direct compensation arrangements exception. The indirect compensation arrangements exception would not apply.

Where, after applying the "stand in the shoes" provision, an arrangement still meets the definition of an indirect compensation arrangement in § 411.354(c)(2) (for example, a chain of financial relationships involving a hospital, a leasing company, and a physician), the only available exception is the indirect compensation arrangements exception. As we explained in Phase I and Phase II, indirect compensation arrangements cannot fit in any of the direct compensation arrangements exceptions; the only available exception for an arrangement that meets the definition of an "indirect compensation arrangement" is the indirect compensation arrangements exception (66 FR 866–867, 69 FR 16060–16061). To satisfy the requirements of the indirect compensation arrangements exception, it is not necessary for each link in the chain of financial relationships to also satisfy the requirements of a separate exception. Consistent with the statutory scheme, the only financial relationship that triggers liability under section 1877 of the Act is the financial relationship between the DHS entity and the referring physician. (66 FR 864.)

Comment: Two commenters asked for confirmation that a contract based on a percentage of collections can satisfy the requirement in the indirect compensation arrangements exception that the compensation be fair market

value and not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician for the DHS entity. The commenter gave the example of a hospital contracting for outpatient radiology with a joint venture owned by the hospital and physicians, and basing payment on a percentage of collections. This commenter stated that, because the hospital is billing and collecting payment for the services, it is the entity furnishing DHS for purposes of the physician self-referral law. This commenter noted that, in Phase II, we acknowledged that the position we took in Phase I on percentage compensation arrangements was overly restrictive and that we amended § 411.354(d)(1) to permit percentage compensation arrangements under certain conditions (69 FR 16068). The commenter stated that, if the percentage compensation arrangement is at fair market value and is not inflated to compensate for the generation of business, the parties should be entitled to rely on the indirect compensation arrangements exception for the transaction described.

Response: The discussion in Phase II regarding percentage compensation arrangements and the modification to § 411.354(d)(1) pertained to the "set in advance" requirement that is contained in certain exceptions, but not in the indirect compensation arrangements exception. The joint venture relationship between the hospital and the physicians creates an indirect compensation arrangement between the hospital and the physicians that must satisfy the requirements of an exception. A percentage contract as described by the commenter will cause the arrangement to fall outside the indirect compensation arrangements exception if the return to the physician from the radiology joint venture takes into account in any manner the physician's referrals to the hospital (whether or not these referrals involve services provided by the joint venture). Moreover, a second indirect compensation arrangement exists between the hospital and the physicians, created by virtue of the ownership interest that does not meet an ownership exception (which, thus, creates a compensation arrangement), in the chain of relationships that runs: hospital—radiology venture—physicians. This arrangement would also need to satisfy the requirements of the indirect compensation arrangements exception. With respect to the second indirect compensation arrangement, the inquiry would be whether the compensation

under the percentage contract between the hospital and the radiology venture (the compensation arrangement nearest the referring physician) is fair market value not taking into account in any manner the volume or value of referrals or other business generated by the referring physician. We note that the indirect compensation arrangements exception requires that the compensation "received" by the referring physician (or immediate family member) is fair market value for services and items provided. A compensation arrangement based on a percentage of collections may not, depending on how the actual collections progress, result in fair market value received by the referring physician (or immediate family member).

Comment: Two commenters requested clarification regarding the potential application of the indirect compensation arrangements exception to medical foundations. One of the commenters noted that, whereas the agency had suggested that the personal service arrangements exception was available, most medical foundations contract with a physician group, thereby creating an indirect financial relationship between the foundation and the physicians. The commenter asked whether a group: (1) That received a percentage of collections from the foundation; (2) in which the physicians were both employees and shareholders; and (3) that compensated physicians based on RVUs and quality measures, would qualify under the indirect compensation arrangements exception.

Response: The new stand in the shoes provision should address the commenters' concerns. Physicians will stand in the shoes of their group practices. Thus, in the example given by the commenter, the arrangement between the medical foundation (as DHS entity) and the referring physicians would be treated as a direct compensation arrangement (rather than an indirect compensation arrangement) and the personal service arrangements exception would apply, provided that all conditions of the exception are satisfied. In section VI.C, we addressed the treatment of percentage compensation in exceptions, such as the personal service arrangements exception, that include the "set in advance" requirement. (If, by way of example, the hospital were to contract with a medical foundation for services provided to the hospital by the physician group with which the foundation contracts, the arrangement created between the hospital and the group physicians would be an indirect

compensation arrangement that would need to satisfy the requirements of the indirect compensation arrangements exception. The physicians would stand in the shoes of their group practice, but not in the shoes of the foundation.)

Comment: One commenter asked whether a DHS entity that intentionally restructures an unprotected direct compensation arrangement to form a protected indirect compensation arrangement is engaging in a prohibited circumvention scheme under section 1877(g)(4) of the Act. The commenter described a situation in which a hospital elects to contract with an intervening entity for the medical director services of a physician rather than contract with the physician directly.

Response: Under the physician self-referral law, all financial relationships between DHS entities and referring physicians must be structured to satisfy the requirements of an exception. Restructuring an arrangement that does not meet a direct compensation arrangements exception so that it complies with the indirect compensation arrangements exception is not *per se* prohibited. Whether the restructuring of an arrangement constitutes a prohibited circumvention scheme under section 1877(g)(4) of the Act would depend on the specific facts and circumstances. The commenter has not clearly identified a set of specific circumstances sufficient for us to judge whether a circumvention scheme exists.

Q. Referral Services

In the Phase I rulemaking, we solicited comments on creating exceptions to the physician self-referral prohibition for arrangements that fit squarely in an anti-kickback statute "safe harbor" in § 1001.952 (66 FR 863). In Phase II, we created two new compensation exceptions for arrangements that fit in the anti-kickback safe harbors for referral services (§ 411.357(q)) and obstetrical malpractice insurance subsidies (§ 411.357(r)) (69 FR 16115). We received no comments on § 411.357(q) and this Phase III final rule makes no changes to the exception in § 411.355(q) for referral services.

R. Obstetrical Malpractice Insurance Subsidies

As discussed above in section IX.Q, we created a new exception in Phase II for compensation arrangements that fit in the anti-kickback safe harbor for obstetrical malpractice insurance subsidies (§ 411.357(r)) (69 FR 16115). This Phase III final rule makes no changes to the exception in § 411.357(r).

Comment: One commenter suggested that we permit the fair market value compensation exception in § 411.357(l) to be used for additional malpractice insurance assistance for medical staff.

Response: We see no reason why the fair market value compensation exception in § 411.357(l) cannot be used to offer medical staff assistance with malpractice insurance, provided that the value of the assistance is fair market value for services actually provided by the staff and the other requirements of the exception are satisfied.

Comment: Several commenters complained that the exception for malpractice insurance subsidies is too narrow and the limitation to health professional shortage areas (HPSAs) should be expanded to include all specialties and hospitals. One commenter urged us to revise the exception to include non-HPSA areas where at least 50 percent of the deliveries come from patients who reside in a HPSA. The commenters urged us to consult with the OIG and to develop a broader exception. Another commenter suggested that hospitals should be permitted to provide assistance if there is a community need.

Response: The exception in § 411.357(r) is one of several exceptions that allow DHS entities to provide assistance with malpractice insurance. Other exceptions that permit DHS entities to provide such assistance are the fair market value compensation exception (as discussed above in response to the previous comment) in § 411.357(l), the exception for *bona fide* employment relationships in § 411.357(c), and the exception for personal service arrangements in § 411.357(d) (provided that the value of the assistance is commensurate with the value of actual services furnished to the hospital by the physician). These exceptions allow any DHS entity to provide assistance with malpractice insurance, without regard to the specialty of the physician or the area in which the physician practices. The exception in § 411.357(r), on the other hand, is intended to mirror the anti-kickback safe harbor for malpractice insurance in § 1001.952(o). The OIG has not issued any guidance of general application that is broader than this exception and safe harbor. Finally, apart from the availability of other exceptions, we do not believe that it is advisable to relax the criteria of § 411.357(r) where a "community need" is present, because "community need" is too ambiguous a standard and does not, by itself, eliminate the potential for program or patient abuse. We note that, in the CY 2008 Physician Fee Schedule notice of

proposed rulemaking, we proposed to amend the exception in § 411.357(r) to remove the incorporation of the safe harbor for malpractice insurance in § 1001.952(o) and to include more flexible criteria.

Comment: One commenter asserted that we did not have the authority to create exceptions that were limited to specific geographic areas, for example, limiting the malpractice insurance subsidies exception to physician practices in HPSAs.

Response: Section 1877(b)(4) of the Act allows us to create additional exceptions to the general prohibition on physician self-referral where doing so would not result in a risk of program or patient abuse. It does not require us, where we exercise such authority, to make the additional exceptions available to all types of entities and physicians, or make them applicable in all areas. The Congress and CMS have long recognized the special needs and character of rural, urban, and underserved areas. Malpractice insurance availability in HPSAs poses specific concerns not present in other areas and supports a targeted exception.

S. Professional Courtesy

In Phase II, we established a new compensation arrangements exception (§ 411.357(s)) for professional courtesy provided to a physician or his or her immediate family members (69 FR 16116). We defined “professional courtesy” at § 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 (69 FR 16116)—

- 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;
- The health care items and services provided are of a type routinely provided by the entity;
- The entity's professional courtesy policy is set out in writing and approved in advance by the governing body of the health care entity;
- 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;
- If the professional courtesy involves any complete or partial waiver of any coinsurance obligation, the insurer is informed in writing of the reduction so

that the insurer is aware of the arrangement; and

- The professional courtesy arrangement does not violate the anti-kickback statute or any billing or claims submission laws or regulations.

This Phase III final rule makes one substantive change to § 411.357(s), deleting the requirement that an entity notify an insurer when the professional courtesy involves the whole or partial reduction of any coinsurance obligation. We have also modified the exception to make clear our intent that § 411.357(s) applies only to hospitals and other providers with formal medical staffs.

Comment: A commenter noted that one of the conditions of the exception is that the arrangement does not violate the anti-kickback statute. The commenter questioned whether, given the 1994 OIG Special Fraud Alert, clinical laboratories would be prohibited from offering professional courtesy, notwithstanding that the actual language of § 411.357(s) does not exclude any specific type of entity or services and, therefore, appears applicable to clinical laboratory services. The commenter stated that, unlike the situation in which one physician extends professional courtesy to another physician, when a laboratory offers professional courtesy to a physician, it does not expect the same in return, a fact that makes kickback issues more significant. The commenter suggested that we clarify that the 1994 OIG Special Fraud Alert continues to be applicable to the provision of professional courtesy by all laboratories, including hospital outreach laboratories. The commenter also stated that, to the extent that the exception permits a hospital to offer professional courtesy only to physicians on its medical staff, instead of to all physicians in its local community or service area, the exception creates an inducement for referrals to the hospital.

Response: Nothing in these regulations affects in any respect the application of the OIG's guidance regarding the anti-kickback statute. We conclude from the comment that some clarification may be helpful with respect to the scope of the exception. The exception was promulgated in response to comments requesting an exception for providers that offer certain professional courtesy to physicians and their family members. We are clarifying the regulatory language to state specifically that the professional courtesy exception applies only to DHS entities with formal medical staffs. The exception does not apply to suppliers, such as laboratories or DME companies. The traditional reasons for professional courtesy

provided by entities with medical staffs do not pertain to suppliers and such “courtesy” offered by suppliers would pose a risk of program abuse.

We believe that the exception contains sufficient safeguards to protect against abuse. In particular, we note that:

- Professional courtesy must be extended to all members of the *bona fide* medical staff (or in such entity's local community or service area) without regard to the volume or value of referrals (thus prohibiting expensive courtesy for high-referring physicians and only less costly courtesy for low-referring physicians);
- The entity's professional courtesy policy must be set out in writing and approved in advance by the entity's governing body; and
- The arrangement must not violate the anti-kickback statute.

Based on a comment received in response to Phase II, we are concerned that the current § 411.357(s)(3) may be misinterpreted as meaning that the requirements of the exception apply only if an entity, *in fact*, has a written policy regarding professional courtesy (that is, if an entity's policy is not reduced to writing, the entity need not comply with the requirements of the exception at all). Therefore, we are amending § 411.357(s)(3) to clarify that, as a prerequisite to extending professional courtesy, the entity *must* have a written policy that is approved by the entity's governing body.

Comment: Two commenters objected to limits placed on physicians extending professional courtesy. One commenter requested that we revise the regulation so as not to prohibit the longstanding practice of professional courtesy, including physician-to-physician professional courtesy. Another commenter approved of the exception generally, but objected to the restriction requiring the courtesy to be extended either to the entire medical staff or to all physicians in the community. This commenter requested that a hospital be able to extend the courtesy on the same terms as medical staff incidental benefits; that is, for example, to members of the medical staff practicing in the same specialty rather than to the entire medical staff.

Response: With respect to the first comment, physician-to-physician professional courtesy is unlikely to need a separate exception, unless the recipient physician is a source of DHS referrals to the physician (or physician practice) extending the courtesy. We believe the more typical situation would involve a group practice offering professional courtesy to its physicians

and their families. The in-office ancillary services exception would be available in such situations. Moreover, for purposes of the professional courtesy exception, we consider a group or other physician practice to be an entity with a formal medical staff that could use the exception, if all of the requirements of the exception were satisfied.

Second, we do not agree that a hospital, or other entity with a formal medical staff, should be allowed under the exception to extend professional courtesy only to certain members of its medical staff. The selective provision of professional courtesy to a physician gives rise to an inference that the recipient of the courtesy may have been chosen in a manner that took into account the volume or value of referrals from the recipient (or his or her family member or employer-physician) to the physician providing the professional courtesy or other business generated between the parties.

Comment: One commenter sought clarification as to the applicability of the exception to DHS entities that did not have medical staffs.

Response: The exception would not apply to such entities, for the reasons noted above. We are clarifying the regulatory text in § 411.357(s).

Comment: One commenter asked for clarification as to which Federal health care programs are referred to in § 411.357(s)(4) and how to document financial need.

Response: For purposes of the exception, the Federal health care programs are all Federal health care programs as defined at section 1128B(e) of the Act (69 FR 16115–16116). The determination and documentation of financial need should be reasonable, consistent, and contemporaneous.

Comment: Two commenters objected to the requirement that a hospital notify the insurer if any coinsurance obligation is waived in whole or in part. According to the commenters, the requirement is unreasonable and serves no purpose. The commenters requested that the condition be deleted.

