

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

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

Response: We agree with the commenter that some accommodation should be made for new group practices. Nothing in the statutory language precludes such accommodation.

Accordingly, the final regulations provide that during the "start up" period for a new group practice (not to exceed 12 months), a group practice must make a reasonable, good faith effort to ensure that the group practice complies with the "substantially all test" as soon as practicable, but no later than 12 months from the date of the initial formation of the group practice. This "start up" provision does not apply when an existing group practice admits a new member or when an existing group practice reorganizes.

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

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

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

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

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

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

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

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

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

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

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

7. Unified Business Test

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

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

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

We indicated that the methods must reflect "centralized decision making, a pooling of expenses and revenues, and a distribution system that is not based on each satellite office operating as if it were a separate enterprise."

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

8. Profit Shares and Productivity Bonuses

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

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

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

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

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

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

The distribution methods for overall profit shares are as follows:

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

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

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

The methods for productivity bonuses are as follows:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Comment: On page 1691 of the preamble to the January 1998 proposed regulations, we explained our view that "profits should not be pooled and divided between group members so that they relate directly to the number of designated health services for Medicare or Medicaid patients physicians referred to themselves or the value of those self-referrals (such as a value based on complexity of the service)." A commenter objected to the parenthetical statement, asserting that barring consideration of the complexity of the service is contrary to other Medicare payment provisions, which take into consideration the level of training necessary to perform, and difficulty of, certain procedures.

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

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

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

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

Comment: Several commenters were confused by our use of the terms "revenues" and "profits" throughout the preamble to the January 1998 proposed regulations. For example, on page 1691 we stated that "the referring physician can receive a portion of the group's overall pooled revenues from these services as long as the group does not share these profits in a manner that relates directly to who made the referrals for them." Similarly, on the same page we stated that we "regard 'over-all profits of the group' to mean all of the profits or revenues a group can distribute in any form to group members * * *." These commenters requested that the terms "profits" and "revenues" be used in a manner that is consistent with their generally accepted meanings or that definitions of the terms be provided in the regulations.

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

9. Group Practice Attestations

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

furnished through the group. Any group that intended to meet the definition of a group practice in order to qualify for one of the exceptions provided in the regulations was required to submit the required attestation to its carrier by December 12, 1995. On December 11, 1995, we published in the **Federal Register**, at 60 FR 63438, a final rule that delays the date by which a group of physicians must file an attestation statement. The December final rule amended § 411.360 to require that a group that intends to meet the definition of a group practice must submit an attestation statement to its carrier no later than 60 days after the group receives attestation instructions from its carrier. The preamble to the December rule points out that a group could regard itself as a group practice in the interim period before it receives attestation instructions, provided the group believes that it meets the definition of a group practice under § 411.351.

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

The Final Rule: We have eliminated the attestation requirement.

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

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

Response: We agree with the commenters. After reviewing the attestation requirement, we have concluded that it would impose an unwarranted burden on group practices. We intend instead to allow groups to treat the information they need to establish that they are a group practice in the same manner as any information a furnishing entity must provide to us under the reporting requirements in § 411.361. In order to make reporting requirements more manageable, we

intend to develop a streamlined "reporting" system that does not require entities to retain and submit large quantities of data. We believe instead that entities should retain enough records to demonstrate, in the event of an audit, that particular relationships are excepted under the law. In the case of the in-office ancillary services exception and physician services exceptions in section 1877(b)(1) and (b)(2), an entity may need to establish that the services it provided were referred by members of a genuine group practice. Thus, a group should retain records that demonstrate that it meets the requirements in section 1877(h)(4) of the Act and § 411.351.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We believe these provisions will address the commenters' concerns.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Response: The various reporting requirements associated with, or triggered by, the regulation will be addressed in Phase II of this rulemaking.

VII. New Regulatory Exceptions

This section describes new regulatory exceptions that are not in the statute, but which appeared in the January 1998 proposed rule or that we have created in response to comments and pursuant to statutory authority conferred on the Secretary. The new exceptions discussed here include: Academic medical centers, fair market value, and non-monetary compensation up to \$300 (and medical staff benefits). Other new exceptions described elsewhere in this preamble include: Implants in an ASC (§ 411.355(e); section VIII.J of this preamble); EPO and other dialysis-related drugs (§ 411.355(f); section VIII.L of this preamble); preventive screening tests, immunizations, and vaccines (§ 411.355(h); section VIII.L of this preamble); risk-sharing arrangements (§ 411.357(n); section VI.D of this preamble); compliance training programs (§ 411.357(o); section VII.C of this preamble); eyeglasses and contact lenses (§ 411.355(i); section VIII.J of this preamble); and indirect compensation arrangements (§ 411.354(c)(3); section III.A of this preamble).

A. Academic Medical Centers

The Existing Law: Section 1877(h)(4) of the Act contains a special rule for faculty practice plans. The rule provides that “in the case of a faculty practice plan associated with a hospital, institution of higher education, or medical school with an approved medical residency training program in which physician members may provide a variety of different specialty services and provide professional services both within and outside the group, as well as perform other tasks such as research, subparagraph (A) [the definition of “group practice”] shall be applied only with respect to the services provided within the faculty practice plan.”

Several commenters to the August 1995 final rule suggested that we create a separate exception for faculty practice plans, since these plans are typically involved in complex organizational arrangements that do not fit comfortably—or at all—in the group practice definition. At the time of the August 1995 final rule, we rejected the suggestion for a new exception based on

our view that the personal service arrangements exception and the employment exception would provide physicians in academic medical settings with appropriate protection under section 1877 of the Act.

The Proposed Rule: We proposed no changes.

The Final Rule: We have revisited our prior position. The comments have persuaded us that academic medical practices raise numerous questions under section 1877 of the Act that are not adequately addressed by existing exceptions.

Though the relevant provision in the group practice definition is somewhat obscure, we believe it demonstrates congressional intent to address the circumstances of physicians practicing in academic medical settings. We do not believe, however, that the core problem of how to treat academic medical practices under section 1877 of the Act is amenable to resolution under the group practice definition; the problem lies elsewhere.

Academic medical settings often involve multiple affiliated entities that jointly deliver health care services to patients (for example, a faculty practice plan, medical school, teaching hospital, outpatient clinics). There are frequent referrals and monetary transfers between these various entities, and these relationships raise the possibility of indirect remuneration for referrals. The exceptions under section 1877 of the Act do not easily apply. For example, faculty practice plan physicians refer patients for ancillary services to entities that are outside of (and not wholly owned by) the single legal entity in which they conduct their medical practices (that is, the "group practice"), but with which they may have direct or indirect compensation relationships (for example, part of the physician's compensation may come from an affiliated medical school or teaching hospital). These referrals typically will not qualify under the in-office ancillary services exception, and it may be difficult to structure compensation relationships for faculty practice plan physicians that securely fit in the personal service arrangements exception because the physician's compensation often comes directly or indirectly from several separate sources.

Having reviewed the comment letters addressing the problems facing faculty practice plans under section 1877 of the Act, we believe the fundamental need of faculty practice plans is for a separate compensation exception for payments to faculty of academic medical centers that takes into account the unique circumstances of a faculty practice,

including the symbiotic relationship among faculty, medical centers, and teaching institutions, and the educational and research roles of faculty in these settings. Therefore, we are using our regulatory authority under section 1877(b)(4) of the Act to create a separate compensation exception for payments to faculty of academic medical centers that meet certain conditions that ensure that the arrangement poses essentially no risk of fraud or abuse. This exception is in addition to other exceptions that may apply in particular circumstances; an arrangement need only fit in one available exception.

The conditions applicable under the new exception in § 411.355(e)(1)(i) are that the referring physician is a *bona fide* employee of a component of an academic medical center on a full-time or substantial part-time basis, is licensed to practice medicine in the State, has a *bona fide* faculty appointment at the affiliated medical school, and provides either substantial academic or substantial clinical teaching services for which the faculty member receives compensation as part of his or her employment relationship with the academic medical center. The purpose of this condition is to ensure that protected physicians are truly engaged in an academic medical practice. The exception does not apply to payments to physicians who provide only occasional academic or clinical teaching services or who are principally community rather than academic medical center practitioners.

Under the new exception in § 411.355(e)(1)(i)(A), a "component" of an academic medical center means an affiliated medical school, faculty practice plan, hospital, teaching facility, institution of higher education, or departmental professional corporation. For purposes of this exception, an academic medical center may have some, but need not have all, of these components. As indicated in the preceding provision, however, the minimum requirements are a medical school, a faculty practice plan, and a hospital.

Under the new exception in § 411.355(e)(1)(ii), the total compensation paid for the previous 12-month period (or fiscal year or calendar year) from all academic medical center components to the referring physician is set in advance and, in the aggregate, does not exceed fair market value for the services provided, and is not determined in a manner that takes into account the volume or value of any referrals or other business generated within the academic medical center. As

with the corresponding provisions in the personal service arrangements, employee, and fair market value exceptions, this provision requires that remuneration to physicians be for *bona fide* services provided by the physicians and not for referrals. In determining fair market value for services in an academic medical practice, we believe the relevant comparison is aggregate compensation paid to physicians practicing in similar academic settings located in similar environments. Relevant factors include geographic location, size of the academic institutions, scope of clinical and academic programs offered, and the nature of the local health care marketplace. Nothing in this regulation is intended to preclude productivity bonuses paid to academic medical center physicians on the basis of services they *personally* perform.

Under the new exception in § 411.355(e)(2), the "academic medical center" for purposes of this section shall consist of—(1) an accredited medical school (including a university, when appropriate); (2) an affiliated faculty practice plan that is a nonprofit, tax-exempt organization under section 501(c)(3) or (c)(4) of the Internal Revenue Code (or is a part of such an organization under an umbrella designation); and (3) one or more affiliated hospital(s) in which a majority of the hospital medical staff consists of physicians who are faculty members, and where a majority of all hospital admissions are made by physicians who are faculty members. This provision ensures that the exception only protects physician compensation in genuine academic medical settings. This new exception reflects our view that the predominant purpose of an academic medical center is to teach new physicians and to run medical practices that support the teaching mission.

To fit within the new exception in § 411.355(e)(3), the academic medical center must meet the following conditions:

- All transfers of money between components of the academic medical center must directly or indirectly support the missions of teaching, indigent care, research, or community service. This provision ensures that the academic medical center is *bona fide* and that transfers of funds are not inappropriate payments of indirect compensation for referrals. We believe that patient care is integral to an academic medical center's community service mission.
- The relationship of the components of the academic medical center must be set forth in a written agreement that has

been adopted by the governing body of each component. This provision requires a *bona fide* affiliation between the medical center components.

- All money paid to a referring physician for research must be used solely to support *bona fide* research. We are concerned that research funding could be used to disguise additional payments for referrals. We are including this provision to ensure that money earmarked (intended or designated) for research is used solely for research purposes.

Under the new exception in § 411.355(e)(4), the referring physician's compensation arrangement must not violate the anti-kickback statute (section 1128B(b) of the Act) and billing and claims submission must be proper. As with all exceptions created under section 1877(b)(4) of the Act, this provision is necessary to ensure that the arrangement poses no risk of fraud or abuse.

Comment: As noted above, commenters pointed out that the structure of faculty practice plans can be very complicated; for example, physicians in a faculty practice plan may be compensated by one entity, but conduct their medical practice through a separate entity and order laboratory and other ancillary services from additional related entities (for example, the teaching hospital, the university's research laboratory for highly specialized testing, in-office laboratories within the faculty departments that may or may not be incorporated as professional corporations). As a result, arrangements between and among the various sub-entities of such faculty practice plans can raise a number of issues under section 1877 of the Act. In particular, the question arises whether each separate legal entity and relationship among legal entities must meet an exception under section 1877 of the Act.

Commenters appealed for a separate exception for faculty practice plans, insisting that faculty practice plans pose a minimal risk of abuse under section 1877 of the Act. First, they asserted that physicians in faculty practice plans are less likely to make abusive referrals than their more entrepreneurial counterparts in private practice because they practice in a setting that focuses on academic pursuits and patient care at affiliated teaching hospitals and clinics. Second, they stated that many faculty practice plans include not-for-profit organizations that are regulated under IRS rules that forbid private inurement and private benefit.

Response: As explained in the introduction to this section of the

preamble, we have revisited the issue of academic medical practices and are persuaded that academic medical practices present unique concerns under section 1877 of the Act that warrant a separate exception. Our new exception is described in the introduction. We believe that faculty practice plans will pose little risk of fraud or abuse under the conditions set forth in the new exception. We are not persuaded that physicians in faculty practice plans are necessarily less economically-motivated than their private practice counterparts or that regulation under IRS rules, though beneficial, is sufficient to prevent fraud or abuse.

Comment: A commenter suggested that the group practice definition and the requirements of the in-office ancillary services exception or personal service arrangements exception should be applied only at the level of the "umbrella" organization (that is, the organization that encompasses all the physicians within the faculty practice plan) for the entire faculty practice, thus obviating the need for each legal entity within the same academic setting to meet the provisions of section 1877 of the Act.

Response: In light of the new exception, we see no need to create new rules under existing exceptions for faculty practice plans. Parties may use the new exception or existing exceptions, depending on their individual circumstances.

Comment: As an alternative to a separate exception for faculty practice plans, one commenter urged that faculty practice plans be permitted to have independent contractors as "members" during the time they are providing services to the group. The commenter expressed the view that this solution would be preferable to requiring the faculty practice plan to employ such individuals.

Response: In light of the new compensation exception for physicians in faculty practice plans, we see no need to alter the definition of "member of the group" for academic medical practices. The definition of a "group practice" expressly includes a "faculty practice plan," and any faculty practice plan that fits in the definition is a "group practice" for purposes of section 1877 of the Act.

Comment: A commenter observed that under section 1877(b)(4)(B)(ii) of the Act a faculty practice plan qualifies as a group practice based solely on the services provided and revenue generated by the participating physicians within the faculty practice plan, regardless of the outside activities of those physicians. The commenter

sought clarification that the converse would also be true, that time and revenue allocable to a physician's faculty practice would not count against the "group practice" status of his outside medical group.

Response: The outside medical group must qualify for group practice status under the tests described in section 1877(h)(4) of the Act (§ 411.352 of the regulations) and in this preamble at V.I.C. Time and revenue allocable to a physician's faculty practice would be treated as all other outside time and revenue for purposes of those tests. In other words, such time and revenue would be treated no differently than time group practice physicians who are not in faculty practice plans spend supervising residents or conducting research.

B. Fair Market Value (§ 411.357(l))

The Proposed Rule. This proposed rule created an exception for compensation relationships that are based upon fair market value and meet certain other criteria. This exception is available for compensation arrangements between an entity and either a physician (or immediate family member) or any group of physicians (even if the group does not meet the definition of group practice set forth in § 411.351), as long as the compensation arrangement—

- Is in writing, is signed by the parties, and covers only identifiable items or services, all of which are specified in the agreement;
- Covers all of the items and services to be provided by the physician (or immediate family member) to the entity or, alternatively, cross refers to any other agreements for items or services between these parties;
- Specifies the time frame for the arrangement, which can be for any period of time and contain a termination clause, provided the parties enter into only one arrangement covering the same items or services during the course of a year. An arrangement made for less than 1 year may be renewed any number of times if the terms of the arrangement and the compensation for the same items or services do not change;
- Specifies the compensation that will be provided under the arrangement, which has been set in advance. The compensation must be consistent with fair market value and not be determined in a manner that takes into account the volume or value of any referrals (as defined in § 411.351), payment for referrals for medical services that are not covered under Medicare or Medicaid, or other business generated between the parties;

- Involves a transaction that is commercially reasonable and furthers the legitimate business purposes of the parties; and

- Meets a safe harbor under the anti-kickback statute or otherwise is in compliance with the anti-kickback provisions in section 1128B(b) of the Act.

The Final Rule: Except for the revisions described below, Phase I of this rulemaking adopts the proposed regulation. The revisions include:

- Elimination of the requirement that the written document cross-reference other agreements between the parties.

- Revision of the “set in advance” language to conform the exception to other exceptions in which that language appears. “Set in advance,” as used in the fair market value exception, will have the uniform meaning described in section V of this preamble and § 411.354(d) of the regulations.

- Revision of § 411.357(l)(3) to conform to our uniform interpretation of the volume or value standard in § 411.354(d) (discussed at section V of this preamble).