Response: We agree that, in order to eliminate the risk of program or patient abuse, our standard under section 1877(b)(4) of the Act, we do not have to require a hospital or other DHS entity to notify a private insurer if it intends to waive in whole, or in part, any coinsurance obligation of the insurer's beneficiary. We are deleting the notification provision. Nonetheless, we believe that it would be a prudent practice for DHS entities to provide such notification; in fact, insurers may require such notification.

T. Retention Payments in Underserved Areas

In Phase II, in accordance with our authority under section 1877(b)(4) of the Act, we created a new exception for retention payments made to a physician by a hospital or federally qualified health center located in a HPSA (regardless of whether the HPSA is specifically designated for the physician's particular specialty) (69 FR 16097). In order to qualify for the exception under Phase II, the following conditions must be met—

- The physician must have 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;
- The offer must 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;
- The retention payment must be limited to the lower of: (1) The amount obtained by subtracting the physician's current income from physician and related services from 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 (2) 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;
- Any retention payment must be subject to the same obligations and restrictions, if any, on repayment or forgiveness of indebtedness as the *bona fide* recruitment offer;
- 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;
- The requirements of § 411.357(e)(1)(i)–(iv), relating to physician recruitment arrangements, must be satisfied; and
- The arrangement must not violate the anti-kickback statute or any Federal or State law or regulation governing billing or claims submission.

The exception in § 411.357(t) requires that retention payments be made directly from the hospital or federally qualified health center to the retained physician. A hospital or federally qualified health center may not enter into a retention payment arrangement with a physician more frequently than once every 5 years. Also, Phase II provided for approval of retention payments to physicians practicing in other underserved areas (or to physicians serving underserved patient populations), as determined on a case by case basis through an advisory opinion.

As discussed below, we are modifying § 411.357(t) in several respects, including expanding the exception by permitting (under certain circumstances) retention payments in the absence of a written recruitment offer, by adding flexibility for retention payments to physicians who serve underserved areas and populations, and by allowing rural health clinics to make retention payments. In addition, retention payments may be made on the basis of a written offer of employment as well as a *bona fide* firm, written recruitment offer.

Comment: A commenter that is the only hospital providing labor and delivery services for its county and the 100,000 people who reside in its service area requested modifications to the exception. The commenter believed that the exception should not be limited to retention payments in HPSAs or other underserved areas. According to the commenter, in 2003, the five obstetricians who were delivering babies at the hospital received an offer from an academic medical center located 30 miles away. Under the terms of the offer, the academic medical center would have provided through its captive insurance company malpractice insurance that was much less expensive than the insurance the obstetricians then carried. The commenter stated that the academic medical center required that the obstetricians perform their deliveries in a community hospital in a neighboring county with which the academic medical center was affiliated. The commenter wrote that its attorneys advised the hospital that the physician self-referral regulations prohibited it from countering the academic medical center's offer because the commenter's hospital is not located in a HPSA. The commenter proposed two alternative modifications to the retention exception: (1) Permit tax-exempt organizations to make retention payments if the payments would not constitute an improper private benefit or an excess benefit transaction under

applicable IRS principles; or (2) replace the HPSA requirement in both the retention exception and the obstetrical malpractice insurance subsidies exception with a super-majority board approval requirement.

Response: We intend for the retention payments exception to be limited to those areas in which there is a demonstrated shortage of physicians, and where special efforts are often necessary to attract and maintain physicians. As noted below, we are expanding the exception to permit retention payments where the physician's *current medical practice* is in a rural area or HPSA, or where at least 75 percent of the physician's patients either reside in a medically underserved area or are members of a medically underserved population.

With respect to the suggested modifications to the exception, we believe that they are too broad and subject to abuse. Compliance with the IRS excess benefit and private benefit rules, or securing a super-majority vote of the governing board, does not ensure that the physician is needed or cannot easily be replaced. Neither proposed modification necessarily would prevent retention payments from being abused to reward high referring physicians.

Comment: A number of commenters requested that we eliminate the requirement in § 411.357(t)(1)(iii) of a written offer. According to the commenters, many offers are not in writing until agreement is imminent, at which point it is too late for the hospital to retain the physician. Other commenters believed that the requirement for a written offer encourages physicians both to solicit offers, and to engage in insincere negotiations with others. One commenter believed that an entity should be able to offer retention payments provided it has a good faith belief that a physician may be recruited by another entity.

Response: We are revising § 411.357(t) to permit a hospital, rural health clinic, or federally qualified health center to offer assistance to a physician who does not have a *bona fide* written offer of recruitment or employment if the physician certifies in writing to the hospital, rural health clinic, or federally qualified health center that, among other things, he or she has a *bona fide* opportunity for future employment by a hospital, academic medical center, or physician organization that would require relocation of his or her medical practice at least 25 miles to a location outside of the geographic area served by the hospital, rural health clinic, or federally qualified health center.

Revised § 411.357(t) also requires the physician to certify in writing: details regarding the steps taken by the physician to effectuate the employment opportunity; details of the physician's employment opportunity, including the identity and location of the physician's future employer and/or employment location, and the physician's anticipated income and benefits (or a range for income and benefits); that the future employer is not related to the hospital, rural health clinic, or federally qualified health center making the payment; the date on which the physician anticipates relocating his or her medical practice; and information sufficient for the hospital, rural health clinic, or federally qualified health center to verify the information included in the written certification. The hospital, rural health clinic, or federally qualified health center must take reasonable steps to verify the information in the certification.

In circumstances in which the retained physician provides a written certification to the hospital (or rural health clinic or federally qualified health center) rather than a *bona fide* written offer of recruitment or employment, the retention payment may not exceed the lower of the following: (1) an amount equal to 25 percent of the physician's current annual income (averaged over the previous 24 months) using a reasonable and consistent methodology that is calculated uniformly; or (2) the reasonable costs the hospital would otherwise have to expend to recruit a new physician to the geographic area served by the hospital in order to join the medical staff of the hospital to replace the retained physician. Where the physician has a written offer, the hospital may match the written offer, as provided in § 411.357(t)(1). (We note that the exception for retention payments applies to federally qualified health centers and rural health clinics in the same manner as it applies to hospitals.)

Comment: Several commenters asked that we broaden the exception to allow facilities in any medically underserved area to offer retention payments. Two commenters asked for clarification regarding whether the entity paying the retention payment must be located in an area of demonstrated need or whether the physician's patients must live in the area of demonstrated need. The commenters stated that the latter should be the test. For example, a hospital should be permitted to offer retention payments to keep a physician in an outreach area that is underserved. Another commenter urged that the

exception be made available to rural health clinics.

Response: We agree generally with the comments and are expanding the exception in § 411.357(t) to permit retention payments that otherwise satisfy all of the conditions of the exception when: (1) the physician's current medical practice is located in a rural area, a HPSA, or an area of demonstrated need as determined by the Secretary in an advisory opinion issued under section 1877(g)(6) of the Act; or (2) at least 75 percent of the physician's patients either reside in a medically underserved area or are members of a medically underserved population. The location of the hospital in a HPSA is no longer a requirement of the exception. A retention payment may be made to a physician whose current medical practice is located in a HPSA, regardless of whether the HPSA has been designated for physicians in the retained physician's specialty. Further, we are also permitting retention payments to be made by rural health clinics under the same terms and conditions that apply to hospitals and federally qualified health centers. The purpose of this exception is to retain the physician's practice in a rural or underserved area.

Comment: Two commenters questioned why the exception requires a retention payment to be contingent on an offer from a hospital. According to the commenters, any offer of employment, including an offer from a group practice, should be sufficient.

Response: We agree and have modified the regulatory text in § 411.357(t)(1) to allow retention payments if a physician has a written offer from a hospital, academic medical center, or physician organization (as defined in this Phase III final rule at § 411.351) that is not related to the hospital, rural health clinic, or federally qualified health center making the retention payment. We have included a similar provision in new § 411.357(t)(2) related to the certification of an employment opportunity for which no written offer has been received.

Comment: In light of the prohibition against entering into a retention payment arrangement with the same physician more frequently than once every 5 years, several commenters objected to the provision requiring that retention payments be limited to the difference between the compensation set forth in the recruitment offer and the physician's current annual income averaged over a 24-month period. According to the commenters, the net effect is to make the retention payment offer non-competitive. Another

commenter asked whether an offer that is for a smaller amount than the difference over a 24-month period would qualify for the exception.

Response: We are not persuaded to revise the regulation to permit the hospital, rural health clinic, or federally qualified health center to make a retention payment that would match the physician's compensation specified in the recruitment offer (or offer of employment), irrespective of the period of the recruitment offer. Under our present rule, we allow entities to make a retention payment that takes into account the difference between what the physician earns in his or her current position and what the physician would earn if he or she accepted the recruitment offer, for a period of up to 24 months. For example, if a physician's monthly total compensation package in his or her current position is \$13,000, and he or she has a *bona fide* written recruitment offer that would, over the next 36 months, provide the physician with total monthly compensation of \$15,000, we would allow an entity to make a retention payment of up to \$48,000 (24 months (the maximum number of months permitted) × \$2000). We believe that allowing a retention payment that takes into account the difference between what the physician earns in his or her current position and what the physician would earn if he or she accepted the recruitment offer (or offer of employment) may create a potential for abuse if that payment is calculated over a period greater than 24 months. An entity is always free to offer a lesser amount. For clarity, we have amended the language in § 411.357(t)(1)(iv) that stated the retention payment "is limited to the lower of" to "does not exceed the lower of."

Comment: A hospital trade association objected to the provisions limiting the total retention payment to an existing physician to the costs of recruiting a new physician. The commenter believed that the restriction would require hospitals to limit their retention offers to the costs of a newly practicing physician. The commenter contended that hospitals should be permitted to take into account the physician's experience, training, and length of service in the area. Other commenters asked for confirmation that, in determining the costs of a replacement, a hospital could include all costs, both direct and indirect.

Response: We did not intend to limit the amount of a retention payment to the amount that it would cost to recruit a newly practicing physician in the same specialty to the same geographic

area. Hospitals, rural health clinics, and federally qualified health centers may take into account experience, training, and length of service in the area. Both direct and indirect costs of a replacement can be included, provided that they are actual costs.

Comment: Two commenters asked whether a hospital could make retention payments to a group practice, rather than to the physician directly. One of these commenters noted that the physician recruitment exception in § 411.357(e) permits remuneration to be paid to the group on behalf of the physician.

Response: We do not believe that it is appropriate for the payment to be made to the group practice because the hospital, rural health clinic, or federally qualified health center should not be subsidizing expenses of the group practice through the retention payment. The purpose of the retention payment exception is to allow hospitals, rural health clinics, and federally qualified health centers to retain the physician receiving the retention payment in the facility's service area. We note that a written or other offer of employment by a local group practice with whom the physician is affiliated would not qualify for this exception. We note further that the commenter misunderstands the recruitment exception, which does not protect remuneration provided to a group practice. It protects remuneration provided directly or indirectly to a recruited physician, some part of which may pass through a group practice subject to specific conditions.

Comment: Several commenters complained that the exception did not permit hospitals to provide malpractice insurance assistance to physicians on their medical staffs facing exorbitant increases in their premiums.

Response: As noted in section IX.R of this preamble (in response to a comment on the exception for obstetrical malpractice insurance subsidies), there are several exceptions available to entities that wish to provide assistance with malpractice insurance. Moreover, we do not believe it is accurate to say that the retention payment exception does not permit assistance for malpractice insurance premiums. Remuneration in the form of a retention payment paid by an entity to a physician may be applied by the physician to malpractice insurance premiums.

Comment: One commenter questioned whether an arrangement that fully complies with the retention payments exception in § 411.357(t) at the time that it is entered into will be considered out of compliance if the HPSA designation

is lost before the arrangement expires. Specifically, the commenter wanted to know whether a retention payment arrangement would be out of compliance after all payments have been made, but the physician remains under a community service obligation at the time of the HPSA redesignation.

Response: We have amended § 411.357(t)(3) to permit the payment of a retention payment to a physician whose current medical practice is in a rural area or a HPSA, or to a physician when 75 percent of his or her patients reside in a medically underserved area or are members of a medically underserved population. It is likely that a retention payment made by a hospital to a physician whose practice location was within an area that formerly was designated as a HPSA would satisfy one of the new, more flexible requirements in § 411.357(t)(3). Retention payments may be made only if the arrangement meets the conditions of the amended exception; however, a retention agreement may remain in compliance despite a continuing community service obligation (provided no additional retention payments are made) even if the HPSA designation was changed. We note that, under Phase II, the *entire* geographic area served by the hospital need not be located in a HPSA.

Comment: One commenter asked for clarification of the term "relocation requirement" in the Phase II regulation text in § 411.357(t)(2). According to the commenter, it is unclear from this provision as to whether the Secretary has the authority to waive the requirement that the physician receive a *bona fide* written offer from a facility to which the physician intends to relocate, or whether the Secretary has the authority to waive the requirement that the *bona fide* written offer would require the physician to relocate his practice at least 25 miles from its present location and outside the geographic area served by the entity that would make the retention payment, or both.

Response: The term "relocation requirement" refers to the requirement that the *bona fide* written offer requires the physician to relocate his or her practice at least 25 miles from its present location to a location outside the geographic area served by the hospital that would make the retention payment.

Comment: One commenter stated that the advisory opinion alternative in the exception in § 411.357(t)(2) is unworkable because the process takes too long and has an uncertain result. The commenter asserted that a physician would not delay his or her

decision to relocate his or her practice pending the receipt of a favorable advisory opinion. Moreover, according to the commenter, the availability of an advisory opinion has limited utility because only the relocation requirement in § 411.357(t)(1) may be waived by the Secretary. The commenter suggested that CMS should be given more latitude through the advisory opinion process to approve retention payment agreements.

Response: The advisory opinion process is the vehicle for CMS to use in determining whether the relocation requirement in this exception will be waived for a particular retention payment arrangement. We believe that the modifications to § 411.357(t) may alleviate many of the commenter's concerns regarding a hospital's ability to offer a retention payment to a physician in a manner timely enough to affect the physician's decision to relocate out of the hospital's geographic service area. With respect to the commenter's suggestion that CMS be given more latitude to approve retention payment agreements, we are not convinced that additional changes to this exception would pose no risk of program abuse.

U. Community-Wide Health Information System

In Phase II, using our authority under section 1877(b)(4) of the Act, we created a new exception for community-wide health information systems (69 FR 16113). If certain conditions are met, § 411.357(u) permits compensation in the form of 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. We are making no changes to this exception.