- Revision of the proposal in § 411.357(l)(5) that required “compliance with” the anti-kickback statute. Under the final regulations, the compensation arrangement must—(1) not violate the anti-kickback statute, (2) comply with a statutory or regulatory anti-kickback safe harbor, or (3) have been approved by the OIG pursuant to a favorable advisory opinion issued in accordance with part 1008 (Advisory Opinions of the OIG) of this chapter. In addition, billing and claims submission must be proper.

- Addition of a provision to mirror section 1877(e)(3)(A)(vi) of the Act, which clarifies that the services performed under the agreement cannot involve the counseling or promotion of a business arrangement or other activity that violates Federal or State law. While we believe this condition is implied throughout the statute, we are conforming the new fair market value exception to the Congress’s inclusion of this same standard in the personal service arrangements exception.

Comment: Several commenters objected to the requirement that an arrangement must meet a safe harbor under the anti-kickback statute or otherwise be in compliance with the anti-kickback provisions in section 1128B(b) of the Act. First, commenters pointed out that the anti-kickback statute is an intent-based statute that prohibits certain knowing and willful conduct, whereas section 1877 of the Act is not based upon intent. In addition, one commenter was concerned

that a violation of the anti-kickback statute by one party would preclude both parties from using the fair market value exception. Thus, the innocent party who might be unaware of the other party’s violation of the anti-kickback statute and relying on the fair market value exception could unknowingly violate section 1877 of the Act. Second, several commenters stated that few arrangements would meet the requirements necessary to obtain safe harbor protection under the anti-kickback statute. Therefore, such arrangements would be excepted from section 1877 of the Act only if they met the standard of being “in compliance with the anti-kickback statute.” These commenters were concerned that “being in compliance with the anti-kickback statute” was a nebulous standard that could only be accomplished with certainty by obtaining an OIG advisory opinion.

Response: In response to the concerns of commenters, we have revised § 411.357(l)(5) of the regulations to make it clear that for a compensation arrangement to qualify for the fair market value exception, it must meet one of the following criteria:

- It must not violate the anti-kickback statute.

- It must comply with a statutory or regulatory anti-kickback safe harbor.

- It must have been approved by the OIG pursuant to a favorable advisory opinion issued in accordance with part 1008 of this title.

This revision is both a clarification of the text set forth in the January 1998 proposed rule and an expansion of the types of arrangements that may qualify for the fair market value exception. In particular, we are changing the requirement from “being in compliance with” the anti-kickback statute to requiring that the arrangement not violate the anti-kickback statute. The revised language is more appropriate with respect to a criminal statute, such as the anti-kickback statute. In addition, since the broad statutory language of the anti-kickback statute technically covers some relatively innocuous commercial arrangements, and since the OIG has promulgated regulations granting safe harbor protection for some of these arrangements (§ 1001.952 of this title), we are revising the criteria to permit compensation arrangements that comply fully with a regulatory safe harbor. Arrangements that comply with the statutory exceptions at section 1128B(b)(3) of the Act also satisfy the new criteria. Finally, any compensation arrangement that has been approved by the OIG pursuant to a favorable advisory

opinion issued in accordance with part 1008 of this title would meet the criteria of § 411.357(l)(5). (We caution, however, that only the requestor of an OIG advisory opinion may rely on the opinion for any purposes, including, without limitation, the fulfillment of this criteria. Therefore, all parties that intend to rely on the advisory opinion should be included as requestors.)

Finally, we address the scenario where only one party has the requisite intent (that is, acting knowingly and willfully) to violate the anti-kickback statute. In such a case, only the party with the requisite intent would have violated the anti-kickback statute. However, if both parties relied on meeting the “not in violation of the anti-kickback statute” standard to qualify for the fair market value exception, the anti-kickback statute violation would preclude the use of the fair market value exception to section 1877 of the Act and both parties would have violated section 1877 of the Act. Although we understand the dilemma, we believe that it would be unusual that only one party to a compensation arrangement would have the requisite intent for violation of the anti-kickback statute. If any *one* purpose of remuneration is to induce or reward referrals of Federal health care program business, the statute is violated. (See *United States v. Kats*, 871 F.2d 105 (9th Cir. 1989); *United States v. Greber*, 760 F.2d 68 (3d Cir.), *cert. denied*, 474 U.S. 988 (1985).) Also, if the “innocent” party knows that the compensation arrangement would violate the anti-kickback statute but for the lack of the requisite intent, that party should be aware of the risk he or she is facing and take action to ensure that prohibited payments are not made. In that situation, we would advise structuring the arrangement to fit within a safe harbor, if possible, or obtaining an OIG advisory opinion.

For a discussion on the differences between section 1877 of the Act and the anti-kickback statute, together with an analysis of the impact that the anti-kickback statute has on these regulatory exceptions, see section II of this preamble.

Comment: Some commenters requested clarification regarding whether services provided by an entity to a physician would fit within the fair market value exception. One commenter was confused by the fact that the preamble to the January 1998 proposed rule implied that the exception would cover any compensation arrangements based upon fair market value, but the rule itself implied that it only covered arrangements where the physician (or

immediate family member) provided items or services.

Response: This fair market value exception only covers items or services provided by a physician or any immediate family member to an entity. Depending on the facts, payments made by a physician to an entity for items or services furnished by the entity might qualify for the exception for payments by a physician which is set forth under § 411.357(i), provided that the compensation is consistent with fair market value and the payments are not specifically excepted under another provision in §§ 411.355 through 411.357.

Comment: One commenter requested clarification regarding whether this exception would be available if another exception could apply.

Response: In the preamble to the January 1998 proposed rule, we stated that parties involved in a compensation arrangement should use the fair market value exception if they have doubts about whether they meet the requirements in the other exceptions listed in § 411.357. We have reconsidered our position. The parties may use the fair market value exception even if another exception potentially applies. We believe that the safeguards against overutilization included in the fair market value exception are sufficient to cover various types of compensation arrangements, including some arrangements that are covered by other exceptions.

Comment: A couple of commenters expressed concern regarding the application of the fair market value exception to legitimate physician recruitment practices that do not otherwise qualify for exception under the physician recruitment exception set forth at § 411.357(e). One commenter was concerned that in order to meet the “commercially reasonable” and “legitimate business purposes” prerequisites, hospitals would be forced to obtain costly experts’ reports regarding recruiting incentives provided in comparable situations. Another commenter sought clarification regarding whether the “commercially reasonable” prerequisite was based upon the specific business in which the parties are involved or business in general. This commenter was concerned that some arrangements (for example, loan forgiveness programs) might be commercially reasonable in the context of hospital/physician relationships, but might not be commercially reasonable from a general business perspective.

Response: Physician recruitment arrangements might be covered by this fair market value exception or the

physician recruitment exception, depending on the specific facts involved. However, we recognize that many physician recruitment arrangements that offer “extra” payments to induce physicians to relocate will not be covered by the fair market value exception, because compensation offered for the physician’s services exceeds the fair market value for such services. We will consider the comments on the recruitment exception in Phase II of this final rule.

With respect to determining what is “commercially reasonable,” any reasonable method of valuation is acceptable, and the determination should be based upon the specific business in which the parties are involved, not business in general. In addition, we strongly suggest that the parties maintain good documentation supporting valuation. Finally, with respect to difficult cases, the parties could seek an advisory opinion under section 1877 of the Act. (See § 411.370.) However, we cannot express opinions on whether compensation represents fair market value. (See § 411.370(c)(1).) For further discussion of “fair market value”, see section VIII.B.3 of this preamble.

Comment: One commenter thought that it would be burdensome to require inclusion of all items and services provided by the physician (or immediate family member) or a cross reference to other pertinent agreements. First, the commenter noted that there may be no written agreement for certain *bona fide* employment arrangements. Therefore, if an immediate family member of a physician is employed by the entity and there is no written employment agreement, the physician’s compensation arrangement with the entity could not satisfy this requirement of the fair market value exception. Second, the commenter stated that arrangements between an entity and a physician (or immediate family member) may change from time to time as a result of new arrangements, terminations, renewals, etc. Therefore, the list of other agreements would become outdated quickly. Third, the commenter asserted that the requirement duplicated the information that was already required under the reporting requirements. To rectify the foregoing problems, the commenter suggested that the exception should only require a reference to a master list of contracts that could be updated periodically. Finally, the commenter requested clarification regarding what contracts must be cross-referenced when there is a compensation arrangement

between an entity and a member of a physician group practice. The commenter questioned, with respect to a contract between an entity and an immediate family member of a physician who is a member of a group practice, whether the contract must cross-reference arrangements between the entity and—(1) the group practice, (2) each member of that group practice, and (3) any family member of a member of the group practice.

Response: We agree that it is burdensome to require that the written agreement either cover all items and services to be provided by the physician or immediate family member to the entity, or cross refer to any other agreements for items or services between any of these parties. To alleviate this burden, we are eliminating the requirement that the agreement cross refer to any other agreements. Nevertheless, we note that cross-referencing other agreements and arrangements is a good practice and will enable contracting entities, as well as auditors, to review more efficiently the full scope of a physician’s relationship to the entity. In cases where a physician or an immediate family member of a physician is employed by the entity and there is no written employment agreement, the commenter’s conclusion that the physician’s compensation arrangement with the entity could not satisfy this requirement of the fair market value exception is correct. Another exception, such as the employment exception, may apply, since it does not require a written agreement.

Comment: Some commenters were concerned that by requiring that the compensation not be related to the volume or value of program referrals, non-program referrals, or other business generated between the parties, we had undermined the usefulness of the fair market value exception, as well as many other exceptions which are subject to the same restriction. One commenter suggested that an arrangement should not pose a risk of abuse as long as the compensation does not reflect the volume or value of the physician’s own referrals.

Response: For a discussion of the “value or volume of referrals” standard, refer to the discussion at section V of this preamble. We are conforming the language of the new fair market value exception to our uniform interpretation of the standard, which is discussed at section V of this preamble.

C. Non-Monetary Compensation up to \$300 (and Medical Staff Benefits (§§ 411.357(k) and (m))

The Proposed Rule. Physicians and their immediate family members are often given noncash items or services that have a relatively low value and are not part of a formal, written agreement. For example, a physician might receive free samples of certain drugs or chemicals from a laboratory or free coffee mugs or note pads from a hospital. Although these free or discounted items and services fall within the definition of "compensation arrangement," we believe that such compensation is unlikely to cause overutilization, if held within reasonable limits. Therefore, we proposed a new exception, titled De Minimis Compensation, for compensation from an entity in the form of items or services that would not exceed \$50 per gift and an aggregate of \$300 per year. In addition, to qualify for the proposed exception, the entity providing the compensation would have to make it available to all similarly situated individuals, regardless of whether these individuals refer patients to the entity for services, and the compensation could not be determined in any way that would take into account the volume or value of the physician's referrals to the entity.

The Final Rule. Except for the revisions discussed below, the regulations in Phase I of this rulemaking are the same as the proposed rule:

- Changing the name of this exception from "De Minimis Compensation" to "Non-Monetary Compensation Up To \$300" to avoid any unintentional implication that the dollar limits set forth in the exception are minimal or inconsequential in all circumstances. That is, although the \$300 dollar limit may be relatively low when compared to the average physician's annual income, we believe the amount could be sufficient to induce referrals. However, we believe that the dollar limit, together with the other conditions of the exception, are sufficient to protect against abuse.

- Elimination of the \$50 per gift limit. Therefore, if the other conditions of the exception are met, an entity can give a physician one noncash gift per year valued up to \$300 or two or more noncash gifts per year, as long as the annual aggregate value of the gifts does not exceed \$300.

- Addition of a provision that precludes protection for gifts solicited by physicians to prevent physicians from making such gifts a condition or expectation of doing business.

- Elimination of the "similarly situated" standard. This standard was designed to ensure that compensation was not paid primarily to reward high referrers. To ensure the same end, we are augmenting the standard that prohibits compensation that takes into account the volume or value of referrals by also prohibiting compensation that takes into account the volume or value of any other business generated between the parties.

- Addition of a new exception (§ 411.357(m)) to allow certain incidental benefits of low value provided by hospitals to their medical staffs.

Comment: Several commenters argued that section 1877 of the Act does not apply to relationships between physicians and drug manufacturers, because a drug manufacturer is not an "entity" that furnishes health services to which a physician purchasing drugs makes a "referral" under section 1877 of the Act. Applying this interpretation, commenters concluded that free drug samples, free training, and other gifts (for example, pens, notepads, and other items) provided to physicians by drug manufacturers are not prohibited by section 1877 of the Act, and, therefore, do not need to qualify for any of the exceptions. Also, many expressed concern that, if section 1877 of the Act is interpreted as applying to physicians' relationships with drug manufacturers, then free drug samples and training provided to physicians by pharmaceutical companies would be prohibited, because they would exceed the proposed per gift and annual dollar limits of the *de minimis* exception. They reasoned that free drug samples should be exempt from section 1877 of the Act, because they are extensively regulated by Federal law that restricts their use and prohibits their sale, and, therefore, free drug samples pose little risk of abuse. They also stressed that free training given in connection with free samples should be exempt, because it is part of the sales effort which benefits patients, as well as physicians.

Response: We agree that drug manufacturers typically are not "entities" that furnish health services to which physicians purchasing drugs make "referrals" under section 1877 of the Act. (See section VIII.B of this preamble.) Therefore, as a general rule, neither free drugs, free training, nor gifts provided to physicians by drug manufacturers are prohibited by section 1877 of the Act. We caution, however, that free or discounted items or services provided by drug manufacturers to physicians must be scrutinized to ensure compliance with other

applicable laws and regulations, including, without limitation, the anti-kickback statute and the Federal laws restricting the sale and distribution of drug samples, 21 U.S.C. § 353(c) through (d).

Comment: Many commenters expressed concern regarding the per gift and annual dollar limits. In particular, they stated that the dollar limits were so low that they precluded protection for many legitimate compensation arrangements. For example, many commenters were concerned that no protection would be provided for free or discounted benefits provided by a hospital for its medical staff. Commenters believe that free or discounted benefits (for example, free or discounted meals and refreshments, free or discounted parking, free continuing medical education or other training, free computer/Internet access, free laboratory coats, free or discounted malpractice insurance, free transcription of medical records, and free photocopying) would add up and exceed the dollar limits quickly. Concern was also expressed about the administrative burden of tracking the exact dollar amounts for benefits provided to each medical staff physician.

Finally, one commenter questioned whether, with respect to group practices, the dollar limit would apply to each individual member of the group or to the group as a whole. Another commenter suggested that the dollar limits should be indexed for inflation.

Response: First, we have added a new exception (§ 411.357(m)) for incidental benefits given to a hospital's medical staff members. The question of incidental benefits given by a hospital to members of its medical staff was addressed previously in the preamble to the January 1998 proposed rule at 63 FR 1713-1714. In particular, we noted that:

Entities, such as hospitals, often provide physicians with certain incidental benefits, such as their malpractice insurance, or with reduced or free parking, meals or other incidental benefits. We believe the answer to this question hinges on the nature of any other financial relationship the physician has with the entity. For example, if a physician receives free "extras" such as malpractice insurance, parking, or meals while he or she serves as the entity's employee, then these extras might qualify as part of the compensation that the physician receives under a *bona fide* employment relationship, provided they are specified in the employment agreement. If the physician or entity can demonstrate that the extras constitute part of the payment that such entities typically provide to physicians, regardless of whether they make referrals to the entity, the extras constitute payment that

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

We recognize that many of the incidental benefits that hospitals provide to medical staff members do not qualify for the employment exception because most members of a hospital's medical staff are not hospital employees, and do not qualify for the fair market value exception because, to the extent that the medical staff membership is the only relationship between the hospital and certain physicians, there is no written agreement between the parties to which these incidental benefits could be added. While we still believe that medical staff incidental benefits could be structured in a way that would reward physicians for referrals and, thereby, lead to overutilization, we also recognize that many medical staff incidental benefits are customary industry practices that are intended to benefit the hospital and its patients. For example, free computer/Internet access benefits the hospital and its patients by facilitating the maintenance of up-to-date, accurate medical records and the availability of cutting edge medical information. Consequently, we have added a new exception (§ 411.357(m)), which provides that medical staff incidental benefits are excepted from section 1877 of the Act, if the benefits in question are—

- Offered by a hospital to all members of the medical staff without regard to the volume or value of referrals or other business generated between the parties;
- Offered only during periods when the medical staff members are making rounds or performing other duties that benefit the hospital and its patients;
- Provided by the hospital and used by the medical staff members only on the hospital's campus;

- Reasonably related to the provision of, or designed to facilitate directly or indirectly the delivery of, medical services at the hospital;

- Consistent with the types of benefits offered to medical staff members by other hospitals within the same local region or, if no such hospitals exist, by comparable hospitals located in comparable regions; and

- Of low value (that is, less than \$25) with respect to each occurrence of the benefit (for example, each benefit must be of low value).

Regardless of compliance with the foregoing, we caution that medical staff incidental benefits should be reviewed to ensure compliance with other applicable laws and regulations, including, without limitation, the anti-kickback statute.

Medical staff incidental benefits that do not meet the foregoing conditions could constitute prohibited remuneration and, therefore, would be permitted under section 1877 of the Act only if an exception applies. For example, malpractice insurance offered by a hospital only to its emergency room physicians would not meet the foregoing conditions. Therefore, to be exempt from section 1877 of the Act, it would have to qualify for one of the exceptions. Malpractice insurance would not qualify for the exception for non-monetary compensation up to \$300, because it would exceed the applicable dollar limits. Nor would it qualify for the exception for remuneration unrelated to the provision of DHS, because such payments would be related to the provision of emergency services, which are included in the definition of inpatient hospital services and, therefore, are DHS. Malpractice insurance provided to emergency room physicians might qualify for the employee exception if the physician is employed by the hospital and the insurance is part of the employment agreement. Similarly, we do not believe medical transcription services are an incidental benefit of nominal value.

We are aware that some hospitals are offering compliance training programs for physicians on their medical staffs or in their local communities. Because we believe such programs are beneficial and do not pose a risk of fraud or abuse, we are creating a new exception for such compliance training programs.

We intentionally set the dollar limits in the proposed exception at a low level to decrease the likelihood that the items or services would influence utilization. However, in response to the comments, we have eliminated the \$50 per gift dollar limit. Therefore, under the final

rule, an entity could give a physician either one noncash gift per year of up to \$300 in value or two or more noncash gifts per year, as long as the annual aggregate value of the gifts does not exceed \$300. This change permits larger one-time gifts. For example, a noncash gift valued at \$150 would have exceeded the per gift dollar limit of the proposed rule, but would be permitted under the final rule, as long as the annual aggregate does not exceed \$300 and the other conditions of the exception are met.

The exception for non-monetary compensation up to \$300 only protects gifts to individual physicians. Thus, gifts given to a group practice would not qualify for this exception. Noncash gifts could, however, be given to one member, several individual members, or each member of a group practice, if each such gift meets all of the conditions of the exception for non-monetary compensation up to \$300. We caution, however, that the exception will not apply to gifts, such as holiday parties or office equipment or supplies, that are valued at not more than \$300 per physician in the group, but are, in effect, given or used as a group gift.

Notwithstanding the foregoing, we recognize that the aggregate dollar amount could be substantial for gifts to individual physician members of very large groups. For example, if a group consists of 50 physicians, each physician of the group could be given an aggregate of \$300 in non-cash gifts within a given year, equaling a total of \$15,000 from one entity. Such a large gift could provide an economic incentive for overutilization. Therefore, to counter-balance the removal of the \$50 per gift limit and to further guard against abuse, we have added a provision that excludes gifts solicited by the receiving physicians or their group practice. This change also serves to clarify that our use of the term "gift" refers to the ordinary meaning of the term; that is, a gift must involve a voluntary transfer made without consideration or compensation expected or received in return. This new provision prevents members of group practices, as well as solo practitioners, from making noncash gifts a condition of doing business with a particular entity. We intend to monitor the provision of gifts to group practice physicians under this exception and may revisit our position if abuses occur. Such gifts remain subject to the anti-kickback statute.

Finally, we have decided not to index the \$300 annual aggregate dollar limit for inflation. Removal of the per gift dollar limit gives entities much greater

flexibility with respect to the value of noncash gifts. That is, under the proposed rule, a single gift could not exceed \$50; whereas, under the final rule, the value of a single gift could be up to \$300, as long as the other conditions are met. We believe that this revision decreases the need for adjustment for inflation. In addition, we think it would create confusion as to the actual limit in succeeding years if we were to provide for an inflation adjuster. The rule as it stands creates an easy-to-follow bright line. However, we will continue to monitor the effect of the \$300 limit and may revisit the limit in the future.

Comment: One commenter asked for clarification regarding the relationship between the de minimis exception and the statute's exception for remuneration provided by a hospital to a physician "if such remuneration does not relate to the provision of designated health services." (See section 1877(e)(4) of the Act.)

Response: The exception for non-monetary compensation up to \$300 and the statutory exception for remuneration unrelated to the provision of DHS are totally separate exceptions with different criteria. The determination as to which of these exceptions, if any, is applicable depends on the facts and circumstances of the case involved.

Comment: One commenter questioned whether the requirement that compensation must be made available to all similarly situated individuals would prohibit hospitals from hosting meals on a person-to-person basis. Another commenter suggested that the similarly situated requirement should be eliminated because the type of promotional items that would be covered by the exception would probably be provided only to referrers or potential referrers, and such minimal gifts were unlikely to cause overutilization.

Response: We agree that, on balance, the "similarly situated" test does not add significantly to the protections of the exception. Accordingly, we have eliminated the "similarly situated" standard. This standard was designed to ensure that compensation was not paid primarily to reward high referrers. To ensure the same end, we are augmenting the standard that prohibits compensation that takes into account the volume or value of referrals by also prohibiting compensation that takes into account the volume or value of any other business generated by the referring physician.

Comment: Two commenters questioned how professional courtesy discounts (that is, free or discounted

services provided to physicians) would be handled under section 1877 of the Act. One of the commenters suggested that professional courtesy discounts should not violate section 1877 of the Act, because they fall within the non-monetary compensation up to \$300 exception or they do not constitute "remuneration."

Response: The term "professional courtesy" is used (or misused) to describe a number of analytically different practices, including the practice by a physician of waiving the *entire fee* for services provided to the physician's office staff, other physicians, and/or their families (the traditional meaning); the waiver of coinsurance obligations or other out-of-pocket expenses for physicians or their families (that is, insurance only billing); and similar payment arrangements by hospitals or other institutions for services provided to their medical staffs or employees. Therefore, we cannot generalize about the application of section 1877 of the Act to such arrangements. Some such arrangements may fit in an existing exception, depending on the circumstances (for example, the non-monetary compensation up to \$300 exception if the value of the courtesy services is less than \$300 and the other conditions of the exception are satisfied). However, some such arrangements may not fit in an exception. We are considering whether an exception could be developed for such arrangements and will address the matter further in Phase II of this rulemaking. We are soliciting comments about appropriate conditions for such an exception and an appropriate definition of "professional courtesy." In addition to conducting an analysis of professional courtesy arrangements under section 1877 of the Act, these arrangements must be analyzed with respect to other fraud and abuse, as well as payment, authorities, including the anti-kickback statute, the False Claims Act (31 U.S.C. § 3729 *et seq.*), and the prohibition of inducements to beneficiaries (section 1128A(a)(5) of the Act).

VIII. Definitions of the Designated Health Services

A. General Principles

Basis for the Definitions

As we pointed out in the preamble to the January 1998 proposed rule (63 FR 1673), section 1877(h)(6) of the Act lists the DHS, but does not define them. Moreover, the list in section 1877(h)(6) of the Act does not necessarily correspond to specific service categories as they are defined under either

Medicare or Medicaid. For example, section 1877(h)(6)(D) of the Act uses the phrase, "[r]adiology services, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services," although ultrasound is not usually considered a radiology service. In defining the DHS in § 411.351 of the January 1998 proposed rule, we stated that we chose, as much as possible, to base the definitions in section 1877 of the Act on existing definitions in the Medicare program. We also explained that in situations in which it was not clear whether a service was included, we would look to the intent of the statute. In general, we believe the Congress meant to include specific services that are or could be subject to abuse.

Because we had received a number of inquiries from individuals who were confused about whether a particular service fell under one of the DHS categories, we proposed defining the DHS whenever we could by cross-referencing existing definitions in the Medicare statute, regulations, or manuals or by including specific language whenever we believed the definitions should deviate from standard Medicare definitions.

Many of the comments we received on the proposed rule reflected that commenters were still unclear about which services fall under the DHS categories. Many commenters specifically requested that we establish a "bright line" test for identifying these services, and suggested that we base the services on an established list, such as the Current Procedural Terminology (CPT) codes. We agree that more precise definitions will make it much easier administratively for physicians and entities to comply with the law.

Accordingly, we have determined that we will define certain DHS (clinical laboratory services, physical therapy, occupational therapy, radiology and certain other imaging services, and radiation therapy services (sections 1877(h)(6)(A) through (h)(6)(E) of the Act) by publishing specific lists of CPT and HCFA Common Procedure Coding System (HCPCS) codes that physicians and providers most commonly associate with a given designated health service. The lists of codes will define the entire scope of the designated services category for purposes of section 1877 of the Act. While the definitions section of the regulations will contain a general explanation of the principles used to select the codes, in all cases the published list of codes will be controlling.

For services described in section 1877(h)(6) of the Act, paragraphs (F)

through (K), we will not be publishing a service-by-service list. The codes for these services may be just one component used for identifying the service; the codes may be all those that appear in a specific "level," such as all HCPCS level 2 codes, for a service; or the service is not defined using HCPCS codes at all. The definitions for the services in paragraphs (F) through (K) are explained in detail below under each service category.

The HCPCS is a collection of codes and descriptors that represent procedures, supplies, products, and services that may be provided to Medicare beneficiaries and to individuals enrolled in private health insurance programs. We believe that these codes will already be familiar to many in the health care industry. These codes must be used when billing Medicare for Part B services and supplies. The codes are divided into three levels, the first two of which are used in this final rule and are described below; they are listed in HCPCS 2001:

Level I: Codes and descriptors copyrighted by the American Medical Association in its Current Procedural Terminology, Fourth Edition (CPT-4). These are 5-position numeric codes primarily representing physician services.

Level II: These are 5-position alpha-numeric codes representing primarily items and nonphysician services that are not represented in the level I codes. Included are codes and descriptors copyrighted by the American Dental Association's Current Dental Terminology, Second Edition (CDT-2). These are 5-position alpha-numeric codes comprising the "D" series. All other level II codes and descriptors are approved and maintained jointly by the alpha-numeric editorial panel (consisting of HCFA, the Health Insurance Association of America, and the Blue Cross and Blue Shield Association).

Because these specific codes change and can quickly become out-of-date, we are not including the lists of DHS codes in the regulations text, but rather in an accompanying attachment. The definitions of specific services in the regulations text will cross refer to a comprehensive table that will appear initially in the **Federal Register** along with Phase I of this rulemaking and thereafter in an addendum to the annual final rule concerning payment policies under the physician fee schedule rule. This list titled, "List of CPT/HCPCS Codes Used to Describe Certain Designated Health Services Under the Physician Referral Provisions (Section 1877 of the Social Security Act)," will

also be posted on the HCFA web site at <http://www.hcfa.gov> on the date of **Federal Register** publication of this final rule. The table published each year will be a comprehensive listing of all codes for DHS and not merely a listing of changes to the prior year's table. The updates will also be posted on the HCFA web site. The physician fee schedule rule is generally published in late October or early November. We will consider comments on each year's revised list if we receive them during the applicable comment period for that rule. If any changes are made, we will then publish a revised table and respond to any public comments that we receive. This approach will provide an annual comprehensive list of codes for those DHS noted above (sections 1877(h)(6)(A) through (h)(6)(E) of the Act).

We are not providing lists of codes for the following categories of DHS (sections 1877(h)(6)(F) through (h)(6)(K) of the Act): Durable medical equipment and supplies; parenteral and enteral nutrients, equipment, and supplies; prosthetics, orthotics, and prosthetic devices and supplies; home health services; outpatient prescription drugs; or inpatient and outpatient hospital services. We believe the definitions in Phase I of this rulemaking for these DHS provide sufficiently clear "bright line" rules.

In the preamble to the January 1998 proposed rule, we had stated that we believed the Congress intended to include specific services that are or could be subject to abuse and that we would attempt to define the services accordingly. In the January 1998 proposed rule preamble and regulations text, we then attempted in some cases to include or exclude services or types of services based on our view as to their potential for abuse. Many commenters disagreed with our views about particular services (for example, lithotripsy), and many more argued that the particular service they provided should also be excluded because it was not overutilized. In light of these comments and upon further review of the statutory scheme, we have decided that the Congress did not intend that we categorize DHS by determining the potential for overutilization or abuse on a service-by-service basis. Accordingly, in Phase I of this rulemaking, we are including all services that we believe come within the general categories; we have created limited exceptions for a few specific cases (that is, implants in ambulatory surgical centers, legislatively mandated preventive screening tests and immunizations subject to frequency limits, eyeglasses

and contact lenses subject to frequency limits, and erythropoietin (EPO) provided by end-stage renal disease (ESRD) facilities) for which we believe an exception poses a limited risk of abuse and is necessary to avoid needless disruption of patient care. However, even for those rare exceptions, we will continue to monitor the services for abuse and, if necessary, revisit the exclusions.

We also stated in the preamble to the January 1998 proposed rule (63 FR 1673) that we consider a service to be a designated health service, even if it is billed as something else or is subsumed within another service category by being bundled with other services for billing purposes. We gave as an example skilled nursing facility (SNF) services, which can encompass a variety of DHS, such as physical therapy (PT), occupational therapy (OT), or laboratory services. Commenters complained that this interpretation would result in an expansion of the DHS beyond the services specifically listed in the law. According to the commenters, when the Congress intended to cover specific Medicare services (including composite rate services, such as hospital or home health services), it did so expressly. Upon review, we agree with the commenters. Under the final rule, services that would otherwise constitute DHS, but that are paid by Medicare as part of a composite payment for a group of services as a separate benefit (for example, ambulatory surgical center (ASC) or SNF rate), are not DHS for purposes of section 1877 of the Act. (As expressly provided in section 1877(h)(6) of the Act, hospital and home health services remain DHS although they are paid through a composite rate.) We note, however, that because of SNF consolidated billing, most, if not all, SNFs will also be considered entities providing DHS (for example, PT or OT) under Part B to SNF patients who have exhausted their Part A benefit or to other nursing home residents (that is, patients for whom the services are not covered as part of a composite rate). The consolidated billing requirement places with the SNF the Medicare billing responsibility for most of the services that a SNF resident receives (except for certain practitioner services and a limited number of other services) under Part A and under Part B. (Presently, consolidated billing is in effect only for patients in a covered Part A stay, but will become effective for Part B services in the near future.) Accordingly, a physician will not be able to refer Medicare patients who will require DHS to a SNF in which he or she has an

ownership or investment interest, unless the interest is protected under an exception to section 1877 of the Act.

In the August 1995 final rule relating to clinical laboratory services, we created an exception for laboratory services furnished in an ASC or ESRD facility or by a hospice if the services were included in a composite rate or per diem hospice charge. (See § 411.355(d)). In the January 1998 proposed rule, we had proposed extending this composite rate exception to include all DHS furnished in an ASC or ESRD facility or by a hospice if payment is included in the ASC payment rate, the ESRD composite payment rate, or as part of the hospice payment rate. This proposal was intended to address problems faced by ASCs, ESRD facilities, and hospices in the light of our proposed stance on DHS subsumed by bundled payments. However, since under the final rule DHS that are subsumed by a bundled payment do not implicate section 1877 of the Act, we have not adopted our proposal to extend § 411.355(d) beyond clinical laboratory services. Moreover, given our final interpretation, we are reconsidering the need for § 411.355(d) as applied to clinical laboratory services and intend to address the matter further in Phase II of this rulemaking. We are soliciting comments on this issue.

B. General Comment: Professional Services as Designated Health Services

Comment: Many commenters expressed the view that the professional component of DHS (particularly clinical laboratory and radiology services) should not implicate section 1877 of the Act. Commenters asserted that the Congress did not intend for professional services to come within the physician self-referral law prohibition and that we exceeded our authority to promulgate regulations by including them. Commenters also contended that limiting DHS under section 1877 of the Act solely to the technical components of services would sufficiently control the risk of program or patient abuse. Other commenters stated that if we included professional components of some DHS, we should do so for all DHS. The commenters pointed out that our proposed position on productivity bonuses (that is, that they may not reflect the volume or value of any DHS referrals) would require special bookkeeping to segregate professional fees when calculating bonuses that will burden practices, without serving a public policy purpose.

Response: We believe that it was not the intent of the statute to exclude all professional services from the list of DHS. Many of the DHS, such as

radiology and radiation therapy, have substantial physician service components. If the Congress intended to exclude them, we would expect the statute to specifically do so. While some services are not viewed as having a professional component that is paid separately, Medicare still requires professional supervision of them to qualify for Medicare payment.