Comment: We received 13 comments regarding the community-wide health information system exception, all of which supported the new exception in § 411.357(u). Several commenters recommended further clarification of the definition of a "community" and of "community-wide health information system." Several commenters recommended that hospitals be allowed to provide to physicians items and services needed for non-clinical functions. Commenters also raised questions about patient access and whether physicians may be charged to use a system. Several commenters suggested that hospitals be able to provide access to health information to

physicians only, rather than all residents of the community. Two commenters urged that "maximum flexibility" be allowed. A few commenters recommended that interoperability should be encouraged.

Response: Subsequent to the receipt of the public comments, on October 11, 2005, we published a notice of proposed rulemaking creating an exception for electronic prescribing technology as required by section 101 of the MMA (70 FR 59182). In addition, in that same notice, using our authority under section 1877(b)(4) of the Act, we proposed an exception for electronic health records software and information technology and training services. After taking into account public comments, on August 8, 2006, we published a final rule promulgating these two exceptions (71 FR 45140). The exception for electronic prescribing items and services appears in § 411.357(v) and the exception for electronic health records software and information technology and training services appears in § 411.357(w). We are republishing both exceptions with nonsubstantive technical changes in this Phase III final rule. In addition to requiring compliance with criteria designed to safeguard against program and patient abuse, both exceptions provide that neither the donor nor any person on the donor's behalf may take any action to limit or restrict the use, compatibility or interoperability of the items or services. The electronic health records exception in § 411.357(w) requires interoperability at the time the remuneration is provided to the physician. Neither exception requires community-wide application.

At this time, we are not making any changes to, or issuing any further guidance concerning, the community-wide health information systems exception while we observe how the new exceptions for electronic prescribing and electronic health records technology in § 411.357 (v) and (w), respectively, are received. We are continuing to consider the issues that commenters raised and, if appropriate, we will issue clarifications and changes in a future rulemaking.

X. Reporting Requirements—§ 411.361

Section 1877(f) of the Act sets forth certain reporting requirements for all entities providing covered items or services for which payment may be made under Medicare. The required information must be provided in a form, manner, and at such times that the Secretary specifies. Section 1877(g)(5) of the Act provides that any person who is required, but fails, to meet one of these reporting requirements is subject to a

civil money penalty of not more than \$10,000 for each day for which reporting is required to have been made.

Section 411.361 of our regulations, as modified in Phase II, states that the information that we may require to be furnished 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 with an immediate family member (as defined at § 411.351) who has a financial relationship with the entity;

(3) The covered items and services provided by the entity; and

(4) With respect to each physician identified under (1) and (2), the nature of the financial relationship (including the extent and/or value of the ownership or investment interest or the compensation arrangement).

In Phase II, we—

- Specifically excluded from the definition of "reportable financial relationships" ownership or investment interests in publicly-traded securities and mutual funds if such interests satisfy the requirements of the exceptions in § 411.356(a) or (b), respectively. This exclusion from the definition of reportable financial relationships for publicly-traded securities and mutual funds is limited to *shareholder information*; contractual arrangements concerning these ownership or investment interests are reportable financial relationships.

- Modified § 411.361(c)(4) to specify that the information required to be reported is only that information that the entity knows or should know in the course of prudently conducting business, including, but not limited to, records that the entity is already required to retain to comply with IRS and Securities and Exchange Commission rules and other rules under the Medicare and Medicaid programs.

We are making no substantive changes to § 411.361 in this Phase III final rule. However, we are revising § 411.361(c) to account for the transition from the UPIN to the National Provider Identifier (NPI).

Comment: One commenter sought clarification of our statement in Phase II that, to the extent we are obligated under the Freedom of Information Act (FOIA), 5 U.S.C. 552, to disclose records we have received pursuant to the physician self-referral reporting requirements, we cannot maintain the records as confidential (69 FR 17934). The commenter believes that most such records will be exempt from disclosure under Exemption 4 of the FOIA, 5

U.S.C. 552(b)(4), as they will involve confidential business information.

Response: The commenter is correct that Exemption 4 of the FOIA protects confidential business information from required disclosure. Moreover, the Trade Secrets Act, 18 U.S.C. 1905, prohibits Federal agencies from disclosing confidential business information, absent a law or regulation permitting such disclosure. We agree that much of the information that we may receive pursuant to our reporting requirements under the physician self-referral regulations will be exempt from disclosure under the FOIA and prohibited from disclosure by the Trade Secrets Act. However, when we receive a FOIA request for information reported to us, we must evaluate whether the particular information is exempt or prohibited from disclosure. (Generally, information that is exempt from disclosure under the FOIA is also prohibited from disclosure by the Trade Secrets Act.) We cannot state categorically, however, that all information that we receive will be confidential business information within the meaning of the FOIA and the Trade Secrets Act.

Comment: A commenter suggested that we exclude from the definition of "reportable financial relationship" compensation arrangements that qualify under any of the following exceptions: Medical staff incidental benefits (§ 411.357(m)); nonmonetary compensation (§ 411.357(k)); professional courtesy (§ 411.357(s)); or referral services (§ 411.357(q)). According to the commenter, treating these compensation arrangements as "reportable financial relationships" would require a hospital to furnish the required information for virtually all physicians on its medical staff (and perhaps for others as well), which would create an unnecessary burden for the hospital. Another commenter asserted that an entity's obligation under our reporting requirements is staggering because of the breadth of the physician self-referral statute. According to this commenter, the most acute burdens relate to the requirement in § 411.361(c)(2) to maintain records of financial relationships with family members of physicians. The commenter further asserted that most DHS entities do not have a means to catalog all such financial relationships, as they have no reason to create records of transactions that are at fair market value. The commenter suggested that various types of financial relationships involving immediate family members of physicians (such as charitable donations by family members or fair market value

lease arrangements) be excepted from the reporting requirements. A third commenter also expressed concern that the inclusion of financial relationships with immediate family members of physicians imposed a substantial burden on DHS entities. This commenter suggested that if basic information, such as the UPIN of each physician who has a reportable financial arrangement with the entity, the covered items or services provided by the entity, and the nature of the financial arrangement for each such physician is provided, CMS could verify that exceptions are met and it would not be necessary in many cases for the entity to report information pertaining to immediate family members who have financial relationships with the DHS entities. Where such information is needed from the immediate family members of physicians, the commenter asserted that 30 days is an unreasonable amount of time in which to provide the information, and suggested that extensions of at least 90 days should be available.

Response: We decline to adopt the commenters' suggestions for the reasons stated in Phase II (69 FR 17934). There, we stated that we are concerned that an entity could decide that one or more of its financial relationships falls within an exception, fail to retain data concerning those financial relationships, and thereby prevent the government from reviewing the arrangements to determine if they qualify for an exception. In particular, we disagree that, where the financial relationship that triggers the physician self-referral statute is between an immediate family member of a physician and the DHS entity, it is not necessary for the entity to maintain information concerning the financial relationship and to report it upon our direction to do so. We fail to see how reporting information pertaining only to physicians who have financial relationships provides us with assurance that financial relationships concerning immediate family members meet one or more of the exceptions.

Section 411.361(e) provides that entities must be given at least 30 days to provide the required information. Where we agree that the nature or scope of the request for information is such that the information cannot reasonably be furnished within 30 days, we will extend the time for supplying the information.

Comment: A commenter requested that we create an exception to the reporting requirements for the situation in which a DHS entity seeks to obtain the required information but was denied access to it, such as where a physician

has a reportable financial relationship solely by virtue of the hospital's financial arrangement with an immediate family member.

Response: We fail to see the basis for the commenter's concern. An entity that has a financial relationship with a physician or an immediate family member of the physician should have its own records of the details of such relationship.

XI. Miscellaneous (Other)

A. Specialty Hospital Moratorium

Section 507(a) of the MMA amended the hospital and rural provider ownership exceptions to the physician self-referral prohibition. Section 507 of the MMA specified that, for the 18-month period beginning on December 8, 2003 and ending on June 7, 2005, physician ownership and investment interests in "specialty hospitals" would not qualify for the whole hospital exception. Section 507 of the MMA further specified that, for the same 18-month period, the exception for physician ownership or investment interests in rural providers would not apply in the case of specialty hospitals located in rural areas. For purposes of section 507 of the MMA only, a "specialty hospital" was defined as a hospital in one of the 50 States or the District of Columbia that is primarily or exclusively engaged in the care and treatment of one of the following: (1) Patients with a cardiac condition; (2) patients with an orthopedic condition; (3) patients receiving a surgical procedure; or (4) patients receiving any other specialized category of services that the Secretary designates as being inconsistent with the purpose of permitting physician ownership and investment interests in a hospital. The term "specialty hospital" did not include any hospital determined by the Secretary to be in operation or "under development" as of November 18, 2003, and "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."

Phase II modified the hospital ownership exception to reflect the MMA moratorium provisions. We received several comments on Phase II regarding the implementation of the 18-month moratorium on referrals of Medicare patients to specialty hospitals by physician investors.

Comment: One commenter suggested that, during the 18-month moratorium, any entity applying to receive a Medicare provider agreement as a hospital should be required to submit, as part of the application process, the

information required under § 411.361(c)(1) through (c)(4).

Response: The commenter's suggestion is moot as the moratorium ended on June 7, 2005. However, as we noted in the Secretary's August 8, 2006 final Report to Congress on specialty hospitals, which was required by section 5006 of the DRA, we are exploring changes to the enrollment form for hospitals (the CMS-855A) to capture information regarding whether an applicant hospital is, or is projected to be, a specialty hospital.

Comment: A commenter noted that Phase II defined a specialty hospital as a hospital that is primarily or exclusively engaged in the care and treatment of patients with a cardiac condition, patients with an orthopedic condition, or patients receiving a surgical procedure, but that no clear guidance exists as to what "primarily engaged in" means.

Response: For purposes of implementing the 18-month moratorium imposed by section 507 of the MMA, we considered a hospital to be "primarily engaged" in the care and treatment of cardiac, orthopedic, or surgical patients if 45 percent of the hospital's Medicare cases were (or were projected to be) in Major Diagnostic Category (MDC) 5, Diseases and Disorders of the Circulatory System (cardiac), MDC 8, Diseases and Disorders of the Musculoskeletal System and Connective Tissue (orthopedic), or were surgical in nature (surgical). As noted in response to the previous comment, we are exploring changes to the CMS-855A to enable us better to determine whether an applicant hospital is a specialty hospital. We may define "primarily engaged" for that purpose.

Comment: A commenter noted that, in Phase II, we defined specialty hospital for purposes of the 18-month moratorium to exclude a hospital for which the number of physician investors at any time on or after November 18, 2003 is no greater than the number of investors as of such date. The commenter stated that this requirement unfairly restricted any group practice that had invested in a specialty hospital prior to November 18, 2003 from increasing the number of its physician owners. It suggested that we interpret section 507 of the MMA to mean that there is no increase in physician investors, notwithstanding an increase in the number of physician equity owners in a group practice, if the group practice owned its interest in the specialty hospital prior to November 18, 2003 and the group was not formed for the purpose of investing in the hospital.

Response: For purposes of implementing the 18-month moratorium, we considered there to be an increase in the number of physician investors in a specialty hospital if a group practice that had an investment interest in a specialty hospital increased the number of physician equity owners in the group at any time on or after November 18, 2003 (and there was no corresponding decrease in the specialty hospital's investors). The suggested interpretation by the commenter does not comport with the plain language of section 507 of the MMA.

B. Physician Certification Requirements for Home Health Services—§ 424.22

Section 903 of the Omnibus Reconciliation Act of 1980 amended sections 1814(a) and 1835(a) of the Act to require the Secretary to issue regulations prohibiting a physician from certifying the need for home health services, or establishing and reviewing home health plans of treatment if the physician had a "significant ownership interest in, or a significant financial or contractual relationship with, a home health agency." In October 1982, we published a rule (47 FR 47388) interpreting the prohibition to apply to physicians having, among other things: (1) a direct or indirect ownership interest of 5 percent or more in a home health agency; or (2) direct or indirect business transactions with the home health agency that totaled more than \$25,000 or 5 percent of the agency's operating expenses, whichever was less. The 1982 regulatory provision, which was ultimately codified in § 424.22(d), was superseded by the physician self-referral prohibition when the prohibition became applicable in 1995 to physician referrals for home health services.

In Phase I, we amended the home health certification requirement in § 424.22(d) to provide that a physician may not certify the need for home health services or establish or review a plan of treatment if his or her "financial relationship" (as defined in the physician self-referral regulations) with the home health agency did not satisfy the requirements of an exception under the physician self-referral law. In Phase II, we republished § 424.22(d) without change, and we received no comments on this provision. This Phase III final rule makes no substantive change to § 424.22(d), although we are revising the provision to reference more explicitly the regulatory exceptions.

XII. Provisions of the Final Rule

A summary of the major changes to the regulations in this Phase III final

rule are discussed below. No major regulatory changes were made to § 411.352 (Group Practices), § 411.353 (Prohibition on Certain Referrals by Physicians and Limitations on Billing), or § 411.356 (Exceptions to the Referral Prohibition Related to Ownership or Investment Interests). However, certain provisions of these sections were clarified in this preamble.

Three definitions are added at § 411.351 ("downstream contractor," "physician organization," and "rural area"). Also, in the definition of "fair market value," we are not retaining the safe harbor regarding hourly payments for a physician's personal services.

Section 411.354 defines "financial relationships" for purposes of the physician self-referral law. A new provision was added in § 411.354(b)(3)(v) which specifies that an ownership interest in an entity [the whole hospital or a subdivision (that is, portion) of the hospital] does not include a security interest taken by a physician in equipment sold to the entity and financed with a loan by the physician to the entity. However, the security interest is a compensation arrangement.

A new "stand in the shoes" provision was added to § 411.354(c)(2) under which a physician is deemed to "stand in the shoes" of his or her physician organization (defined at § 411.351 as a "physician (including a professional corporation of which the physician is the sole owner), a physician practice, or a group practice that complies with the requirements of § 411.352." A physician who stands in the shoes of his or her physician organization is deemed to have the same compensation arrangements with the DHS entity that the physician organization has with the DHS entity. As a result, many compensation arrangements that were analyzed under Phase II as indirect compensation arrangements are now analyzed as direct compensation arrangements that must comply with an applicable exception for direct compensation arrangements.

The Phase III changes to the general exceptions in § 411.355 for both ownership/investment interests and compensation arrangements are concentrated in the exceptions for academic medical centers and intra-family rural referrals in § 411.355(e) and (j), respectively. With respect to the academic medical centers exception, we clarified that the total compensation from *each* academic medical center component to a faculty physician must be set in advance and not determined in a manner that takes into account the volume or value of the physician's

referrals or other business generated by the referring physician within the academic medical center. In addition, when determining whether the majority of physicians on the medical staff of a hospital affiliated with an academic medical center consists of faculty members, the affiliated hospital must include or exclude all individual physicians holding the same class of privileges at the affiliated hospital.

We amended the exception for intra-family rural referrals to include an alternative test to determine whether a physician may refer a patient to an immediate family member for DHS. Specifically, if, in light of the patient's condition, no other person or entity is available to furnish the DHS in a timely manner within 45 minutes transportation time from the patient's home, a physician is not prohibited from making a referral for the DHS to an immediate family member or to an entity with which the immediate family member has a financial relationship, provided that all other conditions of the exception are satisfied. The Phase II 25-mile test remains an option for complying with the exception.

Section 411.357 sets out the exceptions for various compensation arrangements. The revisions to the exceptions for physician recruitment in § 411.357(e) and retention payments in underserved areas in § 411.357(t) are significant.

The physician recruitment exception protects certain remuneration that is provided by a hospital to a physician as an inducement for the physician to relocate his or her medical practice into the "geographic area served by the hospital," which we defined in Phase II as the lowest number of contiguous zip codes from which the hospital draws at least 75 percent of its inpatients. Under the revised definition of "geographic area served by the hospital," a hospital that draws fewer than 75 percent of its inpatients from all of the contiguous zip codes from which it draws inpatients may recruit a physician into the geographic area composed of *all* of the contiguous zip codes from which it draws its inpatients, provided that all other requirements of the exception are satisfied. In addition, the revised definition sets forth a special optional rule for rural hospitals under which a rural hospital may determine its geographic service area using the lowest number of contiguous zip codes from which the hospital draws at least 90 percent of its inpatients or, if the hospital draws fewer than 90 percent of its inpatients from all of the contiguous zip codes from which it draws inpatients, its service area may include

certain noncontiguous zip codes. A rural hospital may also recruit physicians to an area outside the geographic area served by the hospital if the Secretary has determined in an advisory opinion that the area into which the physician is to be recruited has a demonstrated need for the recruited physician, provided that all other requirements of the exception are satisfied.

In the case of an income guarantee provided by a hospital to a physician who relocates his or her practice into a rural area or HPSA and joins a physician practice to replace a physician who retired, died, or relocated (from the service area) during the previous 12-month period, the costs allocated by the physician practice to the recruited physician may be either: (1) the actual additional incremental costs attributable to the recruited physician; or (2) the lower of a per capita allocation or 20 percent of the practice's aggregate costs.

This Phase III final rule also clarifies that a physician must move his or her medical practice from a location outside of the geographic area served by the hospital to a location within the geographic area served by the hospital. In addition, we have revised the exception to provide that the relocation requirement will not apply to a physician who: (1) for at least 2 years immediately preceding the recruitment arrangement, was employed on a full-time basis by a Federal or State bureau of prisons (or similar entity operating correctional facilities), the Department of Defense or Veterans Affairs, or facilities of the Indian Health Service, provided that he or she had no private medical practice during the same time period; or (2) the Secretary has determined in an advisory opinion not to have an established medical practice that serves a significant number of patients who are or could become patients of the recruiting hospital. In the case of recruitment assistance provided by a hospital to a physician who joins a physician practice, we have revised the exception to prohibit the physician practice from imposing on the recruited physician any practice restrictions that unreasonably restrict the recruited physician's ability to practice medicine in the geographic area served by the hospital. Finally, the exception in § 411.357(e) is now applicable to a rural health clinic in the same manner as it applies to a hospital (or federally qualified health center).

We have expanded the exception in § 411.357(t) for retention payments in underserved areas to permit a hospital to make a payment to retain a physician

on its medical staff even if the physician does not have a *bona fide* firm, written recruitment offer, provided that the physician certifies in writing that, among other things, he or she has a *bona fide* opportunity for future employment that would require the physician to move his or her medical practice at least 25 miles to a location outside the geographic area served by the hospital, and certain other conditions are satisfied. We have also expanded the retention payments exception to permit retention payments in the case of a physician with a *bona fide* firm, written offer of employment from, or a *bona fide* opportunity for future employment with, an academic medical center or physician organization. Also, we have expanded the exception to permit a hospital to make a retention payment to a physician whose current medical practice is not located in a HPSA. Under the revised exception, a retention payment may be made to a physician whose current medical practice is located in a rural area or an area with demonstrated need for the physician, as determined by the Secretary in an advisory opinion.

Changes to the remaining exceptions found in § 411.357 include—

- Under the personal service arrangements exception in § 411.357(d), allowing a "holdover" personal service arrangement on terms similar to those in the exceptions for the rental of office space and equipment;
- Under the nonmonetary compensation exception in § 411.357(k), in certain circumstances, upon repayment of nonmonetary compensation in excess of the applicable limit, deeming the nonmonetary compensation to be within the limit, and allowing an entity with a formal medical staff to hold one local medical staff appreciation event per year;
- Under the exception for charitable donations by a physician in § 411.357(j), clarifying that the donation may neither be solicited nor *offered* in any manner that takes into account the volume or value of referrals or other business generated between the physician and the entity;
- Under the professional courtesy exception in § 411.357(s), eliminating the requirement that the entity offering the professional courtesy inform the insurer in writing of the reduction of any coinsurance obligation on the part of the recipient of the professional courtesy, and clarifying that the exception is applicable only to entities that have formal medical staffs;
- Under the fair market value compensation exception in § 411.357(l),

clarifying that the exception is applicable to both compensation provided to a physician from an entity and compensation provided to an entity from a physician; and,

- Under the compliance training exception in § 411.357(o), permitting the provision of training programs for which CME is available, provided that the primary purpose of the program is compliance training.

XIII. Technical Corrections

1. Web site Change

Because the address of the physician self-referral Web site has changed, we are correcting the references to our Web site in the definition of “List of CPT/HCPCS Codes” at § 411.351, the “nonmonetary compensation” exception in § 411.357(k), and the “medical staff incidental benefits” exception in § 411.357(m).

[REG TEXT—Change]

2. Typographical Error

We are correcting typographical and other errors that appeared in Phase II. For example, we are removing a typographical error (“sbull”) in § 411.355(a)(2). In addition, we are correcting § 411.357(m)(1) to state that medical staff incidental benefits must be “offered” to all members of the medical staff. In Phase II, we intended to change “offered” to “provided” only in § 411.357(m)(2), but the change was inadvertently made to paragraph (m)(1) as well.

3. CMS Manuals

Because CMS has begun re-numbering and posting its manuals on the Internet, we are correcting the citations to the manuals in § 411.351 (the definitions of entity, *locum tenens* physician, parenteral and enteral nutrients, equipments and supplies, and physician in the group practice).

4. Nonmonetary Compensation

We are revising the section heading of § 411.357(k) to remove the reference to “up to \$300.” This change will make the section heading consistent with the provisions of § 411.357(k).

5. Simplification of Regulatory Text

We made several non-substantive grammatical and editorial revisions to the regulatory text. For example, we revised the introductory language in § 411.355(g) concerning EPO and other dialysis related drugs to make it easier to read. We also substituted “nonmonetary” for “non-monetary” throughout the regulations. A similar change is being made to § 424.22 to

simplify language concerning home health services. We have simplified references in the recruitment exception to a recruited physician joining a “physician or physician practice.” Because “joining a physician” is necessarily synonymous with “joining a physician practice,” we have simplified the regulation text so that it now refers only to “joining a physician practice.”

6. Statutory References

Under the definition of “Does not violate the anti-kickback statute” at § 411.351, the statutory references to the anti-kickback statute have been corrected from sections 1128(a)(7) and 1128a(b)(7) of the Act to sections 1128A(a)(7) and 1128(b)(7) of the Act, respectively.

7. References to the Reassignment Rules

In the definition of “physician in the group practice,” we updated the reference to the reassignment rules from § 424.80(b)(3) to § 424.80(b)(2). We also updated the reference to the reassignment rules in the in-office ancillary services exception in § 411.355(b)(3)(v) from § 424.80(b)(6) to § 424.80(b)(5).

8. National Provider Identifier

We revised the Reporting Requirements provision in § 411.361(c) to account for the transition from the Unique Physician Identification Number (UPIN) to the National Provider Identifier (NPI) by inserting the following phrase: “and/or the national provider identifier (NPI).” Specific references to the NPI are found in § 411.361(c)(1) and (c)(2).

9. Advisory Opinions

We are revising § 411.370(a) to remove the sunset provision that had formerly applied to our authority to issue advisory opinions because section 543 of the Medicare, Medicaid, and SCHIP Benefits and Improvement Protection Act of 2000, Pub. L. 106–554, extended the time period indefinitely for our authority to issue advisory opinions.

XIV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork

Reduction Act of 1995 requires that we solicit comment on the following issues—

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Therefore, we previously solicited public comment on each of these issues for the following sections of the regulation that contain information collection requirements.

Group Practice (§ 411.352)

The burden associated with § 411.352 was discussed in detail in both Phase I and Phase II (66 FR 949 and 69 FR 16118–16119, respectively). Section 411.352 sets out the requirements that must be met in order to qualify as a group practice. Section 411.352(d) provides that substantially all of the patient care services of the physicians who are members of the group must be furnished and billed through the group practice. The burden associated with this requirement is the time and effort necessary to collect, document, and maintain the information outlined in § 411.352(d). We believe that the documentation requirements in this section are usual and customary business practices. The burden associated with this requirement, therefore, is not subject to the PRA as stated in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with a collection of information that would be incurred by persons in the normal course of their activities are considered to be usual and customary business practices and are not subject to the PRA. In addition, the burden is not subject to the PRA under 5 CFR 1320.4(a) to the extent that the information is collected during the conduct of a criminal or civil action, or during the conduct of an administrative action, investigation or audit.

Section 411.352(i) addresses the special rule for productivity bonuses and profit shares. The burden associated with the requirements in this section is the time and effort associated with collecting and maintaining the information listed under § 411.352(i)(2) and (i)(3). The burden associated with the recordkeeping requirements in § 411.352(i) is not subject to the PRA, as stated in 5 CFR 1320.3(b)(2). In addition, the burden is not subject to the PRA under 5 CFR 1320.4(a) to the extent

that the information is collected during the conduct of a criminal or civil action, or during the conduct of an administrative action, investigation or audit.

Financial Relationship, Compensation, and Ownership or Investment Interest (§ 411.354)

Both Phase I (66 FR 949) and Phase II (69 FR 16119) contain detailed discussions of the information collection requirements in § 411.354. Section 411.354(d)(4) permits a physician's compensation from a *bona fide* employer or under a managed care or other contract to be conditioned on the physician's referrals to a particular provider, practitioner, or supplier if, among other things, the requirement to make referrals is set forth in a written agreement signed by the parties. Specifically, the burden associated with this requirement in § 411.354(d)(4)(iv)(A) is the time and effort necessary to set forth the required referrals provision in a written agreement signed by both parties. The burden associated with this requirement is not subject to the PRA as stated in 5 CFR 1320.3(b)(2). In addition, the burden is not subject to the PRA under 5 CFR 1320.4(a) to the extent that the information is collected during the conduct of a criminal or civil action, or during the conduct of an administrative action, investigation or audit.

General Exceptions to the Referral Prohibition Related to Both Ownership/Investment and Compensation (§ 411.355)

The burden associated with § 411.355 was discussed in detail in both Phase I (66 FR 949) and Phase II (69 FR 16119). Section 411.355(e) addresses the exception for services provided by an academic medical center. Essentially, § 411.355(e)(1)(iii)(B) states 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 these requirements is not subject to the PRA, as stated in 5 CFR 1320.3(b)(2). In addition, the burden is not subject to the PRA under 5 CFR 1320.4(a) to the extent that the information is collected during the conduct of a criminal or civil action, or during the conduct of an

administrative action, investigation or audit.

Exceptions to the Referral Prohibition Related to Compensation Arrangements (§ 411.357)

Section 411.357(a) addresses the rental of office space. Under § 411.357(a)(1), the rental or lease agreement associated with payments for the use of office space made by a lessee to a lessor must be set out in writing, signed by the parties, and specify the premises covered. The burden associated with these requirements is the time and effort necessary to draft, sign, and maintain the written agreement. The burden associated with this requirement is not subject to the PRA as stated in 5 CFR 1320.3(b)(2). In addition, the burden is not subject to the PRA under 5 CFR 1320.4(a) to the extent that the information is collected during the conduct of a criminal or civil action, or during the conduct of an administrative action, investigation or audit.

Section 411.357(b) requires that the payments made by a lessee to a lessor for the use of equipment meet certain conditions. Specifically, § 411.357(b)(1) requires that a rental or lease agreement be set out in writing, signed by the parties, and specify the equipment covered by the agreement. The burden associated with this requirement is the time and effort associated with drafting, signing, and maintaining the written agreement. The burden associated with this requirement is not subject to the PRA as stated in 5 CFR 1320.3(b)(2). In addition, the burden is not subject to the PRA under 5 CFR 1320.4(a) to the extent that the information is collected during the conduct of a criminal or civil action, or during the conduct of an administrative action, investigation or audit.

Section 411.357(d) addresses personal service arrangements. Section 411.357(d)(1)(i) requires that each personal service arrangement be set out in writing, signed by the parties, and specify the services covered by the arrangement. In addition, § 411.357(d)(1)(ii) requires that the written agreement cover all of the services to be furnished by the physician or his or her immediate family member, or both. This requirement is satisfied if all separate arrangements with the physician and his or her immediate family member incorporate each other by reference or cross-reference a master list of contracts. The burden associated with both § 411.357(d)(1)(i) and (ii) is not subject to the PRA as stated under 5 CFR 1320.3(b)(2). In addition, the burden is

not subject to the PRA under 5 CFR 1320.4(a) to the extent that the information is collected during the conduct of a criminal or civil action, or during the conduct of an administrative action, investigation or audit.

Section 411.357(e) addresses physician recruitment. Specifically, § 411.357(e)(1)(i) requires that all arrangements for remuneration provided by a hospital to recruit a physician 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 must be set out in writing and signed by both parties. In addition, § 411.357(e)(4)(i) provides that, in the case of certain recruitment arrangements in which the recruited physician joins a physician practice, the written agreement must be signed by the hospital, the recruited physician, and the physician practice. The burden associated with these requirements is the time and effort associated with drafting, signing, and maintaining the written agreement. The burden associated with this requirement is not subject to the PRA as stated under 5 CFR 1320.3(b)(2). In addition, the burden is not subject to the PRA under 5 CFR 1320.4(a) to the extent that the information is collected during the conduct of a criminal or civil action, or during the conduct of an administrative action, investigation or audit.