We agree to some extent that limiting referrals for the technical component of a service should greatly reduce the number of unnecessary referrals. Nonetheless, there are some DHS that consist only of a professional component (for example, some radiation therapy services) or are primarily professional in nature, and these would not otherwise be subject to the law if we carved out all professional components.

We agree with the commenters that we should include professional components when relevant in all DHS categories. Therefore, we have revised the definitions of each of the DHS to include the professional components in each case in which a professional component is included in the CPT or HCPCS codes that represent one of those services.

We understand that these rules may impose an administrative burden on some group practices, depending on how they choose to comply with section 1877 of the Act. We think Phase I of this rulemaking has a number of substantive changes that will ease the administrative burden of compliance, including the exception from the definition of "referral" for personally performed services and the greater flexibility afforded group practices over their distribution of revenues. As a practical matter, the professional component of many of these services will be excluded from the definition of a referral as services personally performed by the referring physician.

Individual Designated Health Services

We discuss below each designated health service category in the order in which it appears in section 1877(h)(6) of the Act. Each discussion includes a general summary of the category, summaries of the relevant public comments, and our responses.

C. Clinical Laboratory Services

In the August 1995 final rule covering a physician's referrals for clinical laboratory services, we defined these services in § 411.351 as—

The biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for

the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body.

We had stated in the August 1995 final rule, in response to a commenter who requested a definition of clinical laboratory services, that we believed the most appropriate way for a physician or clinical laboratory to determine if a diagnostic test is a clinical laboratory test subject to the requirements of section 1877 of the Act, is to find out if the test is subject to categorization under the Clinical Laboratory Improvement Act (CLIA). We pointed out that there is a list of clinical laboratory test systems, assays, and examinations categorized by complexity and published by the Center for Disease Control (CDC). We also stated that, given this definition, CPT codes would not be the sole references to identify clinical laboratory services for physician referral purposes.

Commenters also had asked about the professional components of laboratory services. We stated that we believed that CLIA covers the actual examination of materials, their analysis, and any interpretation and reporting of the results that are performed by a facility that qualifies as a laboratory, as defined in § 493.2 (Definitions). However, if a laboratory sent test results to an independent physician, any interpretation performed by the physician would not be performed by the laboratory facility. As a result, the services would not constitute part of the clinical laboratory test.

We stated in the January 1998 proposed rule covering referrals for the other DHS that we would retain the definition of clinical laboratory services that was incorporated into our regulations by the August 1995 final rule. However, in line with our revised approach for identifying the DHS in this final rule, we have amended the rule to refer specifically to CPT and HCPCS codes. We have included as DHS the professional components of laboratory tests when they are listed as such in the codes. It is our belief that the specification of the codes in the attachment to this final rule is consistent with, although not identical to, the definition of clinical laboratory services in our January 1998 proposed rule.

D. Physical Therapy Services

We proposed to define physical therapy services in § 411.351 as those

outpatient physical therapy services (including speech-language pathology services) described at section 1861(p) of the Act and in § 410.100 (Included services), paragraphs (b) and (d). Under section 1861(p) of the Act, the term “outpatient physical therapy services” specifically includes speech-language pathology services. Because section 1877(h)(6) of the Act lists physical therapy services in general, and not just *outpatient* services, we also included in the definition any other services with the characteristics described in § 410.100(b) and (d) that are covered under Medicare Part A or Part B, regardless of who provides them, the location in which they are provided, or how they are billed.

We pointed out that services that are essentially the same as “outpatient physical therapy services” are also covered by Medicare in other contexts and in different settings, and may be billed under different categories. For example, we have a longstanding policy of covering physical therapy and occupational therapy as diagnostic or therapeutic inpatient hospital services. Similarly, these services can also be covered as SNF services, and can be furnished as “incident to” physician services under section 1861(s)(2)(A) of the Act. (Section 1877 implications for DHS provided by SNFs are discussed earlier in this section.)

It was our view in the January 1998 proposed rule that covered outpatient physical therapy services basically included three types of services, which were best described in § 410.100(b) (which specifically concerns services provided by a comprehensive rehabilitation facility (CORF)). This definition covers the testing and measurement of the function or dysfunction of the neuromuscular, musculoskeletal, cardiovascular, and respiratory systems; assessment and treatment related to dysfunction caused by illness or injury and aimed at preventing or reducing disability or pain and restoring lost function; and the establishment of a maintenance therapy program for an individual whose restoration has been reached. Many commenters asserted that the proposed definition was imprecise or improperly included some procedures that are not generally considered physical therapy services.

We have responded to these concerns by redefining physical therapy services, as some commenters suggested, by using a list of HCPCS codes. We believe the list is limited to services that are more traditionally regarded as physical therapy. In general, these services are described in the “Physical Medicine

and Rehabilitation” section (the 97000 series) of the CPT and in other relevant sections of the HCPCS.

In the January 1998 proposed rule, we also included speech-language pathology services as a designated health service since section 1861(p) of the Act includes “speech-language pathology services” in the definition of “outpatient physical therapy services.” These services are defined in section 1861(l)(1) of the Act as speech, language, and related function assessment and rehabilitation services furnished by a qualified speech-language pathologist as this pathologist is legally authorized to perform under State law (or the State regulatory mechanism) as would otherwise be covered if furnished by a physician. Section 1861(l)(3) of the Act defines a “qualified speech-language pathologist.”

We used in the proposed rule the brief description of speech-language pathology services in § 410.100(d), which applies to services provided in CORFs, as those services that are necessary for the diagnosis and treatment of speech and language disorders that create difficulties in communication. In an effort to furnish a “bright line” test, we are defining the services in Phase I of this rulemaking by the specific codes that correspond to the services that we consider to be speech-language pathology services.

As we developed the list of CPT and HCPCS codes relevant to speech-language pathology, we realized that our proposed definition, which cross-refers to the CORF definition in § 410.100(d), did not encompass the full range of services that are commonly considered to be speech-language pathology services. It failed to recognize that speech-language difficulties can be caused by cognitive disorders and failed to recognize that speech-language pathology may be used to treat swallowing and other oral-motor dysfunctions. Therefore, in developing the list of codes for speech pathology in Phase I of this rulemaking, we included the diagnosis and treatment of cognitive disorders including swallowing and other oral-motor dysfunctions.

Finally, because of the overlap between physical therapy, occupational therapy, and speech-language pathology services, we are listing the codes for all three services together. We believe that this set of HCPCS codes represents what most clinicians would define as PT/OT/speech therapy services that are covered by the Medicare program. The list is set out in the attachment to this final rule.

Comment: A number of commenters were particularly concerned that the

proposed definition of physical therapy services implies that physical therapists can perform diagnostic testing and measurements, such as electromyography tests (EMGs). These tests are used primarily to provide medical diagnostic information regarding neuromuscular diseases and occasionally to measure neuromuscular function. Although some States permit physical therapists to perform these tests, the commenters believe that EMGs are typically performed by a physician as part of a physical examination to determine whether a patient is a surgical candidate or if some other course of treatment is warranted.

In addition, other commenters stated that the proposed definition of physical therapy services could be interpreted to include therapeutic procedures such as nerve blocks and arthrocentesis that the commenters believe are physician services. One commenter, a physician who practices physical medicine and rehabilitation, asserted that our proposed definition of physical therapy included services that could be administered by physicians and physical therapists. He feared that this could prohibit him from treating patients he diagnoses. Several commenters responded to the inclusion in the definition of physical therapy of any “assessment and treatment” designed to alleviate pain or disability. The commenters asserted that this phrase captures a large portion of modern medicine, given that pain is the most common presenting symptom in a physician’s office, and virtually any assessment or treatment following therefrom would have as its purpose the alleviation of that pain.

Response: Nothing in the proposed definition affected the scope of any practitioner’s practice. We agree with the commenters that only in certain States are physical therapists licensed to perform EMGs. Additionally, we agree that therapeutic procedures such as nerve blocks and arthrocentesis are typically performed by a physician and are not generally considered to be a part of physical therapy. These procedures are not included on the list of codes that defines the scope of physical therapy for purposes of section 1877(h)(6)(B) of the Act. In the January 1998 proposed rule, we did not intend to convey the message that what is generally considered physical therapy would change. We proposed to use an existing definition of physical therapy (in § 410.100(b), which covers physical therapy services in CORFs) precisely because we did not want to change the existing perception of physical therapy.

In order to avoid confusion, we are revising our proposed definition by providing a list of CPT and HCPCS codes that are, collectively, the PT/OT/speech-language therapy DHS. This list of codes defines the entire scope of PT/OT/speech-language therapy services for purposes of section 1877 of the Act. Finally, we note that under Phase I of this rulemaking, if a physician personally provides a designated health service to his or her patient, there is no "referral" for purposes of section 1877(a)(1) of the Act. See section III.B of this preamble.

Comment: One commenter asserted that pulmonary function tests are for the measurement of the function of the respiratory system and have nothing to do with physical therapy. However, another commenter recommended that the definition of physical therapy include the neuromuscular and pulmonary function tests that test for functional capacity ratings and that are usually performed by a physical therapist without the direct supervision of a physician.

Response: We agree with the commenter that pulmonary function tests for the measurement of the function of the respiratory system are not physical therapy. The only pulmonary function test that may be considered to be a physical therapy service is pulse oximetry testing, CPT code 94762, when it is used to test for functional capacity ratings. A pulse oximetry test that is performed to determine whether a patient has enough oxygen to perform certain activities of daily living is, for example, a physical therapy service.

Comment: One commenter recommended that we define physical therapy as those therapeutic exercises and physical medicine modalities described in the 97000 series of the CPT codes, included in the patient's written plan of physical therapy treatment, and provided by a physical therapist or physical therapy aide.

Response: We agree with the commenter that PT services should be based on the CPT codes and have modified the rule accordingly. With respect to which professionals can provide a given service, we defer in this rule to existing Medicare policy. Many of these DHS can be provided by physicians.

Comment: A number of commenters opposed the inclusion of speech-language pathology services in the definition of physical therapy services. The commenters stated that the Congress did not intend to include these services within the ban on physician referrals and asserted that including

these services as DHS is unnecessary (although they did not state why this would be the case). One commenter asserted that when the Congress intended to include outpatient speech-language pathology services within the category of outpatient physical therapy services, the Congress enacted explicit language that made that intention clear. The commenter pointed to section 4541(a)(1) of the BBA 1997, which added paragraph (8)(A) to section 1833(a) of the Act. That provision states that, for covered individuals, amounts will be paid from the Medicare Trust Fund for "outpatient physical therapy services (which includes outpatient speech-language pathology services) and outpatient occupational therapy services furnished—" * * * by certain entities.

Response: The definition of "outpatient physical therapy services" in section 1861(p) of the Act specifically states that "the term 'outpatient physical therapy services' also includes speech-language pathology services furnished by a provider of services, a clinic, rehabilitation agency, or by a public health agency, or by others. * * *" Thus, by definition, speech-language pathology services are a subset of outpatient physical therapy services under the Medicare statute. We believe that the parenthetical language under the BBA 1997 simply confirms our interpretation.

E. Occupational Therapy Services

In the January 1998 proposed regulations text, we proposed to include those OT services described in section 1861(g) of the Act and the CORF regulations in § 410.100(c). We proposed that occupational therapy services would also include any other services with the characteristics described in § 410.100(c) that are covered under Medicare Part A or Part B, regardless of who furnishes them, the location in which they are furnished, or how they are billed. In proposed § 411.351, OT services included the following:

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

As discussed in the preceding section, we are revising our proposed definition by providing a list of CPT and HCPCS

codes that collectively are the PT/OT/speech therapy DHS. Also, as described above, we are excluding from the definition of DHS any designated health service that is paid for as part of a "bundled" payment (for example, services covered by the SNF Part A rate or the ASC rate), unless the statute otherwise provides that a "bundled" set of services is itself a designated health service (for example, home health services and inpatient and outpatient hospital services).

Comment: A major OT association asserted that the definition of OT is too narrow because it does not adequately capture the scope of the OT benefit. For example, OT is furnished to patients with cognitive impairments as well as to patients with physical impairments and limitations. As another example, OT may also be furnished in partial hospitalization programs for patients with a psychiatric illness. The commenter believes that it is important for the definition in § 411.351 to be as complete and accurate as possible to assure appropriate compliance with the law, and that § 410.100(c) is too narrow to be used as the complete definition of OT services for purposes of these regulations. The commenter suggested that we broaden the definition by adding to it the coverage guidelines stated in section 3101.9, "Occupational Therapy Furnished by the Hospital or by Others under Arrangements with the Hospital and under its Supervision," of the Medicare Intermediary Manual (HCFA Pub. 13-3), Part 3—Claims Process, and section 2217, "Covered Occupational Therapy," of the Medicare Carriers Manual (HCFA Pub. 14-3), Part 3—Claims Process. The commenter recommended that we use the following definition for OT in § 411.351:

Occupational therapy services means those services described at section 1861(g) of the Act, § 410.100(c) of this chapter, and in the occupational therapy coverage guidelines contained in section 3101.9 of the Medicare Intermediary Manual and section 2217 of the Medicare Carriers Manual. Occupational therapy services also include any other services with the characteristics described in § 410.100(c) and the occupational therapy coverage guidelines that are covered under Medicare Part A or B, regardless of who furnishes them, the location in which they are furnished, or how they are billed.

Response: We agree with the commenter that the proposed definition does not clearly recognize that OT is furnished to patients with cognitive impairments. As we have stated previously in this preamble, we did not intend to change what is commonly regarded as OT. We referred to the existing definition in § 410.100(c) so

that we would not be proposing any change. However, as the commenter pointed out, the existing definition at § 410.100(c) is not complete. Therefore, we are expanding the proposed definition by including codes for the “teaching of compensatory techniques to permit an individual with a physical or cognitive impairment or limitation to engage in daily activities.”

However, the commenter is correct that a partial hospitalization program may provide OT services. This is in accordance with section 1861(ff) of the Act, which defines “partial hospitalization services” and specifically includes OT as a partial hospitalization service. However, with respect to partial hospitalization, we have determined that services provided as part of a group of services paid under a bundled rate are not DHS. Partial hospitalization services are paid under a bundled rate. Therefore, partial hospitalization services (including OT services provided as part of the partial hospitalization benefit) furnished by a community mental health center are not DHS. However, partial hospitalization services furnished by a hospital are outpatient hospital services, which is a category of DHS.

In order to eliminate any confusion the January 1998 proposed regulations may have caused and to make Phase I of this rulemaking clear, we are defining OT by a list of specific HCPCS/CPT codes. In light of the changes we have made in Phase I of this rulemaking, it is not necessary for us to include the references to the intermediary and carrier manuals that the commenter suggested.

Occupational therapy services may be furnished by an occupational therapist, an occupational therapy aide who is supervised by an occupational therapist, or by a physician. Section 1861(r) of the Act allows a physician to furnish any medical service that his or her State allows the physician to furnish.

F. Radiology and Certain Other Imaging Services

In the January 1998 proposed rule, we combined the DHS in section 1877(h)(6)(D) of the Act—“radiology services, including magnetic resonance imaging, computerized axial tomography, and ultrasound services”—and 1877(h)(6)(E) of the Act—“radiation therapy services and supplies” into the following definition:

Radiology services and radiation therapy and supplies means any diagnostic test or therapeutic procedure using X-rays, ultrasound or other imaging services, computerized axial tomography, magnetic resonance imaging, radiation, or nuclear

medicine, and diagnostic mammography services, as covered under section 1861(s)(3) and (4) of the Act and §§ 410.32(a), 410.34, and 410.35 of this chapter, including the professional component of these services, but excluding any invasive radiology procedure in which the imaging modality is used to guide a needle, probe, or a catheter accurately.

Commenters found the proposed definition to be confusing in two main respects:

- The definition both combined two different categories of radiology-related services (that is, radiology and radiation therapy and supplies) and included other services not commonly considered to be radiology-related (ultrasound and nuclear medicine). Many commenters thought that all services not strictly considered radiology should be excluded.

- At different places in the January 1998 proposed regulation preamble, we stated that we were excluding DHS that were peripheral, incidental, or secondary to a nondesignated health service. In the proposed definition, however, we only excluded imaging modalities used to “guide a needle, probe, or catheter.” Many commenters thought the scope of excluded radiology and other imaging services should be broader than just guidance, while others thought the distinction between primary and secondary services would be difficult to apply in practice.