Section 411.357(e)(4)(iv) imposes a recordkeeping requirement. 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. The burden associated with this requirement is the time and effort associated with maintaining the required documentation. The burden associated with this collection is not subject to the PRA as it meets the requirements set forth in 5 CFR 1320.3(b)(2). In addition, the burden is not subject to the PRA under 5 CFR 1320.4(a) to the extent that the information is collected during the conduct of a criminal or civil action, or during the conduct of an administrative action, investigation or audit.

Section 411.357(l)(1) requires that all arrangements pertaining to fair market value compensation be set forth in writing. In addition, the written agreement must be signed by the parties and must cover identifiable items or services that are the subject of the arrangement. The burden associated with this requirement is the time and effort necessary to draft, sign, and maintain the written agreement. The burden associated with these

requirements is not subject to the PRA as it meets the requirements set forth in 5 CFR 1320.3(b)(2). In addition, the burden is not subject to the PRA under 5 CFR 1320.4(a) to the extent that the information is collected during the conduct of a criminal or civil action, or during the conduct of an administrative action, investigation or audit.

Section 411.357(p) sets forth an exception for indirect compensation arrangements. The exception requires the arrangement to be set out in a writing that is signed by the parties and specifies the services covered by the arrangement. The burden associated with this requirement is the time and effort necessary to draft, sign, and maintain the written agreement. The burden associated with these requirements is not subject to the PRA as it meets the requirements set forth in 5 CFR 1320.3(b)(2). In addition, the burden is not subject to the PRA under 5 CFR 1320.4(a) to the extent that the information is collected during the conduct of a criminal or civil action, or during the conduct of an administrative action, investigation or audit.

Section 411.357(q) sets forth an exception for remuneration that meets all of the conditions set forth in the voluntary anti-kickback safe harbor at § 1001.952(f). Under § 1001.952(f), the referral service must make certain standard disclosures to each person seeking a referral and must maintain a written record certifying each disclosure. The burden associated with this requirement is the time and effort necessary to draft, sign, and maintain the disclosures. The burden associated with these requirements is not subject to the PRA as it meets the requirements set forth in 5 CFR 1320.3(b)(2). In addition, the burden is not subject to the PRA under 5 CFR 1320.4(a) to the extent that the information is collected during the conduct of a criminal or civil action, or during the conduct of an administrative action, investigation or audit.

Section 411.357(r) sets forth an exception for obstetrical malpractice insurance subsidies that satisfy all of the conditions set forth in the voluntary anti-kickback safe harbor at § 1001.952(o). Under § 1001.952(o)(1), such subsidies must be made in accordance with a written agreement. The burden associated with this requirement is the time and effort necessary to draft, sign, and maintain the agreement. Under § 1001.952(o)(2), the physician receiving the subsidy must certify that for the initial coverage period, he or she has a reasonable basis for believing that at least 75 percent of his or her obstetrical patients will either reside in a HPSA or medically

underserved area, or be part of a medically underserved population, and the physician must make a similar certification for subsequent coverage periods. The burden associated with the requirement for a written agreement is not subject to the PRA as it meets the requirements set forth in 5 CFR 1320.3(b)(2). In addition, the burden is not subject to the PRA under 5 CFR 1320.4(a) to the extent that the information is collected during the conduct of a criminal or civil action, or during the conduct of an administrative action, investigation or audit. The burden associated with the physician certification requirement is considered to be a usual and customary business practice and, as set forth in 5 CFR 1320.3(b)(2), is not subject to the PRA. In addition, the burden is not subject to the PRA under 5 CFR 1320.4(a) to the extent that information is collected during conduct of a criminal or civil action, or during the conduct of an administrative action, investigation or audit.

Section 411.357(s) addresses professional courtesy. Specifically, § 411.357(s)(3) requires that an entity have a written policy approved by the entity's governing body in order to extend professional courtesy. The burden associated with this requirement is the time and effort associated with drafting and maintaining the written policy. The burden associated with this requirement is not subject to the PRA as stated under 5 CFR 1320.3(b)(2). In addition, the burden is not subject to the PRA under 5 CFR 1320.4(a) to the extent that the information is collected during the conduct of a criminal or civil action, or during the conduct of an administrative action, investigation or audit.

Section 411.357(t), under this Phase III final rule, protects payments made by a hospital to a physician on its medical staff to retain the physician's medical practice in an underserved area if certain conditions are satisfied. The exception requires, among other things, that the physician: (1) have a *bona fide* firm written recruitment offer (or offer of employment) from an unrelated hospital (which includes a rural health clinic or federally qualified health center), academic medical center, or physician organization that specifies, among other things, the remuneration being offered; or (2) provide a written certification of a verifiable employment opportunity. Both options require documentation that the new employment would require the physician to move the location of his or her medical practice at least 25 miles and outside of the geographic area

served by the hospital, rural health clinic, or federally qualified health center making the retention payment. The burden associated with this requirement is considered to be a usual and customary business practice and, as set forth in 5 CFR 1320.3(b)(2), is not subject to the PRA. In addition, the burden is not subject to the PRA under 5 CFR 1320.4(a) to the extent that the information is collected during the conduct of a criminal or civil action, or during the conduct of an administrative action, investigation or audit.

Section 411.357(v) sets forth an exception for certain arrangements involving the donation of nonmonetary remuneration consisting of electronic prescribing items and services necessary and used solely to receive and transmit electronic prescription information. Section 411.357(v)(7) requires that such arrangements be set forth in a written agreement that is signed by all parties, specifies the items or services being provided and the donor's cost of the items and services, and covers all of the electronic prescribing items and services to be provided by the donor. This requirement is met if all separate agreements between the donor and the physician incorporate each other by reference or if they cross-reference a master list of agreements that is maintained and updated centrally and is available for review by the Secretary upon request. The burden associated with these requirements is the time and effort associated with drafting, signing, and maintaining the necessary documentation. The burden associated with these requirements is not subject to the PRA as stated under 5 CFR 1320.3(b)(2). In addition, the burden is not subject to the PRA under 5 CFR 1320.4(a) to the extent that the information is collected during the conduct of a criminal or civil action, or during the conduct of an administrative action, investigation or audit.

Section 411.357(w) addresses certain arrangements involving the donation of nonmonetary remuneration consisting of electronic health records software and information technology and training services necessary and used predominantly to create, maintain, transmit, or receive electronic health records. Specifically, § 411.357(w)(7) requires that the arrangement be set forth in a written agreement that is signed by the parties and that specifies the items and services being provided, the donor's cost of the items, and the amount of the physician's contribution. The agreement must cover all of the electronic health records items and services to be provided by the donor. The burden associated with these

requirements is the time and effort associated with drafting, signing, and maintaining the necessary documentation. The burden associated with these requirements is not subject to the PRA as stated under 5 CFR 1320.3(b)(2). In addition, the burden is not subject to the PRA under 5 CFR 1320.4(a) to the extent that the information is collected during the conduct of a criminal or civil action, or during the conduct of an administrative action, investigation or audit.

Reporting Requirements (§ 411.361)

The burden associated with this section was discussed in detail in Phase II (69 FR 16054). The burden associated with the requirements in this section is not subject to the PRA as stated under both 5 CFR 1320.3(b)(2) and 5 CFR 1320.4(a). However, this section does contain requirements that are not exempt from the PRA. As stated in Phase II, we quantified the burden associated with the reporting requirements in § 411.361(c) through (e) (69 FR 16119–16121). While these requirements are subject to the PRA, they are currently approved under OMB control number 0938–0846, with an expiration date of November 30, 2007.

We have submitted a copy of this final rule to OMB for its review of the aforementioned information collection requirements.

XV. Regulatory Impact Statement

A. Overall Impact

We have examined the impact of Phase III of this rulemaking as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 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).

While we cannot specify in advance the aggregate economic impact of this rule, we do not believe that the impact will approach \$100 million or more

annually. This Phase III final rule does not unsettle existing financial relationships or create further restrictions on financial relationships between physicians and health care facilities. Indeed, physicians and DHS entities have been complying with the requirements set forth in the physician self-referral prohibition for many years, specifically in regard to clinical laboratory services since 1992 and to referrals for all other DHS since 1995.

Under Phase I, the physician self-referral prohibition was interpreted narrowly while the exceptions were interpreted broadly. Phase I also 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 using the Secretary's authority 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;
 - Nonmonetary compensation up to \$300;
 - Fair market value compensation;
 - Medical staff incidental benefits;
 - Risk-sharing arrangements;
 - Compliance training; and
 - Indirect compensation arrangements.

Phase II was issued as an interim final rule with comment period on March 26, 2004. Under Phase II, we clarified certain regulatory definitions, broadened certain established exceptions, and created additional regulatory exceptions. Phase II also addressed the public comments provided on the Phase I regulations. Phase II covered the following—

- All 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 using the

Secretary's authority 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 courtesies;
- Retention payments in underserved areas; and
- Community-wide health information systems.

This Phase III final rule primarily clarifies aspects of Phase I and Phase II based on public comments and, again, like Phase I and Phase II, increases the flexibility of the rule's application by expanding the breadth of the exceptions while continuing to protect against program and patient abuse. Phase III covers all of the provisions in section 1877 of the Act except those related to advisory opinions and civil monetary penalties. Among other things, this Phase III final rule—

- Eliminates the proposed safe harbor within the fair market value definition for physician compensation;
- Adds three new regulatory definitions;
- Considers a physician to “stand in the shoes” of a physician organization of which he or she is a member;
- Adds an alternative 45-minute transportation time test to the intra-family rural referrals exception;
- Adds a holdover provision in the exception for personal service arrangements on terms similar to those in the space and equipment lease contexts;
- Expands the geographic area into which a rural hospital may recruit a physician;
- With respect to a physician who is recruited to join another physician or practice in a rural area or HPSA to replace another physician who retired, died, or relocated within the previous 12-month period, permits the allocation of costs by the physician or practice to the recruited physician not to exceed either (A) the actual additional incremental costs attributable to the recruited physician, or (B) the lower of a per capita allocation or 20 percent of the practice's aggregate costs;
- Allows practice restrictions that do not unreasonably restrict the recruited physician from practicing in the geographic area served by the hospital;
- Expands the nonmonetary compensation exception to allow entities to avoid what would otherwise be noncompliance with the exception in

certain circumstances, and to allow an entity with a formal medical staff to provide one local medical staff appreciation event per year; and

- Adds a written certification option as an alternative to the requirement for a *bona fide* written offer under the exception for retention payments in underserved areas.

This Phase III final rule generally does not require existing financial relationships to be restructured; it merely further clarifies the language of Phase I and Phase II, and provides additional flexibility under the regulatory exceptions to enable parties to adjust noncompliant arrangements. Wherever possible, this Phase III final rule attempts to accommodate legitimate financial relationships while reducing the regulatory burden and continuing to protect against program and patient abuse. 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 small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$6 million to \$29 million in any 1 year. Currently, there are approximately 1.1 million physicians, other health care practitioners, and medical suppliers that receive Medicare payment (<http://www.cms.hhs.gov/CapMarketUpdates/Downloads/2006CMSstat.pdf>).

For purposes of the RFA, according to the latest numbers from the Small Business Administration's North American Industrial Classification System, approximately 100 percent of offices of physicians in the United States are considered small businesses according to the Small Business Administration's size standards with total revenues of \$9 million or less and are considered small entities. Individuals and States are not included in the definition of a small entity. We determined that this Phase III 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, this Phase III final rule generally does not require existing financial relationships to be restructured; it provides clarifications of the provisions found in Phase I and Phase II and provides additional flexibility under the regulatory exceptions to enable parties to adjust noncompliant arrangements. Overall, this Phase III final rule is very

accommodating to legitimate financial relationships while reducing the regulatory burden and continuing to protect against program and patient abuse.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) 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. The impact of this rule on small rural hospitals is minimal. In fact, several provisions of the rule benefit small rural hospitals by giving them more flexibility to maintain operations and remain competitive in an increasingly global health care market.

Several provisions of this Phase III final rule benefit rural hospitals and rural health clinics. For example, the rule modifies the physician recruitment exception with respect to a hospital located in a rural area by expanding the geographic area into which a rural hospital may recruit a physician. Under the revised exception, a rural hospital may recruit a physician into an area composed of the lowest number of contiguous zip codes (and in some circumstances, noncontiguous zip codes) from which the hospital draws at least 90 percent of its inpatients. In addition, we have modified the recruitment exception to permit a hospital to offer a more generous income guarantee to a physician who is recruited into a rural area or HPSA to replace a physician who retired, relocated, or died within the previous 12 months. The exception for physician recruitment is also expanded to include rural health clinics. Small rural hospitals also benefit under this rule from the significant expansion of their ability to offer retention payments to physicians. In summary, this Phase III 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 whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately \$120 million. As discussed above, the revisions made to the Phase I and Phase II rules by this Phase III final rule will have an insignificant financial impact. As such,

there are no anticipated expenditures under this rule that would result in expenditures to State, local or tribal governments, in the aggregate, or to the private sector, that would rise above the \$120 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 this Phase III final rule will have a substantial effect on State or local governments, nor do we believe that this final rule preempts State law or draws Federalism issues into question.

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 Phase III 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 Phase III final rule primarily affects physicians and health care entities that furnish certain items and services ("designated health services") to Medicare beneficiaries. We believe that this Phase III final rule addresses many of the industry's primary concerns with the existing regulatory scheme, 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 the reasons stated above, we do not anticipate that this rule will have a significant economic impact on a substantial number of small entities. Nevertheless, we wish to inform the public of what we regard as the major effects of this rulemaking. We discuss below some of the possible economic effects upon physicians and DHS entities. We also briefly discuss the effects of the rules on the Medicare and Medicaid programs as well as Medicare beneficiaries.

1. Effects on Physicians

A physician can have a financial relationship with an entity either through an ownership or investment

interest in the entity, or through a compensation arrangement with the entity. Financial relationships include both direct and indirect ownership and investment interests and direct and indirect compensation arrangements. A physician who has (or whose immediate family member has) a financial relationship with an entity that does not qualify for an exception is prohibited under section 1877 of the Act from referring Medicare patients to that entity for the provision of DHS. 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 Phase III 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 have made every effort in Phase I, Phase II, and Phase III of this 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.

Two major changes under this Phase III final rule directly affect physicians. In Phase II, we clarified that a referring physician may be treated as "standing in the shoes" of his or her wholly-owned PC and we solicited comments on whether to permit a physician to "stand in the shoes" of a group practice of which he or she is a member. In this final rule, we are adopting a broader "stand in the shoes" provision than the provision proposed in Phase II. Essentially, a physician is deemed to stand in the shoes of his or her "physician organization," which is defined to include a physician practice or group practice as well as a professional corporation of which the physician is the sole owner. A physician who stands in the shoes of a physician organization is deemed to have the same compensation arrangements (with the same parties and on the same terms) as

the physician organization. For physicians, this will require some compensation arrangements to comply with an exception for direct compensation arrangements, rather than the indirect compensation arrangements exception. In general, the new stand in the shoes provision will ease compliance by simplifying the analysis of arrangements in which a physician organization is interposed between the referring physician and the entity furnishing DHS.