Based on the comments, we have redefined this category of DHS in a manner that should provide greater clarity. First, we have segregated radiation therapy and supplies from radiology and other imaging services and returned them to a separate category, as in the statute. (We discuss comments relating to radiation therapy services in section VIII.G of this preamble). Second, we are excluding nuclear medicine since those services are not commonly considered to be radiology. Third, for purposes of these regulations we have renamed the category of services covered by section 1877(h)(6)(D) of the Act “Radiology and Certain Other Imaging Services” to make clear the Congress’s intent to include in subsection (D) some imaging services other than radiology. Fourth, consistent with the approach we are following with several other of the DHS categories, we are defining the entire scope of covered services under section 1877(h)(6)(D) of the Act by using lists of CPT and HCPCS codes, which lists control in all circumstances. The lists include those services typically considered as radiology or ultrasound services, or as constituting an MRI or a computerized axial tomography (CAT)

scan. Fifth, we have excluded certain covered preventive screening procedures, such as screening mammography, that are subject to HCFA-imposed frequency limits that mitigate the potential for abuse. In these circumstances, we believe the Congress did not intend the physician self-referral law to interfere with a physician’s or entity’s attempts to provide these preventive procedures to Medicare patients.

Sixth, based on the comments we received, we concluded that the terms “invasive” radiology and radiology “incidental” or “secondary” to a non-DHS procedure used in our proposed definition of “radiology services” created confusion and uncertainty. We agree with commenters that “invasive” radiology includes more than just those procedures used to “guide a needle, probe or catheter.” Consequently, we are revising our definition of radiology and certain other imaging services to exclude from the definitional list of codes x-ray, fluoroscopy, and ultrasound services that are themselves invasive procedures that require the insertion of a needle, catheter, tube, or probe. Thus, cardiac catheterizations and endoscopies will not fall within the scope of “radiology services” for purposes of section 1877 of the Act. All MRIs or CAT scans, however, are within the scope of the DHS because excluding some on the basis that they are “invasive” tests would have the effect of excluding all MRIs and CAT scans that use contrast injection. The use of contrast is not mandatory for the performance of a scan, as it is for the performance of a barium enema, excretory urogram, or traditional vascular angiography. Thus, an exclusion from the DHS definition of contrast for MRIs and CAT scans could have the effect of encouraging the use of contrast when it is not necessary.

In addition, we have concluded that radiology procedures that are integral to the performance of, and performed during, a nonradiology medical procedure are not within the scope of DHS. The list of codes that defines the scope of “radiology and certain other imaging services” will make this distinction clear. Examples of these integral services include, but are not limited to, imaging guidance procedures and radiology procedures used to determine, during surgery, whether surgery is being conducted successfully. In the CPT, these radiology procedures are identified as cross-references to the principle procedures with which they are associated. A radiology procedure, such as a CAT scan or a chest x-ray, performed before or after another

procedure, such as a lung cancer resection, is considered to be a diagnostic radiology procedure that is not integral to the principle procedure (that is, the lung cancer resection). While these radiology procedures are essential to the performance of the principle procedure, physicians have discretion in choosing which entity provides the radiology service independent of the entity providing the principle surgical service. These nonconcurrent services are DHS.

Regardless of our definition of "radiology and certain other imaging services," some services that are not within the scope of that definition may still be DHS if they are inpatient or outpatient hospital services, a separate category of DHS under section 1877(h)(6)(K) of the Act. These services would be subject to the physician referral rule if the referring physician has a financial relationship with the hospital. We anticipate most of these financial arrangements will meet an exception under section 1877 of the Act (for example, the exception for hospital ownership or either the employment or personal service arrangements exception).

We address comments related to the definition of services covered by section 1877(h)(6)(D) of the Act below. To the extent some commenters raised issues such as the general effects of section 1877 of the Act on physicians' practices or on medicine in general, those issues are addressed elsewhere in the preamble, where relevant.

Comment: Several commenters asserted that the proposed definition of "radiology services" that included all sound-based or imaging-based technologies is contrary to congressional intent. The commenters argued that the Congress intended to limit the definition by removing original language that included the phrase "other diagnostic services" along with radiology services.

Response: The phrase "radiology, or other diagnostic services" was added in section 1877(h)(6)(D) of the Act by OBRA 1993 as one of the categories of DHS the Congress chose to cover in addition to clinical laboratory services. This one set of services appeared to include the extremely broad category of "other diagnostic services," in addition to radiology services. The Congress narrowed this category in section 152 of the Social Security Act Amendments of 1994 (SSA 1994), Public Law 103-432, enacted on October 31, 1994, perhaps because it realized the huge scope of "diagnostic services." The amendments revised section 1877(h)(6)(D) of the Act, effective January 1, 1995, by replacing

the category with "radiology services, including magnetic resonance imaging, computerized axial tomography, and ultrasound services." While all of these services might not be subsumed in the category "radiology services," the Congress clearly intended to include them as DHS. We have renamed the category "radiology and certain other imaging services" to reflect the Congress's intent.

Comment: One commenter questioned why cardiac, vascular, and obstetric ultrasound procedures could not be referred. The commenter stated that in most institutions these procedures are not considered radiology procedures since radiologists may never supervise or interpret them. Another commenter argued that although echocardiography is a type of ultrasound procedure, it should not be considered a radiology service because echocardiography is a service developed and performed primarily by cardiologists, billed under cardiologist CPT codes, and furnished to cardiac patients. As a result, the commenter argued that it is inaccurate and inappropriate to include echocardiography within the definition of radiology services.

Response: Cardiac, vascular, and obstetric ultrasound procedures are subject to the physician self-referral provisions because section 1877(h)(6)(D) of the Act specifically includes ultrasound as a designated health service, not because they are ordinarily considered to be "radiology services." Simply stated, the term "radiology services" as applied to the services described by section 1877(h)(6)(D) of the Act is a misnomer. Section 1877(h)(6)(D) of the Act includes any services that are traditionally regarded as "radiology" services, as well as MRIs, CAT scans, and ultrasound services. Cardiac echography and vascular echography are clearly ultrasound services. Nothing in the regulation would prohibit a vascular surgeon, neurologist, or other specialist from ordering a particular service from an entity with which he or she has no prohibited financial relationship.

Comment: Several commenters were opposed to our proposal to exclude as "invasive" radiology only those invasive procedures used to guide a needle, probe, or catheter accurately. Two of the commenters were concerned that invasive radiology procedures, which use an imaging modality not only to guide a needle, probe or catheter, but also to record an accurate picture of the areas of the body being probed or catheterized, would be included in the definition of radiology. (An example of this would be an ultrasound device

placed at the end of a catheter or endoscope.)

Response: We agree and have not included x-ray, fluoroscopy, and ultrasound services that require the insertion of a needle, catheter, tube, or probe on the list of HCPCS/CPT codes that defines the full scope of radiology and other imaging services for purposes of section 1877 of the Act. Some of these services may still be DHS when they fall within the category of inpatient and outpatient hospital services.

Comment: Several commenters objected to our proposal to exclude radiology services that were "merely incidental or secondary" to another procedure that the physician has ordered. (See our January 1998 proposed rule, 63 FR 1676.) Some commenters noted that it is generally not possible to establish, based on the CPT code used, whether or not the primary purpose of the procedure was the interventional procedure itself (with the imaging being an adjunct procedure) or whether the primary purpose was to take a picture with an imaging modality. Because it is extremely difficult and impractical in the commenters' view to separate the radiology component from the underlying procedure, the commenters recommended that we exclude all invasive radiology services, encompassing those procedures that may include an adjunct radiology procedure performed at the same time as the interventional procedure. Other commenters thought that the definition of radiology services should also exclude imaging services when they are performed before and/or after a surgical procedure. For example, a commenter requested that we add language to the proposed definition of radiology to exclude any radiology procedure in which the imaging modality is used to plan the invasive procedure. The commenter noted that for many invasive procedures, an ultrasound before the actual procedure might be routinely necessary in order to plan the manner in which the needle, catheter, or probe would be guided during the actual invasive procedure. In these circumstances, the patient already has received the diagnosis that the invasive procedure is necessary. The commenter believes that we should maintain the view that a physician would not refer a patient for these procedures in order to profit from unnecessary radiology services. Another commenter stated that under our proposed interpretation of invasive procedures, an echocardiogram that showed a need for bypass surgery would be a designated health service, while one that ruled out surgery would not, since there would be no surgical

procedure to which the imaging service would be "incidental." Finally, a neurologist commented that there are a number of radiology procedures performed by neurologists that are incidental to other procedures, particularly certain surgical services. One of the examples given by the commenter was carotid duplex or transcranial Doppler ultrasound, which are tests performed after carotid endarterectomy to look for clots. The commenter believes these radiology services should be excluded.

Response: We agree with the commenter that the "incidental/secondary" test in the January 1998 proposed rule has led to some confusion and uncertainty and have abandoned it in Phase I of this rulemaking. We believe the list of codes set forth in Phase I of this rulemaking (and annually thereafter in the physician fee schedule rule) will create a "bright line" test that will ease compliance. In selecting the codes for radiology and ultrasound, we are not including any codes for radiology or ultrasound procedures that have an invasive component; that is, that include the insertion of a needle, catheter, tube, or probe through the skin or into a body orifice. ("Invasive" would encompass radiology services involving contrast that must be injected, but not contrast materials that are ingested by the patients themselves.) In addition, we are not including radiology and ultrasound procedures that are integral to and performed during the time a nonradiology procedure is being performed, such as ultrasound used to provide guidance for biopsies and major surgical procedures or used to determine, during surgery, whether surgery is being conducted successfully. Phase I of this rulemaking requires that to be considered integral to a nonradiology procedure (and therefore not a radiology or other imaging service for purposes of section 1877(h)(6)(D) of the Act), the imaging procedure must be performed during the nonradiology procedure. A radiology or ultrasound procedure performed before or after another procedure (for example, a scan or a chest x-ray before a lung cancer resection, an echocardiogram before a bypass, or a duplex carotid ultrasound before or after surgery) is a diagnostic radiology procedure that is not integral to another procedure and therefore is a radiology or other imaging service under section 1877(h)(6)(D) of the Act. In the case of services performed before or after a procedure, referring physicians have discretion in choosing the entity that provides the radiology service independent of the entity providing the

surgical service. Depending on the facts, referrals for these services to entities with which the referring physician has a financial relationship may be protected under the various exceptions to the statute.

In all cases, the definitional list of codes controls in determining whether a service falls within the scope of "radiology or certain other imaging services" for purposes of section 1877 of the Act.

Comment: Two commenters were opposed to our proposal to exclude "invasive" or "interventional" radiology procedures from the definition of radiology services. The commenters believe that these procedures should be included as DHS in order to safeguard against overutilization and ensure that appropriately trained physicians perform the services. One commenter argued that as a clinical matter, "invasive" or "interventional" radiology services rarely are performed in an office setting. Typically, interventional radiologists perform such procedures as angiography or angioplasty in a hospital because they involve significant and delicate work on a patient's cardiovascular system. Patients who undergo invasive procedures must then be monitored for a period of time in an appropriate medical setting. Consequently, that commenter, as well as another, objected to our statement in the preamble to the January 1998 proposed rule (63 FR 1676) that invasive procedures ordinarily are "merely incidental or secondary to another procedure that the physician has ordered." One of the commenters stated that the radiology services are neither incidental nor secondary, but a vital and integral part of the invasive procedure performed. The procedures are as much radiological as they are any other portion. One commenter stated that if invasive procedures occur in an office, they should be performed by a radiologist. The commenter believes that excluding invasive or interventional radiology procedures could result in certain referral arrangements by physicians that might pose some risk of patient or program abuse. One of the commenters noted that when interventional radiologists perform invasive radiology procedures, there is no risk of program or patient abuse. This is because interventional radiologists do not typically make referrals; they merely perform the invasive radiology procedures and return the patient to the care of the referring physician. The commenter believes, however, that physicians other than interventional radiologists may have an incentive to self-refer.

Response: We agree with the commenter that we were incorrect to characterize interventional radiology as "secondary" to many procedures, when it can in fact be a vital and integral part of the invasive procedure being performed. It is not the purpose of the physician self-referral law to discourage any physicians from furnishing their own services, such as interventional radiology, within their own practices, provided the physicians are functioning within the scope of their license to practice.

Comment: Many commenters asserted that all or particular invasive cardiology services should be excluded from the definition because they are not subject to program or patient abuse. Another commenter asked that we be consistent with regard to all forms of cardiac catheterizations and endoscopy procedures. The commenter stated that providers want to be able to perform all endoscopy services or cardiac catheterization services in the same setting and not have to limit their services.

Response: Cardiac catheterizations and endoscopy procedures are not included on the CPT code list that defines the scope of "radiology and certain other imaging services," because they do not involve imaging services that are covered under any of the categories in section 1877(h)(6)(D) of the Act. These services may still constitute DHS as inpatient or outpatient hospital services.

Comment: Two commenters noted that in the preamble to the January 1998 proposed rule (63 FR 1676), we stated that percutaneous transluminal angioplasty was an example of an invasive radiology procedure that we would exclude from the definition of radiology. The commenters stated that this procedure is not commonly considered to involve "invasive radiology."

Response: The commenters are correct in stating that percutaneous transluminal angioplasty is not fundamentally radiological in nature; it is predominantly a therapeutic intervention. Our wording in the examples for invasive radiology may have been confusing. We intended to convey that the imaging procedures associated with percutaneous transluminal angioplasty would be considered integral to the performance of the angioplasty. However, by using specific CPT codes to define the scope of services covered by section 1877(h)(6)(D) of the Act, we have now narrowed the definition of radiology services so that it does not include radiology that is integral to

interventional procedures, such as angioplasty.

Comment: One commenter supported our proposal to exclude screening mammography from the definition of DHS. The commenter believes that we should expand the exclusion to cover all DHS for which we have specified coverage or frequency limits. The commenter stated that screening tests by definition are not subject to overutilization.

Response: We agree with this commenter and have modified Phase I of this rulemaking to exclude from the reach of section 1877 of the Act certain legislatively mandated preventive screening and immunization services that are subject to HCFA-imposed frequency limits and are paid based on a fee schedule. The preventive services to which this exception applies are identified in Appendix A. We will add codes for new preventive screening tests and immunizations, as appropriate, through the annual updating of the attachment to this final rule.

Comment: One commenter recommended that all mammography be excluded from the definition of "radiology services." The commenter argued that generally diagnostic mammography procedures are performed only when a woman has clinical indications for a diagnostic mammogram. Thus, any risk of program or patient abuse is significantly reduced, if not eliminated. The commenter also mentioned that the quality-centered requirements of the Mammography Quality Standards Act of 1992 minimize the risk of potential overutilization of mammography services. Another commenter recommended the exclusion of "diagnostic" mammography services because he stated that it is necessary to perform the mammography on the same equipment for purposes of comparing the initial screening with the second diagnostic mammography. To prohibit patients from using the same facility adds an unnecessary element of potential error to the equation.

Response: Diagnostic mammography is clearly a radiological service under section 1877(h)(6)(D) of the Act, and it could be subject to abuse. It is our understanding that most women receive mammography from a radiologist who is requesting diagnostic radiology services. These physicians have not made a referral under section 1877(h)(5)(C) of the Act if they request diagnostic mammography as the result of a consultation requested by another physician. We are regarding this exception as applying to diagnostic mammography that results when a radiologist has first performed a

screening mammography as the result of a consultation, and then recommends follow-up diagnostic mammography, or begins his or her consultation with diagnostic mammography. (The physician who initiated the consultation with the radiologist has made a referral that could fall within the scope of the physician self-referral law if he or she has a financial relationship with the radiology facility.)

Comment: A commenter asked if stress tests are DHS. The commenter noted that some stress tests use nuclear medicine procedures.

Response: Stress tests are generally considered to be a physician service that does not involve radiology, and stress tests are not specifically listed in the law as DHS. Some stress tests use nuclear medicine procedures to create an image of the heart. Because these services are not included on the definitional CPT code list for radiology or other imaging services, they are not DHS.

Comment: One commenter stated that unless changed or clarified, the proposed regulations could inhibit the development and application of telemedicine technology to populations covered by the physician referral rules. Of specific concern was the area of ultrasound and a "unified" payment (that is, a combined payment for the technical and professional components of the service). The commenter asserted that Medicare and many State Medicaid programs provide a unified payment for ultrasound. The commenter described the problems of a unified payment with an example of a community physician performing the technical component of an ultrasound service and a distant tertiary hospital's physician performing the professional component. If the tertiary provider billed for the ultrasound service under a "unified" (that is, global) fee-for-service payment to cover the professional component of the ultrasound service, the tertiary facility logically should determine a payment for the technical component to pay the community physician who provides that service. However, since the community physician would be referring to the tertiary facility for the ultrasound study, such a payment could violate the physician referral regulations (that is, it would not fall within an exception).