The second major change relates to revisions to the physician recruitment exception. For hospitals located in rural areas, we have expanded the geographic area into which they may recruit a physician. Under the revised exception, a rural hospital may recruit a physician into an area composed of the lowest number of contiguous zip codes (and in some circumstances, noncontiguous zip codes) from which the hospital draws at least 90 percent of its inpatients. In addition, we have modified the recruitment exception to permit a hospital to offer a more generous income guarantee to a physician who is recruited into a rural area or HPSA to replace a physician who retired, relocated, or died within the previous 12 months. This change will make it easier for such physicians and physician practices to recruit new physicians.

This Phase III final rule also allows a physician practice to impose on a recruited physician practice restrictions that do not unreasonably restrict the ability of the recruited physician to practice in the geographic area served by the recruiting hospital. Allowing certain kinds of practice restrictions makes it more likely that physician practices will take on new physicians and, as a result, hospitals will be able to attract new physicians and satisfy what would otherwise be unmet health care needs of their communities.

Beyond the adoption of the more expansive "stand in the shoes" provision, and the revisions to the physician recruitment exception, the effect of the remaining changes on physicians under the Phase III final rule are relatively minor. Some of these changes include—

- Not retaining the safe harbor within the fair market value definition for hourly payments to physicians;
- Clarifying that group practices can compensate members, employed physicians, and other physicians in the group by directly taking into account the volume and value of items and services that are provided "incident to" the physicians' professional services, in certain circumstances; and

- Expanding the exception for retention payments in underserved areas to permit retention payments to be made in the case of a physician who does not have a *bona fide* written offer of recruitment or employment, provided that the physician certifies that he or she has a *bona fide* opportunity for future employment and the arrangement satisfies all other conditions of the exception.

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 the 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.

2. Effects on Other Health Care Providers and Suppliers

As we stated above, the physician self-referral rules affect entities that furnish DHS by preventing them from receiving payment for services that they furnish as a 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 Phase III final rule. However, we believe that the number will be fewer than we had anticipated in the prior physician self-referral rules for two reasons—

- First, hospitals and other DHS entities were required to restructure any non-compliant financial arrangements after Phase I and Phase II became effective (January 4, 2002 and July 26, 2004, respectively); and

- Second, this Phase III final rule does not adopt any changes that significantly narrow existing exceptions, or which would require termination or substantial modification of existing arrangements. As with Phase I and Phase II, we have interpreted the prohibition narrowly and the exceptions broadly under Phase III.

We have made every effort in Phase I, Phase II, and in Phase III of this rulemaking to address the concerns of health care providers and suppliers while remaining faithful to the statute. We discuss below the major provisions of this rule that affect health care providers and suppliers.

This Phase III final rule makes two substantive changes to the nonmonetary compensation exception that affect health care providers and suppliers: (1) The revised exception allows physicians to repay certain excess nonmonetary compensation within the same calendar year in which the excess compensation was received, thereby preserving compliance with the exception; and (2) entities are allowed, without regard to the nonmonetary compensation limit, to provide one local medical staff appreciation event per year for the entire medical staff (such as a holiday party).

The Phase III final rule also—

- Revises the exception for charitable donations by a physician to clarify that the donation may neither be solicited nor offered in any manner that takes into account the volume or value of referrals;

- Revises the exception for compliance training programs to permit entities to provide compliance training programs for which CME is available, provided that compliance training is the primary purpose of the program; and

- Allows a hospital, rural health clinic, or federally qualified health center to make a retention payment to a physician if the hospital receives a written certification from the physician, in lieu of documentation of a written offer, that he or she has a *bona fide* opportunity for future employment that would require the physician to relocate his or her medical practice at least 25 miles and outside of the geographic area served by the entity.

Again, to the extent that expanded exceptions permit additional legitimate arrangements to comply with the law, Phase III reduces the potential costs of restructuring such arrangements, and the consequences of noncompliance may be 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 program abuses that occur when physicians have financial relationships with certain 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. Over-utilization increases program costs because it causes Medicare (or Medicaid) to pay for more items or services than are medically necessary.

We expect this Phase III final rule to generate savings to the program by minimizing anti-competitive business arrangements as well as over-utilization or other program abuse, similar to the effects of Phase I and Phase II. For example, we declined to eliminate the requirement in many exceptions that the arrangement at issue comply with the anti-kickback statute. We believe this requirement is necessary to protect the Medicare and Medicaid programs by preventing individuals or entities with fraudulent intent from paying for referrals.

Phase III continues to balance the risk of program and patient abuse with the need to support legitimate business arrangements. For example, we are not excluding DHS ordered by anesthesiologists pursuant to a consultation from the definition of a referral under Phase III, because we are not satisfied that this modification poses no risk of program or patient abuse. While we cannot gauge with certainty the extent of these savings to the programs at this time, this Phase III final rule reflects our continued efforts to prohibit arrangements that have the potential to increase utilization improperly or promote anti-competitive behavior.

4. Effects on Beneficiaries

We have sought to ensure that this rule will not adversely impact the medical care of Federal health care program beneficiaries. In most cases, this Phase III final rule should not require substantial changes in delivery arrangements. This Phase III final rule makes no significant changes that have the potential to impede patient access to health care facilities and services. In fact, as noted above under the “Effects on the Medicare and Medicaid Programs,” we believe that this 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. We believe the protections included under this Phase III final rule will minimize the number of medically unnecessary tests performed on, and items or services ordered for, Federal health care program beneficiaries.

C. Alternatives Considered

After reviewing the voluminous number of comments we received, we considered in Phase I and Phase II many alternatives to accommodate the practical problems that commenters raised. As noted throughout the Phase III preamble, we have considered alternatives raised in comments received on Phase II. We have modified the regulations to accommodate those alternatives that comport with the statutory language and intent.

For example, we received many comments suggesting that we revise our restrictions on retention payments to physicians in underserved areas in § 411.357(t). Under Phase II, this exception protected retention payments made only: (1) By a hospital whose geographic service area was located in a HPSA; and (2) to a physician with a firm, written recruitment offer from an unrelated hospital or federally qualified health center (provided that certain other conditions were satisfied). Some commenters requested that we broaden the exception to permit retention payments when the recruitment offer is made by any entity, including a group practice. In addition, a number of commenters requested that we eliminate the requirement for a written offer; they suggested that the exception be revised to permit a retention payment made on the basis of a “good faith belief” that the physician may be recruited by another entity.

After reviewing the comments, we decided to permit retention payments made in the case of a *bona fide* written recruitment offer from or written offer of employment with a hospital, academic medical center, or physician organization (which is defined to include a physician or group practice). We considered broadening the exception to permit retention payments made in the case of a recruitment or employment offer from any DHS entity, but rejected that alternative as unnecessarily broad and potentially subject to abuse.

In addition, after reviewing the comments, we recognized that it is commonplace for hospitals to become cognizant of a verbal offer received by a physician and that, in order to ensure that hospitals can compete fairly, we should permit hospitals to act based upon a written certification provided by the physician. We considered the “good faith belief” standard suggested by the commenters, but rejected it because it would be too difficult to enforce and would be subject to abuse. Instead, we added a new option in § 411.357(t)(2) to permit retention payments in the

absence of a written offer where a physician provides a written certification stating that the physician has a *bona fide* opportunity for future employment with a hospital, academic medical center, or physician organization that would require relocation of his or her medical practice at least 25 miles and outside the geographic area served by the hospital. The physician's certification must detail the opportunity presented (such as income and benefits), the steps taken by the physician to effectuate the employment opportunity, and other information sufficient for the hospital to verify the offer. We believe that our changes to the retention payments exception strike an appropriate balance between the industry's need for greater flexibility in making retention payments and our need to protect the Medicare and Medicaid programs from abuse while ensuring access to care in underserved areas.

Many commenters to both the Phase I and Phase II rules requested clarification of the definition of "indirect compensation arrangement." In Phase II, we clarified that a referring physician may be treated as "standing in the shoes" of his or her wholly-owned PC when the only intervening entity between the referring physician and the DHS entity is his or her PC. Phase II did not make any changes with respect to the issue of indirect compensation arrangements that are created when a group practice is the only intervening entity between a DHS entity and the referring physician. However, we did solicit comments in Phase II on whether to permit a physician to "stand in the shoes" of a group practice of which he or she is a member. Since the publication of the Phase II interim final rule and in light of the comments we have received, we have concluded that it is in the best program integrity interests of the Medicare and Medicaid programs to adopt a broader "stand in the shoes" provision. In this Phase III final rule, we have modified the regulations to deem a direct compensation arrangement to exist when the only intervening entity between a referring physician and a DHS entity is a group practice or other physician organization. This will require some compensation arrangements to be analyzed for compliance with an exception for direct compensation arrangements, rather than the exception for indirect compensation arrangements exception.

We considered defining a "physician organization" to include entities other than a physician, physician practice, or group practice, but we have rejected that

alternative because we are concerned about the potential for abuse and believe that such an expansion of the "stand in the shoes" doctrine would benefit from additional public comment.

We considered a number of alternatives suggested by commenters regarding the recruitment exception. The Phase II rule modified the physician recruitment exception to allow hospitals to recruit physicians into the geographic area served by the hospital, provided that certain conditions are satisfied. We defined "geographic area served by the hospital" to be the area composed of the lowest number of contiguous zip codes from which the hospital draws at least 75 percent of its inpatients. Several commenters objected to the restriction on recruiting only into the "geographic area served by the hospital," stating that the definition of that term prevents hospitals from recruiting physicians into outlying parts of their service area, where there is likely to be greater need. Additionally, some commenters pointed out that the restriction hurt rural hospitals and was very difficult for federally qualified health centers to satisfy.

Based on the comments we received, we revised the exception to permit a rural hospital to recruit a physician into an area composed of the lowest number of contiguous zip codes (and in some circumstances, noncontiguous zip codes) from which the hospital draws at least 90 percent of its inpatients. We considered expanding the definition of "geographic area served by the hospital" to permit all hospitals to recruit physicians into a broader geographic area, but we rejected that alternative on the grounds that, in many cases, such recruitment arrangements would not be necessary to ensure access to care and may be abusive.

As these examples demonstrate, our approach in this Phase III final rule 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.

In accordance with the provisions of Executive Order 12866, this regulation 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, Reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR Chapter IV as follows:

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, 1860 D–1 through 1860D–42, 1871, and 1877 of the Social Security Act (42 U.S.C. 1302, 1395w–101 through 1395w–152, 1395hh, and 1395nn).

Subpart J—Financial Relationships Between Physicians and Entities Furnishing Designated Health Services

■ 2. Section 411.350 is revised to read as follows:

§ 411.350 Scope of subpart.

(a) This subpart implements section 1877 of the Act, which generally prohibits a physician from making a referral under Medicare for designated health services to an entity with which the physician or a member of the physician's immediate family has a financial relationship.

(b) This subpart does not provide for exceptions or immunity from civil or criminal prosecution or other sanctions applicable under any State laws or under Federal law other than section 1877 of the Act. For example, although a particular arrangement involving a physician's financial relationship with an entity may not prohibit the physician from making referrals to the entity under this subpart, the arrangement may nevertheless violate another provision of the Act or other laws administered by HHS, the Federal Trade Commission, the Securities and Exchange Commission, the Internal Revenue Service, or any other Federal or State agency.

(c) This subpart requires, with some exceptions, that certain entities furnishing covered services under Medicare report information concerning ownership, investment, or compensation arrangements in the form, in the manner, and at the times specified by CMS.

(d) This subpart does not alter an individual's or entity's obligations under—

(1) The rules regarding reassignment of claims (§ 424.80);

(2) The rules regarding purchased diagnostic tests (§ 414.50);

(3) The rules regarding payment for services and supplies incident to a physician's professional services (§ 410.26); or

(4) Any other applicable Medicare laws, rules, or regulations.

■ 3. Section 411.351 is revised to read as follows—

§ 411.351 Definitions.

As used in this subpart, unless the context indicates otherwise:

Centralized building means all or part of a building, including, for purposes of this 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 or management or both 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 that 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)(i) Clinical laboratory services.
- (ii) Physical therapy, occupational therapy, and speech-language pathology services.
- (iii) Radiology and certain other imaging services.
- (iv) Radiation therapy services and supplies.
- (v) Durable medical equipment and supplies.
- (vi) Parenteral and enteral nutrients, equipment, and supplies.
- (vii) Prosthetics, orthotics, and prosthetic devices and supplies.
- (viii) Home health services.
- (ix) Outpatient prescription drugs.
- (x) Inpatient and outpatient hospital services.

(2) 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)(i) through (1)(x) 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)(i) Meets a safe harbor under the anti-kickback statute, as set forth at § 1001.952 of this title, "Exceptions";

(ii) Has been specifically approved by the OIG in a favorable advisory opinion issued to a party to the particular arrangement (for example, 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

(iii) Does not violate the anti-kickback provisions in section 1128B(b) of the Act.

(2) For purposes of this definition, a favorable advisory opinion means an opinion in which the OIG opines that—

(i) 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

(ii) The party will not be subject to any OIG sanctions arising under the anti-kickback statute (for example, under sections 1128A(a)(7) and 1128(b)(7) of the Act) in connection with the party's specific arrangement.

Downstream contractor means a "first tier contractor" as defined at § 1001.952(t)(2)(iii) or a "downstream contractor" as defined at § 1001.952(t)(2)(i).

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

Electronic health record means a repository of consumer health status information in computer processable form used for clinical diagnosis and treatment for a broad array of clinical conditions.

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, nonprofit 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 in accordance with § 424.80(b)(1) (employer) or (b)(2) (payment under a contractual arrangement) of this chapter (other than a health care delivery system that is a health plan (as defined at § 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 under § 424.80(b)(1) and (b)(2) of this chapter, with respect to any DHS 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 30.2.9 of the CMS Internet-only Manual, publication 100-04, Claims Processing Manual, Chapter 1 (general billing requirements), 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.

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 or services "incident to" means those services and supplies that meet the requirements of section 1861(s)(2)(A) of the Act, § 410.26 of this chapter, and sections 60, 60.1, 60.2, and 60.3 of the CMS Internet-only Manual, publication 100-02, Medicare Benefit Policy Manual, Chapter 15 (covered medical and other health services), 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).