At the time of the comment period for the January 1998 proposed rule, the commenter was aware that we were considering the publication of a separate proposed rule that would specify an appropriate "split" of global payments in the area of telemedicine; that is, it would specify separate payment

amounts for the technical and professional components of services. The commenter suggested that if we did issue those regulations, we should also recognize in the physician referral rules that payment by the tertiary provider to the referring community physician for providing the technical component of an ultrasound service performed via telemedicine should be exempted if it is under a HCFA-designated, or insurer-designated, allocation between the two aspects of an otherwise "global" payment.

Response: We believe that Phase I of this rulemaking addresses this issue satisfactorily. The basic principle of Phase I of this rulemaking is that any payment from an entity furnishing a designated health service to a referring physician must be at fair market value, not taking into account the volume or value of any referrals or other business generated by the referring physician (when this latter language is included in an exception). We are revising Phase I of this rulemaking to make clear that "per service" payments are allowed, even with respect to DHS ordered by the physician, provided the payment meets the fair market value standard. In the situation described by the commenter, the split is determined by the Medicare program based on its independent view of the value of the services provided. Of course, any split between a referring physician and another provider may also raise concerns under the Federal anti-kickback statute.

With respect to Medicare reimbursement for telehealth services, we published a proposed rule on June 22, 1998 (63 FR 33882) and final rule on November 2, 1998 (63 FR 58814) to implement section 4206 of the BBA 1997. Specifically, the November 1998 final rule permitted payment for professional consultations via interactive telecommunication systems in rural HPSAs and established separate payment amounts for the referring and consulting practitioners of a teleconsultation in a rural HPSA. As we noted in the preamble (63 FR 58883) to that November 1998 final rule, the rule specifies that the consulting practitioner must submit the claim for the consultation service and must share 25 percent of the total payment with the referring practitioner.

We clarified in the November 1998 telehealth final rule that these provisions only apply to teleconsultation services. Under Medicare, a teleconsultation is a consultation service delivered via telemedicine. These services are represented by CPT codes 99241 through 99275. Diagnostic ultrasound

(CPT code 76506) on the other hand, is a radiology service and would not fall within the purview of a teleconsultation under Medicare. Therefore, the payment methodology requiring the sharing of payment between the consulting and referring practitioners would not apply to diagnostic ultrasound services. In the case of diagnostic ultrasound, the physician providing the interpretation of the image typically would bill for the interpretation, while the technical component (that is, conducting the test) is billed by the practitioner or facility that captured the ultrasound image. Medicare has no national rule stating that the professional and technical components of a service, including ultrasound services, must be billed in a "global" manner. In fact, in the annual update to the physician fee schedule, separate codes for the professional component as well as the technical component of a service are listed, including the diagnostic ultrasound codes. Of course, in those cases in which there is no technical component, one code is used for Medicare payment and billing.

G. Radiation Therapy

Section 1877(h)(6)(E) of the Act includes radiation therapy services and supplies. In the January 1998 proposed rule, we combined radiation therapy with radiology in a single definition.

Because commenters found the combined definition to be confusing, we are amending the January 1998 proposed regulation so that radiology services and radiation therapy services are now separate categories (as in section 1877 of the Act itself). This change makes it clear that the two categories are actually very separate kinds of services. We are basing our definition of radiation therapy services and supplies on section 1861(s)(4) of the Act. This provision includes, as "medical and other health services" covered by Medicare, "x-ray, radium, and radioactive isotope therapy, including materials and services of technicians." However, we want to clarify that, for physician referral purposes, the list of codes that defines "radiation therapy services and supplies" in Phase I of this rulemaking does not include nuclear medicine services. While nuclear medicine involves the injection of radioactive isotopes directly into a patient's bloodstream, these services are not generally regarded as radiation therapy, they involve different equipment and procedures, and physicians who provide nuclear medicine have a separate certification. We have included in the attachment to this final rule a list

of codes that will define radiation therapy services and supplies. This list will be updated and reprinted in full annually as part of the physician fee schedule.

Comment: A commenter noted that because the January 1998 proposed regulations bundle radiology services and radiation therapy and supplies into a single category of DHS, the professional component of radiation therapy services has also been included within the definition of DHS. The commenter stated that some radiation oncologists would effectively be precluded from being paid on a productivity basis for their services, given that virtually all of the professional services that some physicians perform are radiation therapy services for Medicare patients. The commenter believes that the Congress did not intend this result.

Response: The law excludes from the definition of a "referral" any request by a radiation oncologist for radiation therapy if these services are furnished by (or under the supervision of) the radiation oncologist pursuant to a consultation requested by another physician. In addition, we are amending the definition of a "referral" to exclude any professional components personally performed by referring physicians themselves. Together, these provisions should largely address the commenter's concerns.

Comment: Several commenters recommended that we exclude prostate brachytherapy from the definition of radiation therapy. Prostate brachytherapy is the placement of radioactive sources into the prostate, through ultrasound guidance, for the purpose of treating prostate cancer. The commenters argued that this procedure should be excluded because it is performed once and is only performed on persons with a biopsy-proven diagnosis of prostate cancer. They advocated the use of physician ownership of brachytherapy facilities and equipment because it means that the urologists and radiation oncologists involved are actually performing the procedure themselves in a facility contracting with those physicians. The design of this model includes the supervision of every case by an experienced brachytherapist present in the operating room. According to the commenter, physician ownership of the equipment also ensures quality of physician education and of surgical technique.

The commenters asserted that we should allow multiple physicians to own brachytherapy equipment because centralized planning for radiation

physics results in all cases being planned in a controlled and uniform fashion. Uniformity eliminates many empirical physician decisions that in the past led to dosimetry errors. In addition, having two or more physicians owning the equipment encourages reporting of outcome data collection to a central agency, resulting in a continuous and rapid review of treatment results and complications. Commenters pointed out that experts have published restrictive dose guidelines for the various stages of prostate cancer treated with brachytherapy, so there is no risk of overutilization. Also, brachytherapy is less expensive and has a lower complication rate than the other forms of treatment (radical prostatectomy or external beam radiation therapy).

The commenters believe that because of all of these factors the procedure has little potential for program or patient abuse and should be exempt from the physician self-referral prohibition.

Response: We are aware of no logical or empirical evidence that physician ownership improves quality of services or physicians' skills. On the other hand, brachytherapy is one of several therapy options for certain prostate conditions. We believe that ownership of a brachytherapy center by urologists could well influence their recommended therapy and, therefore, affect utilization. In short, the relationship is exactly the type of financial relationship section 1877 of the Act is intended to address. The law excludes from the definition of a "referral" any request by a radiation oncologist for radiation therapy if these services are furnished by (or under the supervision of) the radiation oncologist pursuant to a consultation requested by another physician. In addition, we have amended the definition of a "referral" to exclude any professional components performed by referring physicians themselves.

H. Durable Medical Equipment (DME)

In § 411.351 of the January 1998 proposed rule, we defined DME as having the meaning given in section 1861(n) of the Act and § 414.202 (Definitions). In the preamble to the January 1998 proposed rule (63 FR 1677 through 1678), we offered explanations of the terms and a list of the general DME categories. However, we stated in the preamble (63 FR 1677) that because the number of items considered to be DME was so extensive, we could not in the proposed rule identify all of them. Commenters were concerned about our failure to articulate a "bright-line" definition of DME. The commenters

stated that if we could not do that, physicians would have to assume that the dispensing of all DME falls under the referral prohibition.

The most frequent complaint was the difficulty the commenters had in determining whether a given item was DME or a prosthetic, prosthetic device or orthotic. (The distinction is significant since under section 1877(b)(2) of the Act prosthetics, prosthetic devices, and orthotics may be provided to a patient by a physician under the in-office ancillary services exception, while DME (other than infusion pumps) cannot.) The easiest way to determine the proper classification of an item is to consult the Durable Medical Equipment, Prosthetics/Orthotics, and Supplies (DMEPOS) fee schedule, which is updated quarterly and available on the internet under HCFA's public use files (www.hcfa.gov/stats/pufiles.htm). Under the DMEPOS fee schedule, items are identified by their HCPCS code and also include a category designation that identifies whether the item is DME, prosthetics, orthotics, or prosthetic devices. DME items include the following categories:

CR, capped rental DME.

FS, DME requiring frequent and substantial servicing.

IN, inexpensive or routinely purchased DME.

OX, oxygen and oxygen equipment.

SU, DME supplies.

TE, transcutaneous electrical (or electronic) nerve stimulator.

Additionally, DME includes the HCPCS code E1399. This code covers a number of miscellaneous DME items, but does not appear on HCFA's national fee schedule. Each DMERC (regional DME carrier) is responsible for creating a fee schedule for individual items that are not included on HCFA's fee schedule.

We note that Phase I of this rulemaking does not change existing definitions for DME, prosthetics, prosthetic devices, or orthotics. Thus, the existing classification of an item (that is, its classification as either DME, prosthetic, prosthetic device, or orthotic) will remain the same.

In sum, if, after reviewing the definitions and accompanying explanations that we provided in the January 1998 proposed rule, as well as the DMEPOS fee schedule and the HCPCS codes covering miscellaneous items, physicians and their staffs still have questions about whether a specific item is considered to be DME, we would suggest that they contact their local carrier or DMERC for clarification.

Comment: One commenter asked for clarification on whether prosthetic and orthotic devices that seem to meet the criteria for DME are considered DME supplies and whether they could be provided under the in-office ancillary services exception. The commenter expressed some confusion regarding whether crutches are DME or a prosthetic or orthotic device.

Response: The categories of prosthetics, orthotics, prosthetic devices or DME are mutually exclusive; no item can fall into more than one of these categories. If individuals are concerned about a particular type of equipment or a supply, we would suggest that they review the HCPCS codes or DMEPOS fee schedule or contact their local carrier or DMERC for clarification. Again, we note that DMERCs process more than DME claims. They also are responsible for claims for other types of devices and supplies. Crutches are DME.

Comment: A commenter recommended that we exempt crutches from the definition of DME. The commenter suggested that crutches are provided as peripheral parts of a major service (that is, a diagnosis of a broken leg) and that it is unlikely a physician would over-prescribe crutches for a diagnosis of a broken leg just so that the physician can bill for the crutches. The commenter believes that having the physician provide the crutches and instruct the patient on how to use them helps to prevent further damage to the patient and is essential to good patient care.

Response: We believe that crutches are clearly DME and therefore DHS under section 1877(h)(6)(F) of the Act. As we stated in the January 1998 proposed rule, although we cannot justify excluding crutches as a designated health service, we recognize that including crutches could greatly inconvenience patients if physicians were barred from providing them to patients who need them to ambulate following treatment for an injury or an incapacitating procedure. For this reason, we proposed expanding the in-office ancillary services exception to cover crutches when furnished in a manner that meets the in-office ancillary services exception requirements and in which the physician realizes no direct or indirect profit from furnishing the crutches. We have adopted the proposal in an expanded and modified form—without the proposed profit restriction—as described in section VI.B.1 of this preamble.

Comment: Several commenters opposed the inclusion of DME as a designated health service and argued

that the inclusion of DME will result in additional delays in treatment and barriers to access for the nation's poor and elderly populations. Two of the commenters urged us to support a legislative change to remove DME from the DHS list, while others urged us to revise the January 1998 proposed rule to remove DME entirely as a designated health service. Those commenters argued that when DME is furnished as an in-office service, it has not been associated with program abuse and offers little or no opportunity for overutilization. One of the commenters contended that an unintended effect of the inclusion of DME on the DHS list would be underutilization, because physicians would be prohibited from furnishing DME in their offices.

Response: We believe that we cannot create a separate exception for DME because we cannot guarantee that such an exception would always be free from program or patient abuse. The Congress explicitly included DME as a designated health service in section 1877(h)(6)(F) of the Act; we have no authority to vitiate that judgment. We note that physicians would only be prohibited from furnishing DME services when they have an unexcepted financial relationship with the DME supplier. Moreover, although we are not removing DME from the list of DHS, we are substantially revising the manner in which the in-office ancillary services exception applies to DME. These changes will expand the provision of DME under the in-office ancillary services exception as detailed in section VI.B.1 of this preamble.

I. Parenteral and Enteral Nutrients, Equipment and Supplies

Section 1877(h)(6)(G) of the Act includes as DHS the category of parenteral and enteral nutrients, equipment, and supplies (PEN). Enteral and parenteral therapy as a Medicare Part B benefit is provided under the prosthetic device benefit provision in section 1861(s)(8) of the Act. The regulations cover prosthetic devices in § 410.36 (Medical suppliers, appliances, and devices: Scope), paragraph (a)(2). Details for enteral and parenteral therapy are set forth in section 65–10, “Enteral and Parenteral Nutritional Therapy Covered as Prosthetic Device,” of the Medicare Coverage Issues Manual (HCFA Pub. 6). When the coverage requirements for enteral or parenteral nutritional therapy are met, Medicare also covers related supplies, equipment, and nutrients.

We proposed in § 411.351 of the January 1998 rule to define “enteral nutrients, equipment, and supplies” as

items and supplies needed to provide enteral nutrition to a patient with a functioning gastrointestinal tract who, due to pathology to or nonfunction of the structures that normally permit food to reach the digestive tract, cannot maintain weight and strength commensurate with his or her general condition. (See section 65–10, “Enteral and Parenteral Nutritional Therapy Covered as Prosthetic Device,” of the Medicare Coverage Issues Manual (HCFA Pub. 6) for additional information.)

We proposed in § 411.351 to define “parenteral nutrients, equipment, and supplies” as items and supplies needed to provide nutriment to a patient with permanent, severe pathology of the alimentary tract that does not allow absorption of sufficient nutrients to maintain strength commensurate with the patient’s general condition, as described in section 65–10, “Enteral and Parenteral Nutritional Therapy Covered as Prosthetic Device,” of the Medicare Coverage Issues Manual (HCFA Pub. 6).

We are clarifying in Phase I of this rulemaking that this category includes all HCPCS level 2 codes for these services. We believe this list will address any uncertainties that physicians and providers might have about what constitutes PEN, and is consistent with our definition in the proposed rule.

We also pointed out in the preamble to the January 1998 proposed rule that, like DME, section 1877(b)(2) of the Act specifically excludes PEN as services that can qualify for the in-office ancillary services exception.

Comment: A physician representing himself and an infusion therapy association asserted that physicians should be allowed to prescribe, provide, and be reimbursed for parenteral nutrition for their own patients as an extension of their practices. The commenter asserted that there has been no evidence of abuse, while there have been major problems with fraud and abuse and excessive profits by nonphysician home infusion providers, which function essentially without physician control and minimal input from physicians. The commenter believes that because patients with increasingly complex medical problems are sent home earlier from the hospital, the role of the physician office-based model is increasingly important. The January 1998 proposed referral regulations, the payment schedule for medications, and the restriction on physician reimbursement for ambulatory infusion pumps all discourage a physician’s involvement in these services.

Response: Section 1877 of the Act does not prohibit physicians from prescribing enteral and parenteral nutrition for their own patients; nor does it prohibit infusion companies from contracting with expert or knowledgeable physicians for consulting services provided the remuneration is fair market value and does not take into account referrals or other business between the parties. Section 1877 of the Act does, however, prohibit a physician from furnishing enteral and parenteral nutrition in his or her own office and billing for it unless the physician’s arrangement qualifies for an exception, such as the rural provider exception in section 1877(d)(2) of the Act. The Congress specifically excluded the provision of enteral and parenteral nutrition and durable medical equipment (DME, other than infusion pumps) from the in-office ancillary services exception in section 1877(b)(2) of the Act.

We have the authority to create additional exceptions to the referral prohibition for financial relationships under section 1877(b)(4) of the Act, but only if we determine that there is no risk of program or patient abuse. However, we believe that physicians could potentially over-prescribe parenteral nutrition if they have the financial incentive to do so.

We only cover parenteral nutrition when there is a permanent need (except when covered under the home health benefit). (See the Medicare Coverage Issues Manual (HCFA Pub. 6), section 65–10, “Enteral and Parenteral Nutritional Therapy Covered as Prosthetic Device,” for additional information. Because coverage of nutritional therapy as a Part B benefit is provided under the prosthetic device benefit provision, the patient must have a permanently inoperative internal body organ or function.) We see no reason why a patient should have to go to a physician’s office regularly to receive parenteral nutrition. Medicare already covers parenteral nutrition delivered in the home through the home health benefit or the prosthetic device benefit. Because enteral nutrition is widely available through grocery stores, drug stores, and other retail outlets, we see no reason why a patient must purchase enteral nutrition from a physician. A patient can purchase certain more specialized types of enteral nutrition that are not widely available from a DME supplier.