Interoperable means able to communicate and exchange data accurately, effectively, securely, and consistently with different information technology systems, software applications, and networks, in various settings; and exchange data such that the clinical or operational purpose and meaning of the data are preserved and unaltered.

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 DHS 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.hhs.gov/PhysicianSelfReferral/11_List_of_Codes.asp#TopOfPage.

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 30.2.11 of the CMS Internet-only Manual, publication 100–04, Claims Processing Manual, Chapter 1 (general billing requirements), 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 drugs covered by Medicare Part B or Part D.

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 nutrition 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 108.2 of the National Coverage Determinations Manual, 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 108.2 of the National Coverage Determinations Manual, 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 in 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 in 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 directly 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 satisfy the requirements of the personal service arrangements exception in § 411.357(d)), and the independent contractor's arrangement with the group practice must comply with the reassignment rules in § 424.80(b)(2) of this chapter (see also section 30.2.11 of the CMS Internet-only Manual, publication 100-04, Claims Processing Manual, Chapter 1 (general billing requirements), 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 contractor) 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.

Physician organization means a physician (including a professional corporation of which the physician is the sole owner), a physician practice, or a group practice that complies with the requirements of § 411.352.

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, including (effective January 1, 2007) therapeutic nuclear medicine 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.

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, computerized axial tomography, magnetic resonance imaging, nuclear medicine (effective January 1, 2007), or other imaging services. All codes identified as radiology and certain other imaging services are covered under section 1861(s)(3) of the Act and § 410.32 and § 410.34 of this chapter, but do 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; and

(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.

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 or ancillary services necessary for, and integral to, the provision of 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 self-insured plan) to a physician to satisfy a claim, submitted on a fee-for-service basis, for the furnishing of health services by that physician to an individual who is covered by a policy with the insurer or by the self-insured plan, if—

(i) The health services are not furnished, and the payment is not made, under a contract or other arrangement between the insurer or the self-insured plan (or a subcontractor of the insurer or self-insured 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.

Rural area means an area that is not an urban area as defined at § 412.62(f)(1)(ii) of this chapter.

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) of the Act) that is primarily or exclusively engaged in the care and treatment of one of the following:

(1) Patients with a cardiac condition;

(2) Patients with an orthopedic condition;

(3) Patients receiving a surgical procedure; or

(4) 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 financial 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, or secured by a negotiable promissory note, or subject to a similar mechanism to ensure payment even in the event of default by the purchaser or obligated party.

■ 3a. Section 411.352 is revised to read as follows:

§ 411.352 Group practice.

For purposes of this subpart, a group practice is a physician practice that meets the following conditions:

(a) *Single legal entity.* The group practice must consist of a single legal entity 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, nonprofit 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 at § 411.351.

(c) *Range of care.* Each physician who is a member of the group, as defined at § 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 a HPSA, as defined at § 411.351.

(4) For a group practice located outside of a HPSA (as defined at § 411.351), any time spent by a group practice member providing services in a 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 medical practice under § 411.357(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 medical 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 his or her referrals, 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 the group practice may be paid a share of overall profits of the group, provided that the share is not determined in any manner that is directly related to the volume or value of referrals of DHS by the physician. A physician in the group practice may be paid a productivity bonus based on

services that he or she has personally performed, or services "incident to" such personally performed services, or both, provided that the bonus is not determined in any manner that is directly related to the volume or value of referrals of DHS by the physician (except that the bonus may directly relate to the volume or value of DHS referrals by the physician if the referrals are for services "incident to" the physician's personally performed services).

(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 must 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.

■ 4. Section 411.353 is revised to read as follows:

§ 411.353 Prohibition on certain referrals by physicians and limitations on billing.

(a) *Prohibition on referrals.* Except as provided in this subpart, a physician who has a direct or indirect financial relationship with an entity, or who has an immediate family member who has a direct or indirect financial relationship with the entity, may not make a referral to that entity for the furnishing of DHS for which payment otherwise may be made under Medicare. A physician's prohibited financial relationship with an entity that furnishes DHS is not imputed to his or her group practice or its members or its staff. However, a referral made by a physician's group practice, its members, or its staff may be imputed to the physician if the physician directs the group practice, its members, or its staff to make the referral or if the physician controls referrals made by his or her group practice, its members, or its staff.

(b) *Limitations on billing.* An entity that furnishes DHS pursuant to a referral that is prohibited by paragraph (a) of this section may not present or cause to be presented a claim or bill to the Medicare program or to any individual, third party payer, or other entity for the DHS performed pursuant to the prohibited referral.

(c) *Denial of payment.* Except as provided in paragraph (e) of this section, no Medicare payment may be made for a designated health service that is furnished pursuant to a prohibited referral.

(d) *Refunds.* An entity that collects payment for a designated health service that was performed pursuant to a prohibited referral must refund all collected amounts on a timely basis, as defined at § 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) Paragraph (f)(1) may be used by an entity only once every 3 years with respect to the same referring physician.

(4) Paragraph (f)(1) does not apply if the exception with which the financial relationship previously complied was § 411.357(k) or (m).

■ 4a. Section 411.354 is revised to read as follows:

§ 411.354 Financial relationship, compensation, and ownership or investment interest.

(a) *Financial relationships.* (1) *Financial relationship* means—

(i) A direct or indirect ownership or investment interest (as defined in paragraph (b) of this section) in any entity that furnishes DHS; or

(ii) A direct or indirect compensation arrangement (as defined in paragraph (c) of this section) with an entity that furnishes DHS.

(2) *Types of financial relationships.* (i) 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 between the entity furnishing DHS and the referring physician (or a member of his or her immediate family).

(ii) 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 in the entity 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);

(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); or

(v) A security interest held by a physician in equipment sold by the physician to a hospital and financed through a loan from the physician to the hospital (such an interest 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)(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 acts 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. 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" at § 411.351. (However, any other portion of the arrangement may still constitute a compensation arrangement.)

(1)(i) A direct compensation arrangement 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.

(ii) A physician is deemed to have a direct compensation arrangement with an entity furnishing DHS if the only intervening entity between the physician and the entity furnishing DHS is his or her physician organization. In such situations, for purposes of this section, the physician is deemed to stand in the shoes of the physician organization.

(2) 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 takes into account, 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 paragraphs (d)(2) or (d)(3) of this section. 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 takes into account, 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 takes into account, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS.

(iv) For purposes of paragraph (c)(2)(i), a physician is deemed to "stand in the shoes" of his or her physician organization.

(3)(i) For purposes of paragraphs (c)(1)(ii) and (c)(2)(iv), a physician who "stands in the shoes" of his or her physician organization is deemed to have the same compensation arrangements (with the same parties and on the same terms) as the physician organization. For purposes of applying the exceptions in § 411.355 and § 411.357 to arrangements described in paragraphs (c)(1)(i) and (c)(2)(i), the "parties" to the arrangements are considered to be the entity furnishing DHS and the physician organization (including all members, employees, or independent contractor physicians).

(ii) The provisions of paragraphs (c)(1)(ii) and (c)(2)(iv) need not apply during the original term or current renewal term of an arrangement that satisfied the requirements of § 411.357(p) as of September 5, 2007.

(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 is 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 takes into account 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) is 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 arrangement in any manner that takes into account referrals of DHS.

(3) Unit-based compensation (including time-based or per-unit of service-based compensation) is deemed not to take into account "other business generated between the parties," provided that 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 are not considered "other business generated" by the referring physician).

(4) A physician's compensation from a *bona fide* employer or under a managed care contract or other contract for personal services may be conditioned on the physician's referrals to a particular provider, practitioner, or supplier, provided that the compensation arrangement meets all of the following conditions. 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 both of 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.

(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 arrangement. 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.

■ 5. Section 411.355 is revised to read as follows:

§ 411.355 General exceptions to the referral prohibition related to both ownership/investment and compensation.

The prohibition on referrals set forth in § 411.353 does not apply to the following types of services:

(a) *Physician services.* (1) Physician services as defined in § 410.20(a) of this chapter that are furnished—

(i) Personally by another physician who is a member of the referring physician's group practice or is a physician in the same group practice (as defined at § 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, "physician services" include only those "incident to" services (as defined at § 411.351) that are physician services under § 410.20(a) of this chapter.

(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 that 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 at § 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 at § 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 at § 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 that the billing arrangement meets the requirements of § 424.80(b)(5) 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 purpose of ambulating, a patient uses in order to depart from the physician's office, or is a blood glucose monitor (including one starter set 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 set forth 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 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 (as defined at § 411.355(e)(3)); 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 compensation paid to the referring physician must meet all of the following conditions:

(A) The total compensation paid by each academic medical center component to the referring physician is set in advance.

(B) In the aggregate, the compensation paid by all academic medical center components to the referring physician does not exceed fair market value for the services provided.

(C) The total compensation paid by each academic medical center component 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 one or more written agreements or other written documents 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 hospitals 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 is 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 paragraph, 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. For purposes of determining whether the majority of physicians on the medical staff consists of faculty members, the affiliated hospital must include or exclude all individual physicians with the same class of privileges at the affiliated hospital (for example, physicians holding courtesy privileges).

(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 an ASC that is certified by Medicare under part 416 of this chapter and 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 of this chapter.

(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.* 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, "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 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 at § 411.351 of this subpart;

(ii) Except as provided in paragraph (j)(1)(iii) of this section, in light of the patient's condition, no other person or entity is available to furnish the services in a timely manner within 25 miles of or 45 minutes transportation time from the patient's residence;

(iii) In the case of services furnished to patients where they reside (for example, home health services or 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 of or 45 minutes transportation time from (whichever test the referring physician utilized for purposes of paragraph (j)(1)(ii)) the patient's residence.

■ 6. Section 411.356 is revised to read as follows:

§ 411.356 Exceptions to the referral prohibition related to ownership or investment interests.

For purposes of § 411.353, the following ownership or investment interests do not constitute a financial relationship:

(a) *Publicly-traded securities.* Ownership of investment securities (including shares or bonds, debentures, notes, or other debt instruments) that at the time 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 (as defined at § 411.351 of this subpart) 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.

(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.

■ 7. Section 411.357 is revised to read as follows:

§ 411.357 Exceptions to the referral prohibition related to compensation arrangements.

For purposes of § 411.353, the following compensation arrangements do not constitute a financial relationship:

(a) *Rental of office space.* Payments for the use of office space made by a lessee to a lessor if there is a rental or lease agreement that meets the following requirements:

(1) The agreement is set out in writing, is signed by the parties, and specifies the premises it covers.

(2) The term of the agreement is at least 1 year. 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 the expiration of an agreement of at least 1 year that met the conditions of this paragraph (a) satisfies the requirements of this paragraph (a),

provided that 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 the expiration of an agreement of at least 1 year that met the conditions of this paragraph (b) satisfies the requirements of this paragraph (b), provided that 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 or his or her immediate family member, 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 is 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 must 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 at § 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 (as defined at § 411.351 of this subpart), 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 Federal or State law.

(vii) A holdover personal service arrangement for up to 6 months following the expiration of an agreement of at least 1 year that met the conditions of paragraph (d) of this section satisfies the requirements of paragraph (d) of this section, provided that the holdover personal service arrangement is on the same terms and conditions as the immediately preceding agreement.

(2) *Physician incentive plan exception.* In the case of a physician incentive plan (as defined at § 411.351) between a physician and an entity (or downstream contractor), 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 contractor 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 at § 422.208, the entity or any downstream contractor (or both) complies with the requirements concerning physician incentive plans set forth in § 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 an employment or services contract that complies with § 411.354(d)(4)).

(2)(i) 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. The geographic area served by the hospital may include one or more zip codes from which the hospital draws no inpatients, provided that such zip codes are entirely surrounded by zip codes in the geographic area described above from which the hospital draws at least 75 percent of its inpatients.

(ii) With respect to a hospital that draws fewer than 75 percent of its inpatients from all of the contiguous zip codes from which it draws inpatients, the “geographic area served by the hospital” will be deemed to be the area composed of all of the contiguous zip codes from which the hospital draws its inpatients.

(iii) *Special optional rule for rural hospitals.* In the case of a hospital located in a rural area (as defined at § 411.351), the “geographic area served by the hospital” may also be the area composed of the lowest number of contiguous zip codes from which the hospital draws at least 90 percent of its inpatients. If the hospital draws fewer than 90 percent of its inpatients from all of the contiguous zip codes from which it draws inpatients, the “geographic area served by the hospital” may include noncontiguous zip codes, beginning with the noncontiguous zip code in which the highest percentage of the hospital’s inpatients resides, and continuing to add noncontiguous zip codes in decreasing order of percentage of inpatients.

(iv) A physician will be considered to have relocated his or her medical practice if the medical practice was located outside the geographic area served by the hospital and—

(A) The physician moves his or her medical practice at least 25 miles and into the geographic area served by the hospital; or

(B) The physician moves his medical practice into the geographic area served by the hospital, and 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) The recruited physician will not be subject to the relocation requirement of this paragraph, provided that he or she establishes his or her medical practice in the geographic area served by the recruiting hospital, if—

(i) He or she is a resident or physician who has been in practice 1 year or less;

(ii) He or she was employed on a full-time basis for at least 2 years immediately prior to the recruitment arrangement by one of the following (and did not maintain a private practice in addition to such full-time employment):

(A) A Federal or State bureau of prisons (or similar entity operating one or more correctional facilities) to serve a prison population;

(B) The Department of Defense or Department of Veterans Affairs to serve active or veteran military personnel and their families; or

(C) A facility of the Indian Health Service to serve patients who receive medical care exclusively through the Indian Health Service; or

(iii) The Secretary has deemed in an advisory opinion issued under section 1877(g) of the Act that the physician does not have an established medical practice that serves or could serve a significant number of patients who are or could become patients of the recruiting hospital.

(4) In the case of remuneration provided by a hospital to a physician either indirectly through payments made to another physician practice, or directly to a physician who joins a physician practice, the following additional conditions must be met:

(i) The written agreement in paragraph (e)(1) is also signed by the party to whom the payments are directly made.

(ii) Except for actual costs incurred by the 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 of any type made by the hospital to a recruited physician who

joins a physician practice, the costs allocated by the physician practice to the recruited physician do not exceed the actual additional incremental costs attributable to the recruited physician. With respect to a physician recruited to join a physician practice located in a rural area or HPSA, if the physician is recruited to replace a physician who, within the previous 12-month period, retired, relocated outside of the geographic area served by the hospital, or died, the costs allocated by the physician practice to the recruited physician do not exceed either—

(A) The actual additional incremental costs attributable to the recruited physician; or

(B) The lower of a *per capita* allocation or 20 percent of the practice’s aggregate costs.