If a patient is to receive nutrition via an infusion pump, the in-office ancillary services exception cannot be used for the furnishing of the pump, since this exception only allows physicians’

offices to furnish infusion pumps that are DME. See section VI.B.1 of this preamble for more details about infusion pumps. (To furnish an infusion pump that is DME for use in the home, a physician would have to meet all of the supplier requirements in § 424.57.)

As for the commenter’s concerns about the payment schedule for medications, that issue is not addressed by the physician referral regulation.

J. Prosthetics, Orthotics, and Prosthetic Devices and Supplies

Prosthetics, orthotics, and prosthetic devices and supplies are included as DHS under section 1877(h)(6)(H) of the Act. We proposed in the January 1998 rule to define “prosthetics” at § 411.351 as artificial legs, arms, and eyes, as described in section 1861(s)(9) of the Act. We defined “orthotics” as leg, arm, back, and neck braces, as listed in section 1861(s)(9) of the Act. We proposed to define a “prosthetic device” as a device (other than a dental device) listed in section 1861(s)(8) of the Act that replaces all or part of an internal body organ, including colostomy bags and including one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens, as well as services necessary to design the device, select materials and components, measure, fit, and align the device, and instruct patients in its proper usage. We proposed defining “prosthetic supplies” as “supplies that are necessary for the effective use of a prosthetic device (including supplies directly related to colostomy care).”

We are clarifying in Phase I of this rulemaking that this category includes all HCPCS level 2 codes for these services that are covered under Medicare. Physicians and other persons can readily determine the classification of an item by consulting the DMEPOS fee schedule. However, as with DME, there are several specific HCPCS codes representing miscellaneous items classified as prosthetics, orthotics, or prosthetic devices that do not appear in the fee schedule.

We explained in the preamble of the January 1998 proposed rule (63 FR 1678) that Medicare regards intraocular lenses (IOLs) used as part of cataract surgery as prosthetic devices. We also stated in the preamble that if these lenses are implanted in an ASC, they would be covered under the ASC payment rate and would have been excluded under the exception we proposed to create in § 411.355(d). As explained above, we are no longer considering DHS that are included in a bundled ASC payment to be DHS.

Accordingly, when an IOL is included in an ASC bundled payment rate, it will not be considered to be a designated health service.

We are also addressing a number of commenters' requests by creating exceptions (through our authority under section 1877(b)(4) of the Act) for prosthetic devices that are implanted in a Medicare-certified ASC and for eyeglasses or contact lenses that are prescribed after cataract surgery. We explain our reasons for these exceptions in our responses to specific comments.

Comment: One commenter asserted that the final rule should allow physicians to provide durable medical equipment, orthotics, and prosthetics directly to patients when they are medically necessary. Physicians currently supply splints, braces, or other devices directly to patients who have injuries, thereby ensuring that the patient gets the appropriate device, that the item is properly fitted, and that the patient is properly instructed in its use. To require a patient with an injury to leave the office, go to a DME supplier, purchase the necessary equipment, and return to the physician's office for fitting or placement and instructions on use, would be unwise, inconvenient, and could frequently cause unnecessary pain or further injury.

Response: The splints, casts, and other devices used to treat fractures and dislocations the commenter mentions are covered under section 1861(s)(5) of the Act, a benefit category that is different from the benefit categories that include DME, prosthetics, orthotics, and prosthetic devices. They are therefore not DHS under section 1877(h)(6) of the Act. Leg, arm, back, and neck braces are considered to be "orthotics" and are thus included as DHS. These can be provided by a physician within his or her own practice under the in-office ancillary services exception in section 1877(b)(2) of the Act, which excepts a physician's referral if the services meet certain supervision, location, and billing requirements. This exception could apply to referrals for any prosthetics, orthotics, or prosthetic devices. As modified by these regulations, the in-office ancillary exception could also apply to referrals for certain DME services. (See section VI.B.1 of this preamble.)

Comment: A number of commenters favored our proposal to exclude IOLs implanted during cataract surgery performed in an ASC because the IOLs are included in the ASC payment rate. The commenters asserted that a substantial number of ASCs are owned by the physicians who perform surgical procedures in them and that these

physicians are not members of one group practice. The commenters see the ASCs as an extension of the physician's own office and believe they provide a high quality, low cost setting for outpatient surgery.

Commenters requested that we exempt from the physician self-referral prohibition other prosthetic devices implanted in conjunction with surgical procedures because the provision of the prosthetic devices is incidental to the provision of ASC facility services, which are exempt from the physician self-referral prohibition. The commenter asserted that, as we noted in the January 1998 proposed rule, a physician would not unnecessarily subject patients to a surgical procedure to profit from the implant. In addition, there is no risk of program abuse because the Medicare payment for prosthetic devices implanted in conjunction with ASC facility services is limited to the lower of the actual charge for the device or a fee schedule amount. Commenters emphasized that the use of implanted prosthetic devices in reconstructive surgery is immensely beneficial to patients.

Response: We agree with the commenters that all prosthetic devices implanted in a Medicare-certified ASC by the referring physician or a member of the referring physician's group practice should be excluded. We have chosen this position because, if surgeons refer to an ASC in which they have an ownership interest, there will, in many cases, be no exception that would apply to their financial relationship with the ASC. Implanted prosthetic devices, implanted prosthetics, and implanted DME are not included in the bundled ASC payment rate and thus would retain their character as DHS even when implanted in an ASC. As a practical matter, the absence of an exception for all of these items implanted in ASCs is likely to result in these procedures moving to more costly hospital outpatient settings. We believe that the exclusion of these implants from the reach of section 1877 of the Act (using our authority under section 1877(b)(4)) will not increase the risk of overutilization beyond what is already presented by the surgeon's Part B physician fee and is consistent with the Congress's decision not to include ambulatory surgical services as a specific designated health service. We are specifically providing that the exception does not protect items implanted in other settings. Nor does it protect arrangements between physicians and manufacturers or distributors of implants where the manufacturers or distributors furnish

DHS, for example, through subsidiaries or affiliates. We are providing that the arrangement for the provision of the implant in the ASC may not violate the anti-kickback statute and all billing and claims submission must be proper.

Comment: Some commenters recommended that we exclude some or all implants to assure that there is no chilling of the ability and opportunity of Medicare patients to obtain the most appropriate and up to date technology that will be both effective and cost efficient. In addition, commenters pointed out that invasive surgery always entails a risk to the patient and is not undertaken without a physician seriously evaluating that risk in relation to the therapeutic or diagnostic benefit likely to be brought by the device to be implanted and determining what specialized model and brand of device will be most effective. Commenters believe that including implants in the definition of prosthetic devices will have the counterproductive effect of preventing surgeons from participating in research and development of these products, thereby curtailing research activity and blunting future development. This chilling effect would dramatically affect the quality of patient life and severely limit progress in reducing the cost to patients.

Response: Surgeons should be able to provide implants to their patients in any appropriate setting by meeting exceptions to the physician self-referral law. As we described in responses to earlier comments, we are creating an exception for implants that are performed in Medicare-certified ASCs. As to implants in other settings or those in ASCs that do not meet the new exception, other exceptions may still apply. Physicians who perform implants within their own practices may be able to use the in-office ancillary services exception in section 1877(b)(2) of the Act, which is discussed in section VI.B.1 of this preamble. If a physician performs the surgery in a hospital, and the hospital bills for the implant, the service would be a designated hospital service, regardless of whether the implant is a prosthetic or prosthetic device. In these cases, any financial relationship between the physician and the hospital would have to fit in an exception or the physician could not perform the surgery, much less the implant, since all hospital services are DHS. There are several exceptions that apply to referrals for hospital services.

The commenters seem to be under the misapprehension that section 1877 of the Act would prevent financial relationships between the manufacturer of an implant and a physician. These

financial relationships would not be subject to section 1877 of the Act unless the manufacturer were an entity that bills Medicare directly. However, arrangements between physicians and manufacturers may be problematic under other legal authorities, including, for example, the Federal anti-kickback statute.

Comment: One commenter believes that we should not interpret the definition of prosthetics, orthotics, and prosthetic devices and supplies for physician referral purposes to include hip and knee implants. The commenter believes that hip and knee implants do not fall within the definitions of prosthetics, orthotics, and prosthetic devices and supplies that we included in the January 1998 proposed rule. The commenter pointed out that "prosthetics" is defined as artificial legs, arms, and eyes, that "orthotics" is defined as leg, arm, back and neck braces, and "prosthetic devices" is defined as devices that replace all or part of an internal body organ. The commenter believes that hip and knee replacements do not fall under any of these categories.

The commenter further stated that, if hip and knee implants are somehow considered as prosthetic devices under Medicare, they should be excluded from the referral prohibition on the basis that they are only a component of a primary surgical procedure meant to repair damaged or painful joints. The commenter believes physicians will not ask patients to undergo painful and debilitating surgery for the sake of implanting an unnecessary artificial knee or hip implant. Also, if these items are billed as part of the hospital diagnosis-related group (DRG) payment for a surgical procedure, there is no financial incentive to use more costly or unnecessary implants and there is no increased cost to the program if one implant is chosen over another.

Response: Knee implants are considered to be "prosthetics." They are components of the artificial legs that are identified as prosthetics under section 1861(s)(9) of the Act. Artificial hips are only furnished to hospital inpatients under Medicare Part A, so we consider them to be a component of an inpatient hospital service. If a physician sends a patient to a hospital for a hip or knee implant or the insertion of a prosthetic device, all the services billed by the hospital would qualify as DHS under section 1877(h)(6)(K) of the Act because they are "inpatient or outpatient hospital services." The implants would therefore be subject to the physician self-referral law, even if we excluded them from the separate category of

"prosthetics, orthotics, or prosthetic devices and supplies."

Comment: A commenter asserted that we should exclude cochlear implants from the definition of prosthetic devices. In the January 1998 proposed rule, we had indicated our concern that a physician would choose a particular device because he or she had supplied it to the ASC where the patient's implant surgery was performed or because the physician receives money from a supplier for ordering the particular device. The commenter stated that the professional association he represents is unaware of any abuses in this area and, if there were abuses, they would be subject to the anti-kickback law.

Another commenter from an association of audiologists agreed with us that cochlear implants are a type of prosthetic device that is properly within the scope of the proposed rule. The commenter regards a cochlear implant as clearly being a prosthetic device because it replaces all or part of an internal body organ. A cochlear implant is an electronic device specifically designed to replace the function of a damaged cochlea.

Response: We agree with the second commenter that cochlear implants are covered as prosthetic devices under Medicare and are categorized as such in the CPT codes in the attachment to this final rule. As noted above, we are excepting all implants performed in a Medicare-certified ASC by the referring physician or a member of the referring physician's group practice, subject to certain conditions set forth in the exception.

Comment: A commenter noted that in the January 1998 proposed rule we stated that a prosthetic device includes services necessary to design the device, select materials and components, measure, fit, and align the device, and instruct patients in its proper usage. The commenter requested that we expressly clarify that certain services provided to patients after a cochlear implant are subject to the physician self-referral provisions. These services include device mapping, aural rehabilitation programs for adults to enable them to learn to use the device, and aural habilitation programs for children to maximize speech and language development.

The commenter asserted that these postsurgical services are provided by audiologists without physician involvement or supervision of any kind. In addition, the commenter stated that cochlear rehabilitation services are not included in the global fee for cochlear implantation surgery. Instead, these

services are billed under a unique CPT code, 92510.

Response: The Medicare definition of a prosthetic device ordinarily includes the services necessary to design the device, select materials and components, measure, fit, and align the device, and instruct patients in its proper usage. In fact, the costs of delivery, fitting, measuring and instructing the patient are bundled into the fee schedule payment amount for not only prosthetic devices, but for DME, orthotics, and prosthetics as well. However, cochlear implants are somewhat unique. Because it can be particularly difficult for a patient to learn to use the implant, cochlear rehabilitation services are categorized separately as speech-language pathology services. These services are billed under CPT code 92510 (which is included as a PT service because it is a speech-language pathology service). Therefore, all of these services qualify as "designated health services," but under different categories.

Comment: A commenter pointed out that items such as rib belts, slings, and basic braces (those not custom-fitted) are in the prosthetic/orthotic section of the HCPCS. The commenter asked whether these items would be considered orthotics or DME, since the patient would be wearing the item home. The commenter believes that, in either case, it would be inappropriate to prevent a physician from supplying and billing for these items when the patient has come to the office with an injury. The commenter asserted that requiring a patient to leave the physician's office to purchase necessary equipment is inconvenient and unwise because it may result in unnecessary pain or injury to the patient.

Response: The items described as "rib belts" and "slings" are not included in any DHS category. The items described as "basic braces" are orthotics. Nothing in Phase I of this rulemaking moves any item or device from one coverage category to another coverage category. If the items qualify as in-office ancillary services under section 1877(b)(2) of the Act, a physician who supplies them in his or her office in the course of seeing a patient should be able to use the in-office ancillary services exception in order to provide them to the patient, even if the patient takes the items home. We regard the physician as "furnishing" an item in his or her office if the physician dispenses the item to the patient there.

Comment: Several commenters urged us to exclude eyeglasses and contact lenses from the definition of prosthetic devices. Commenters noted that there is

no incentive to overutilize or abuse this benefit because we acknowledge that one pair of conventional eyeglasses or contact lenses is medically necessary after cataract surgery; Medicare coverage is limited to one pair of conventional eyeglasses or contact lenses; and Medicare payment is on a reasonable charge basis.

Response: We agree with the commenters that eyeglasses and contact lenses should be excluded from the reach of section 1877 of the Act for purposes of Medicare referrals. The Medicare coverage of these items is unique in that it is limited to one pair of either item after each cataract surgery and is available to any patient who has had this surgery. In that respect, the coverage is similar to the coverage of preventive screening services that are subject to frequency limits, as discussed earlier in this section. In addition, the Medicare-approved amount of payment does not vary based on the expense of a particular pair of glasses or contact lenses. Medicare pays fixed amounts for eyeglasses and contact lenses that are single focal, and fixed amounts for eyeglasses and contact lenses that are bifocal. In sum, we see little opportunity or incentive for a physician to either under or overutilize these items in the Medicare program. Accordingly, we are creating a new exception under the authority in section 1877(b)(4) of the Act for eyeglasses and contact lenses after cataract surgery. Like other section 1877(b)(4) exceptions, the new exception is subject to there being no violation of the anti-kickback statute or any billing or claims submission law or regulation.

K. Home Health Services

In the January 1998 proposed rule, we proposed to define home health services as the services described in section 1861(m) of the Act and part 409, subpart E. We included in the preamble to that rule (63 FR 1679), a discussion of how we proposed to reconcile section 1877 of the Act and the physician certification requirements for home health services in § 424.22 (Requirements for home health services), paragraph (d) (Limitations on the performance of certification and plan of treatment functions). In that discussion, we explained that the home health agency (HHA) rule and its exceptions have been superseded by section 1877 of the Act. Phase I of this rulemaking reflects this change. Our responses to comments mostly serve to clarify how the modified home health rule will work.

Comment: Four commenters supported our proposal to reconcile the

physician self-referral law with the physician certification requirements for home health services contained in § 424.22(d). One commenter specifically expressed agreement with our proposed position that the exceptions to the physician self-referral law would also apply to physician certification requirements for home health services. Another commenter specifically supported the proposed changes that would eliminate the 5 percent ownership and \$25,000 financial or contractual relationship limits and replace them with the prohibition on self-referral contained in section 1877 of the Act. The commenter stated that this change would allow HHAs to provide for medical oversight by a salaried physician as permitted under the Medicare hospice benefit. (We believe that commenter meant that the proposed elimination of the \$25,000 financial or contractual relationship provision would allow an HHA to pay a physician medical director more than \$25,000 as long as the HHA meets relevant ownership and compensation exceptions described in the proposed rule.) Another commenter asked that we clarify whether the current \$25,000 limit on financial or contractual relationships as it relates to medical directors of home care agencies will be removed.

Response: We are removing the current 5 percent ownership limit and the \$25,000 limit on financial or contractual relationships from § 424.22(d). The new § 424.22(d) appears exactly as we proposed it: "The need for home health services to be provided by an HHA may not be certified or recertified, and a plan of treatment may not be established and reviewed, by any physician who has a financial relationship, as defined in § 411.351 of this chapter, 'Definitions,' with that HHA, unless the physician's relationship meets one of the exceptions in §§ 411.355 through 411.357 of this chapter * * *." The elimination of the \$25,000 financial or contractual relationship provision will allow an HHA to pay a physician medical director more than \$25,000 as long as the financial relationship meets a relevant ownership or compensation exception under section 1877 of the Act.