(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 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 practice may not impose on the recruited physician practice restrictions that unreasonably restrict the recruited physician’s ability to practice medicine in the geographic area served by the hospital.

(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) Recruitment of a physician by a hospital located in a rural area (as defined at § 411.351) to an area outside the geographic area served by the hospital is permitted under this exception if the Secretary determines in an advisory opinion issued under section 1877(g) of the Act that the area has a demonstrated need for the recruited physician and all other requirements of this paragraph (e) are met.

(6) This paragraph (e) applies to remuneration provided by a federally qualified health center or a rural health clinic in the same manner as it applies to remuneration provided by a hospital, 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.

(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 to the entity.

(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 addressed by 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 merely those defined as “services” for purposes of the Medicare program in § 400.202 of this chapter).

(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 offered, 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) *Nonmonetary compensation.* (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

calendar year, as adjusted for inflation in accordance with paragraph (k)(2) of this section, 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 annual aggregate nonmonetary compensation limit in this paragraph (k) is 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 displays after September 30 each year both the increase in the CPI-U for the 12-month period and the new nonmonetary compensation limit on the physician self-referral Web site: http://www.cms.hhs.gov/PhysicianSelfReferral/10_CPI-U_Updates.asp.

(3) Where an entity has inadvertently provided nonmonetary compensation to a physician in excess of the limit (as set forth in paragraph (k)(1) of this section), such compensation is deemed to be within the limit if—

(i) The value of the excess nonmonetary compensation is no more than 50 percent of the limit; and

(ii) The physician returns to the entity the excess nonmonetary compensation (or an amount equal to the value of the excess nonmonetary compensation) by the end of the calendar year in which the excess nonmonetary compensation was received or within 180 consecutive calendar days following the date the excess nonmonetary compensation was received by the physician, whichever is earlier.

(iii) Paragraph (k)(3) may be used by an entity only once every 3 years with respect to the same referring physician.

(4) In addition to nonmonetary compensation up to the limit described in paragraph (k)(1) of this section, an entity that has a formal medical staff may provide one local medical staff appreciation event per year for the entire medical staff. Any gifts or gratuities provided in connection with the medical staff appreciation event are subject to the limit in paragraph (k)(1).

(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 (other than the rental of office space) by the physician (or an immediate family member) or group of physicians to the entity, or by the entity to the physician (or an immediate family member) or a group of physicians, 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 that 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 is commercially reasonable (taking into account the nature and scope of the transaction) and furthers the legitimate business purposes of the parties.

(5) 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.

(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 Federal or State law.

(m) *Medical staff incidental benefits.* Compensation in the form of items or services (not including cash or cash equivalents) from a hospital to a member of its medical staff when the item or service is used on the hospital's campus, if all of the following conditions are met:

(1) The compensation is offered to all members of the medical staff 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, meets the "on campus" requirement of this paragraph (m) of this section.

(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) is adjusted each calendar year to the nearest whole dollar by the increase in the Consumer Price Index—Urban All Items (CPI-I) for the 12 month period ending the preceding September 30. CMS displays after September 30 each year both the increase in the CPI-I for the 12 month period and the new limits on the physician self-referral web site: http://www.cms.hhs.gov/PhysicianSelfReferral/10_CPI-U_Updates.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 MCO or an IPA 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 set forth 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 that 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, or reporting); specific training regarding the requirements of Federal and State health care programs (for example, billing, coding, reasonable and necessary services, documentation, or 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. For purposes of this paragraph, "compliance training" includes programs that offer continuing medical education credit, provided that compliance training is the primary purpose of the program.

(p) *Indirect compensation arrangements.* Indirect compensation arrangements, as defined at § 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 volume or value 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 at § 411.351) offered by an entity with a formal medical staff 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 such 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 has a professional courtesy policy that 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; and

(5) 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) *Bona fide written offer.*

Remuneration provided by a hospital directly to a physician on the hospital's medical staff to retain the physician's medical practice in the geographic area served by the hospital (as defined in paragraph (e)(2) of this section), if all of the following conditions are met:

(i) The physician has a *bona fide* firm, written recruitment offer or offer of employment from a hospital, academic medical center (as defined at § 411.355(e)), or physician organization (as defined at § 411.351) that is not related to the hospital making the payment, and the offer specifies the remuneration being offered and requires the physician to move the location of his or her medical practice at least 25 miles *and* outside of the geographic area served by the hospital making the retention payment.

(ii) The requirements of § 411.357(e)(1)(i) through § 411.357(e)(1)(iv) are satisfied.

(iii) Any retention payment is subject to the same obligations and restrictions, if any, on repayment or forgiveness of indebtedness as the written recruitment offer or offer of employment.

(iv) The retention payment does not exceed the lower of—

(A) The amount obtained by subtracting the physician's current income from physician and related services from the income the physician would receive from comparable physician and related services in the written recruitment or employment 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 would otherwise have to expend to recruit a new physician to the geographic area served by the hospital to join the medical staff of the hospital to replace the retained physician.

(v) The requirements of paragraph (t)(3) are satisfied.

(2) *Written certification from physician.* Remuneration provided by a hospital directly to a physician on the hospital's medical staff to retain the physician's medical practice in the geographic area served by the hospital (as defined in paragraph (e)(2) of this section), if all of the following conditions are met:

(i) The physician furnishes to the hospital before the retention payment is made a written certification that the physician has a *bona fide* opportunity for future employment by a hospital, academic medical center (as defined at § 411.355(e)), or physician organization (as defined at § 411.351) that requires the physician to move the location of his or her medical practice at least 25 miles *and* outside the geographic area served by the hospital. The certification contains at least the following—

(A) Details regarding the steps taken by the physician to effectuate the employment opportunity;

(B) Details of the physician's employment opportunity, including the identity and location of the physician's future employer or employment location or both, and the anticipated income and benefits (or a range for income and benefits);

(C) A certification that the future employer is not related to the hospital making the payment;

(D) The date on which the physician anticipates relocating his or medical

practice outside of the geographic area served by the hospital; and

(E) Information sufficient for the hospital to verify the information included in the written certification.

(ii) The hospital takes reasonable steps to verify that the physician has a *bona fide* opportunity for future employment that requires the physician to relocate outside the geographic area served by the hospital.

(iii) The requirements of § 411.357(e)(1)(i) through § 411.357(e)(1)(iv) are satisfied.

(iv) The retention payment does not exceed the lower of—

(A) An amount equal to 25 percent of the physician's current income (measured over no more than a 24-month period), using a reasonable and consistent methodology that is calculated uniformly; or

(B) The reasonable costs the hospital would otherwise have to expend to recruit a new physician to the geographic area served by the hospital to join the medical staff of the hospital to replace the retained physician.

(v) The requirements of paragraph (t)(3) are satisfied.

(3) Remuneration provided under paragraph (t)(1) or (t)(2) must meet the following additional requirements:

(i)(A) The physician's current medical practice is located in a rural area or HPSA (regardless of the physician's specialty) or is located in an area with demonstrated need for the physician as determined by the Secretary in an advisory opinion issued in accordance with section 1877(g)(6) of the Act; or

(B) At least 75 percent of the physician's patients reside in a medically underserved area or are members of a medically underserved population.

(ii) The hospital does not enter into a retention arrangement with a particular referring physician more frequently than once every 5 years.

(iii) 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.

(iv) 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.

(4) The Secretary may waive the relocation requirement of paragraphs (t)(1) and (t)(2) 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 in accordance with section 1877(g)(6) of the Act, if the

retention payment arrangement otherwise complies with all of the conditions of this paragraph.

(5) This paragraph (t) applies to remuneration provided by a federally qualified health center or a rural health clinic in the same manner as it applies to remuneration provided by a hospital.

(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.

(v) *Electronic prescribing items and services.* Nonmonetary remuneration (consisting of items and services in the form of hardware, software, or information technology and training services) necessary and used solely to receive and transmit electronic prescription information, if all of the following conditions are met:

(1) The items and services are provided by a—

(i) Hospital to a physician who is a member of its medical staff;

(ii) Group practice (as defined at § 411.352) to a physician who is a member of the group (as defined at § 411.351); or

(iii) PDP sponsor or MA organization to a prescribing physician.

(2) The items and services are provided as part of, or are used to access, an electronic prescription drug program that meets the applicable standards under Medicare Part D at the time the items and services are provided.

(3) The donor (or any person on the donor's behalf) does not take any action to limit or restrict the use or compatibility of the items or services with other electronic prescribing or electronic health records systems.

(4) For items or services that are of the type that can be used for any patient without regard to payer status, the donor does not restrict, or take any action to limit, the physician's right or ability to use the items or services for any patient.

(5) Neither the physician nor the physician's practice (including employees and staff members) makes the receipt of items or services, or the amount or nature of the items or services, a condition of doing business with the donor.

(6) Neither the eligibility of a physician for the items or services, nor the amount or nature of the items or services, is determined in a manner that takes into account the volume or value of referrals or other business generated between the parties.

(7) The arrangement is set forth in a written agreement that—

(i) Is signed by the parties;

(ii) Specifies the items and services being provided and the donor's cost of the items and services; and

(iii) Covers all of the electronic prescribing items and services to be provided by the donor. This requirement is met if all separate agreements between the donor and the physician (and the donor and any family members of the physician) incorporate each other by reference or if they cross-reference a master list of agreements that is maintained and updated centrally and is available for review by the Secretary upon request. The master list must be maintained in a manner that preserves the historical record of agreements.

(8) The donor does not have actual knowledge of, and does not act in reckless disregard or deliberate ignorance of, the fact that the physician possesses or has obtained items or services equivalent to those provided by the donor.

(w) *Electronic health records items and services.* Nonmonetary remuneration (consisting of items and services in the form of software or information technology and training services) necessary and used predominantly to create, maintain, transmit, or receive electronic health records, if all of the following conditions are met:

(1) The items and services are provided by an entity (as defined at § 411.351) to a physician.

(2) The software is interoperable (as defined at § 411.351) at the time it is provided to the physician. For purposes of this paragraph, software is deemed to be interoperable if a certifying body recognized by the Secretary has certified the software no more than 12 months prior to the date it is provided to the physician.

(3) The donor (or any person on the donor's behalf) does not take any action to limit or restrict the use, compatibility, or interoperability of the items or services with other electronic prescribing or electronic health records systems.

(4) Before receipt of the items and services, the physician pays 15 percent of the donor's cost for the items and services. The donor (or any party related to the donor) does not finance the physician's payment or loan funds to be used by the physician to pay for the items and services.

(5) Neither the physician nor the physician's practice (including employees and staff members) makes the receipt of items or services, or the amount or nature of the items or services, a condition of doing business with the donor.

(6) Neither the eligibility of a physician for the items or services, nor the amount or nature of the items or services, is determined in a manner that directly takes into account the volume or value of referrals or other business generated between the parties. For purposes of this paragraph, the determination is deemed not to directly take into account the volume or value of referrals or other business generated between the parties if any one of the following conditions is met:

(i) The determination is based on the total number of prescriptions written by the physician (but not the volume or value of prescriptions dispensed or paid by the donor or billed to the program);

(ii) The determination is based on the size of the physician's medical practice (for example, total patients, total patient encounters, or total relative value units);

(iii) The determination is based on the total number of hours that the physician practices medicine;

(iv) The determination is based on the physician's overall use of automated technology in his or her medical practice (without specific reference to the use of technology in connection with referrals made to the donor);

(v) The determination is based on whether the physician is a member of the donor's medical staff, if the donor has a formal medical staff;

(vi) The determination is based on the level of uncompensated care provided by the physician; or

(vii) The determination is made in any reasonable and verifiable manner that does not directly take into account the volume or value of referrals or other business generated between the parties.

(7) The arrangement is set forth in a written agreement that—

- (i) Is signed by the parties;
- (ii) Specifies the items and services being provided, the donor's cost of the items and services, and the amount of the physician's contribution; and
- (iii) Covers all of the electronic health records items and services to be provided by the donor. This requirement is met if all separate agreements between the donor and the physician (and the donor and any family members of the physician) incorporate each other by reference or if they cross-reference a master list of agreements that is maintained and updated centrally and is available for review by the Secretary upon request. The master list must be maintained in a manner that preserves the historical record of agreements.

(8) The donor does not have actual knowledge of, and does not act in reckless disregard or deliberate ignorance of, the fact that the physician possesses or has obtained items or services equivalent to those provided by the donor.

(9) For items or services that are of the type that can be used for any patient without regard to payer status, the donor does not restrict, or take any action to limit, the physician's right or ability to use the items or services for any patient.

(10) The items and services do not include staffing of physician offices and are not used primarily to conduct personal business or business unrelated to the physician's medical practice.

(11) The electronic health records software contains electronic prescribing capability, either through an electronic prescribing component or the ability to interface with the physician's existing electronic prescribing system that meets the applicable standards under Medicare Part D at the time the items and services are provided.

(12) 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.

(13) The transfer of the items or services occurs and all conditions in this paragraph (w) are satisfied on or before December 31, 2013.

■ 8. Section 411.361 is revised to read as follows:

§ 411.361 Reporting requirements.

(a) *Basic rule.* Except as provided in paragraph (b) of this section, all entities furnishing 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) or the national provider identifier (NPI) of each physician who has a reportable financial relationship with the entity.
- (2) The name and UPIN or NPI of each physician who has an immediate family member (as defined at § 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 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 at § 411.354(b) or any compensation arrangement, as defined at § 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.

■ 9. Section 411.370 is amended by revising paragraph (a) to read as follows:

§ 411.370 Advisory opinions relating to physician referrals.

(a) *Period during which CMS accepts requests.* The provisions of § 411.370 through § 411.389 apply to requests for advisory opinions that are submitted to CMS during any time period in which CMS is required by law to issue the advisory opinions described in this subpart.

* * * * *

PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 10. 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

■ 11. In § 424.22, paragraph (d) is revised to read as follows:

§ 424.22 Requirements for home health services.

* * * * *

(d) *Limitation on the performance of certification and plan of treatment functions.* A physician who has a financial relationship, as defined at § 411.354 of this chapter, with a HHA may not certify or recertify the need for home health services or establish or review a plan of treatment for the HHA unless the financial relationship satisfies the requirements of one of the

exceptions set forth in § 411.355
through § 411.357 of this chapter.
(Program No. 93.774, Medicare—
Supplementary Medical Insurance Program)

Dated: January 4, 2007.
Leslie V. Norwalk,
*Acting Administrator, Centers for Medicare
& Medicaid Services.*

Approved: June 11, 2007.
Michael O. Leavitt,
Secretary.
[FR Doc. 07-4252 Filed 8-27-07; 3:45 pm]
BILLING CODE 4120-01-P