Although we are delaying the effective date for most of Phase I of this rulemaking for 1 year, we are making the change in § 424.22(d) effective February 5, 2001. Having weighed the alternatives, we believe an effective date of February 5, 2001 for the revision of § 424.22(d) is desirable, even though the revisions to §§ 411.355 and 411.357 will not be effective until later. In the

interim, the references to §§ 411.355 and 411.357 will cross-refer to the statutory exceptions set forth in section 1877 of the Act. It is our view that during the interim period, the exceptions set forth in those sections would apply under § 424.22(d) for services other than laboratory services.

Comment: One commenter requested that we retain the provisions in § 424.22(e) (Exceptions to limitations), (f) (Procedures for classification as a sole community HHA) and (g) (Basis for classification as a sole community HHA) that except governmental entities and sole community HHAs from the prohibition on certification of need for home health services by related physicians. The commenter noted that keeping this language would remove the threat of unfair competition for agencies that have historically been the sole providers in their communities. The commenter explained that the "rural provider" exception to the physician self-referral law would permit an urban physician to establish a new HHA in a rural area, as long as the agency's service population is at least 75 percent rural. This would create new and unfair competition for many rural agencies that are small, nonprofit organizations.

Response: We realize that eliminating the exceptions for governmental entities and sole community HHAs in combination with the ownership exception for rural providers under the physician self-referral law may create new competition for small, nonprofit HHAs. Nonetheless, we believe that we do not have the legal authority to retain these exceptions in any meaningful way. As we pointed out in the preamble to the January 1998 proposed rule (63 FR 1680), even if a physician and an HHA are involved in an arrangement that meets one of the home health exceptions at issue, the arrangement simultaneously remains subject to the requirements in section 1877 of the Act. That is, if an exception under the HHA certification regulations is subsumed within the exceptions in section 1877 of the Act, a physician will be able to refer; if it is not, the arrangement will disqualify the physician from referring in spite of § 424.22. Thus, the HHA exceptions have been superseded by section 1877 of the Act.

The Secretary does have the authority to create additional exceptions to the referral prohibition under section 1877(b)(4) of the Act, but only in situations in which she determines that there is no risk of program or patient abuse. We believe that the fact that an entity is run by the government or is a sole community HHA does not guarantee that there will be no

unnecessary referrals. In addition, it is our view that we should treat all providers equally and allow them an equal opportunity to compete, particularly in areas where there have historically been too few providers. In fact, the purpose of the "rural provider" exception in section 1877(d)(2) of the Act is to encourage physicians to invest in or remain invested in under-served areas. (Note that hospitals do not have similar exceptions for governmental entities or sole community hospitals.) Therefore, we do not intend to include the exceptions for governmental entities and sole community providers in the revised HHA certification regulations because we believe that our proposed approach provides the best protection against possible program abuse and fulfills the intent of the law.

Comment: A commenter representing home care physicians asked that we clarify whether physicians making home visits are providing services that qualify as DHS under the January 1998 proposed regulations.

Response: Under the Medicare program, when a physician performs a physician service, including a visit to a home health patient, the physician service is billed as a physician service and is not considered a home health service. This is the case even when the physician has an employment contract with the HHA, such as when a physician is employed as a medical director. Thus, the commenter is correct in noting that physician home visits are not themselves on the list of DHS in section 1877(h)(6) of the Act, and would only qualify as such if the physician was actually performing a specific designated health service (for example, performing physical therapy). In these cases, the service would still be protected if it is personally performed by the referring physician, since it would not be considered a referral under the final rule. (See section III.B of this preamble.) In addition, some in-home services provided by a home care physician may qualify under the in-office ancillary services exception. (See section VI.B of this preamble.)

L. Outpatient Prescription Drugs

Section 1877(h)(6)(j) of the Act provides that "designated health services" includes the category of "outpatient prescription drugs," but does not define this term. Because Medicare does not cover a category of services called "outpatient prescription drugs," we proposed to define this term in the regulation. We proposed to include only drugs (including biologicals) defined or listed under section 1861 (s) and (t) of the Act, and

in part 410, furnished under the Medicare Part B benefit that patients can obtain from a pharmacy with a prescription, even if patients can only receive the drug under medical supervision. In the preamble to the January 1998 proposed regulation (63 FR 1680), we included as an example oncology drugs that are routinely furnished in a physician's office, under the physician's direct supervision, provided the drugs could be obtained by prescription from a pharmacy.

We proposed specifically to exclude from the definition of "outpatient prescription drugs" erythropoietin (EPO) and other drugs furnished as part of a dialysis treatment for an individual who dialyzes at home or in a facility.

Upon further review of the law, existing regulations, and the public comments, we have concluded that our proposed definition of "outpatient prescription drugs" was not clear enough. In Phase I of this rulemaking, we are revising the definition of outpatient prescription drugs to make clear that it includes all prescription drugs covered by Medicare Part B. We are not excluding any outpatient prescription drugs from the DHS category of "outpatient prescription drugs." Including all outpatient prescription drugs is consistent with our policy throughout these final regulations of avoiding carving services out of DHS definitions through service-by-service analyses of the potential for fraud and abuse. Our definition of outpatient prescription drugs provides physicians and DHS entities with a "bright line," common sense rule. Moreover, the breadth of the definition is ameliorated to a very large extent by our expansion of the exception for in-office ancillary services, which includes much greater flexibility with respect to the direct supervision requirement, and our promulgation of a new limited exception under section 1877(b)(4) of the Act for the provision of EPO and certain other dialysis-related drugs by or in ESRD facilities (described in greater detail below). Those changes, together with the changes in the definition of "group practice" and "referral," should permit a physician to furnish patients with covered drugs, either by administering or dispensing the drugs to patients in his or her office or, in the case of EPO and other specific dialysis drugs, by furnishing the drugs in or through a physician-owned ESRD facility. We wish to make clear that nothing in this regulation affects, or is intended to affect, current or future coverage of any particular prescription drug.

We are creating an exception for EPO and certain other specific drugs that are required for the efficacy of dialysis when they are furnished by an ESRD facility with which the referring physician has a financial arrangement. We are similarly excepting certain vaccinations, immunizations, and preventive screening tests that are subject to HCFA-imposed frequency limits. We are also clarifying that physicians who provide drugs in their own offices are not required to pass on to Medicare discounts they receive in purchasing these drugs, unless otherwise required to do so by the Medicare program. These issues are discussed in detail below.

Comment: A number of commenters raised the issue of whether drugs and biologicals provided incident to physician services are included in the definition of outpatient prescription drugs. The commenters pointed out that most drugs and biologicals are covered under Medicare Part B only if they require administration by a physician, and thus typically are covered in the physician office setting only if furnished as "incident to" physician services. Thus, the resulting "self referral" is effectively a requirement for Medicare coverage. In the commenters' view, excluding drugs furnished incident to physician services from the definition of "outpatient prescription drugs" would ensure that the physician self-referral law does not discourage the types of "referrals" that are prerequisites to Medicare coverage.

One commenter asserted that drugs that are covered under Medicare only as a component of a physician service should be excluded because physician services were never intended to be included within the referral prohibition. Another commenter recommended that we make all injectable drugs exempt from the referral prohibition under the in-office ancillary services exception.

Several commenters were particularly concerned about antigens and serums that a patient receives in a physician's office, stating that they should be excluded from the category of outpatient prescription drugs, along with chemotherapy. Another commenter pointed out that if our definition of outpatient prescription drugs includes drugs administered during a patient's office visit, patients could have serious access problems to such drugs as antibiotics, renal therapy, and vaccines. Another commenter recommended that we limit outpatient prescription drugs to those that are self-administered, such as oral cancer drugs, oral antiemetics, and immunosuppressives, for which there is Medicare coverage that does not

depend on administration in a physician's office.

Response: We believe the commenters are conflating two issues: (1) What drugs fit in the term "outpatient prescription drugs" in section 1877(h)(6)(J) of the Act and (2) the scope of the in-office ancillary services exception in section 1877(b)(2) of the Act. Upon review, for purposes of defining "outpatient prescription drugs" under section 1877(h)(6)(J) of the Act, we can ascertain no meaningful distinction between prescription drugs dispensed by pharmacies or those mixed and administered in a physician's office. To the extent the latter is permitted, it is through the vehicle of the in-office ancillary services exception. The scope of that exception is discussed in section VI.B.1 of this preamble.

Comment: Many commenters stated that oncology drugs administered to patients by injection or infusion in a physician's office should be excluded from the definition of outpatient drugs because a patient essentially cannot obtain these drugs from a pharmacy before visiting his or her physician. When a patient comes to a physician's office for chemotherapy, the patient receives a series of blood tests to determine the patient's physiological state. Based on these tests, the chemotherapy agents are mixed and tailored by the oncologist's staff to address the patient's current health status. Therefore, a patient cannot pick up from a pharmacy the medication he or she needs before visiting the physician. We may have misunderstood how chemotherapy drugs are actually administered.

In addition, the commenters pointed out that a great majority of retail pharmacies are not currently prepared to provide chemotherapeutic mixing and dispensing services for infusion drugs. That is because Federal regulations and accepted standards of practice for physicians, oncology nurses, technicians, and pharmacists require that the preparation, storage, transportation, and disposal of chemotherapy drugs and applicable supportive agents be conducted under the most rigorously controlled circumstances.

Response: We agree that chemotherapy agents are not commonly available from retail pharmacies, but are prepared for individual patients. However, these drugs are outpatient prescription drugs; they are available only upon a physician's order and are provided in an outpatient setting. (When provided in an inpatient setting, they would be inpatient hospital services under section 1877(h)(6)(K) of

the Act.) We believe these drugs are usually administered in oncologists' offices and typically should qualify for the in-office ancillary services exception. (See discussion in section VI.B.1 of this preamble.)

Comment: Several commenters have stated that in-office x-rays and laboratory tests that are performed in conjunction with the provision of chemotherapy should be excluded from the definition of DHS. The commenters seemed particularly concerned that if these services are regarded as DHS, a physician would have to directly supervise them. The commenters expressed concern that requiring a physician to be present during the times these services are provided would run directly counter to common practice in oncology offices and would greatly inconvenience patients.

These commenters asserted that it is extremely unlikely that a physician would refer a patient for chemotherapy simply to obtain the revenue from the x-ray and laboratory tests that are performed in conjunction with the provision of chemotherapy. They regard as a precedent for this exception our proposals to exclude from the definition of radiology certain invasive radiology services in which an imaging modality is used to guide a needle, probe, or catheter properly and to exclude EPO from the definition of outpatient prescription drugs when EPO is provided incidental to dialysis treatment. We had proposed to exclude these invasive radiology procedures and EPO because they are merely furnished incidental to, or secondary to, another procedure that the physician has ordered.

Response: The Congress has imposed certain constraints on physicians' financial arrangements with entities to which they refer patients for DHS. The provision of chemotherapy is a designated health service, as is the provision of radiology and clinical laboratory services. In order for a physician to refer patients to an entity with which the referring physician has a financial arrangement, the physician's financial relationship with the entity must come within an exception to section 1877 of the Act.

As discussed elsewhere, we are not prepared to limit the scope of DHS under section 1877(h)(6) of the Act except in rare situations. We believe that most arrangements for the provision of chemotherapy and related ancillary services by physicians to their patients can be restructured to come within the in-office ancillary services exception as modified by this final rule. (See section VI.B of this preamble.) As discussed

above, we are abandoning the "peripheral/incidental" test that was proposed in the January 1998 proposed rule; we point out that even under that test, the primary procedure could not itself be a designated health service.

Finally, we wish to clarify that we are excepting EPO under certain circumstances because we believe that the Congress did not intend to preclude physician ownership of ESRD facilities. Commenters have noted that when the Congress intended to cover specific Medicare services, including composite rate services, it did so expressly. We agree. The Congress did not list ESRD facility services under section 1877(h)(6) of the Act, while it did list home health services and hospital services. Therefore, we do not regard services furnished under a composite rate by an ESRD facility as DHS. Given the high correlation between EPO and ESRD services, the inclusion of EPO as a DHS would vitiate the Congress' apparent intent. Accordingly, we are excepting from the reach of the statute under our section 1877(b)(4) of the Act authority EPO or other drugs required for dialysis when furnished in or by an ESRD facility owned by physicians. The list of these drugs is set forth in the attachment to this final rule. Given the strict utilization and coverage criteria for EPO in particular and ESRD in general, we conclude this narrow exception presents no quantifiable risk of fraud or abuse. We are not protecting any physician investment in a home dialysis supply company or other entity that supplies EPO to ESRD facilities or that supplies EPO to patients pursuant to a contract with an ESRD facility; in such situations, the physician's investment in the dialysis supply company is no different from any other investment in a DHS entity and there is no indication in the legislative history that home dialysis supply companies were not meant to be covered by the statute.

Comment: A substantial number of commenters requested that we not require physicians to pass on to Medicare discounts they receive in purchasing oncology drugs. Commenters pointed out that the proposed regulations appear to require this result. Some commenters believe that this proposed requirement conflicts with section 1877(e)(8)(B) of the Act, which excepts any payment made by a physician for items and services if the price is consistent with fair market value.

Response: Nothing in this section 1877 of the Act or these regulations is intended to impose on physicians a requirement to pass discounts on drugs

on to the Medicare and Medicaid programs; whether a discount must be passed on to a Federal health care program by physicians or others, however, remains the subject of other statutory and regulatory provisions.

Comment: One commenter asked that we confirm that the definition of "outpatient prescription drugs" would apply only to those drugs that are furnished to "outpatients" of any facility, including a SNF or nursing facility. The commenter believes that if the Congress had intended that the statute cover drugs provided to "inpatients" of facilities, it could have easily written the statute to do so. The commenter pointed out that drugs provided to "inpatients" are generally covered under Medicare Part A and are peripheral components of the services being provided and billed for, particularly under the prospective payment system for SNFs under which SNFs receive a per diem rate for virtually all items and services furnished to a Medicare Part A patient.

Response: In the January 1998 proposed rule, we proposed to include only drugs furnished to an individual under the Medicare Part B benefit and to exclude drugs furnished by providers under Medicare Part A. We have reflected this in Phase I of this rulemaking. A patient may reside in a SNF under a Part A stay or a patient may reside in a SNF without being covered under Part A. If the stay is not covered under Part A, it is possible that the patient may receive some drugs under the Part B benefit that are considered "outpatient prescription drugs" under these physician self-referral provisions. In addition, under section 1835(a) of the Act, a SNF may furnish services to an individual who is not a SNF inpatient. That is, it is possible for a SNF to provide services to an individual who does not reside in the SNF. For example, a SNF with an x-ray machine may furnish x-ray services to a nonresident if the individual has a referral for an x-ray and he or she wishes to receive the x-ray at this location. We assume the individuals who receive these services are the "outpatients" to whom the commenter is referring. (We note that drugs provided to patients in a hospital setting would be inpatient or outpatient hospital services under section 1877(h)(6)(K) of the Act.)

Patients in nursing facilities are typically covered under the Medicaid program. We intend to address all Medicaid-related physician referral issues in a separate rulemaking.

Comment: A commenter requested that we amend the January 1998

proposed rule to clarify that immunizations are not DHS under the definition of "outpatient prescription drugs." The commenter pointed out that immunizations, particularly in pediatric and family care practices, are often personally administered by a physician to his or her own patients or are furnished on an "incident to" basis under the physician's direct supervision. In the adult population, there is also an increasing public awareness of the need for preventive immunizations, such as pneumococcal vaccine and influenza vaccine. These immunizations are widely and actively promoted in this country as constituting good preventive medicine. The commenter believes that the January 1998 proposed regulation could discourage immunizations because under the proposed interpretation of productivity bonuses in the group practice definition, a physician would be unable to share in a productivity bonus based on his or her own administration of, or direct supervision of, these immunizations.

Response: The commenter raised issues relating to immunizations that are covered by Medicare under section 1861(s)(10) of the Act, which covers pneumococcal vaccine and influenza vaccine and their administration, as well as hepatitis B vaccine and its administration if furnished to an individual who is at high or intermediate risk of contracting hepatitis B. Under our authority to create additional exceptions in section 1877(b)(4), we are excluding from the reach of section 1877 of the Act certain immunizations and vaccines covered under section 1861(s)(10) of the Act that are subject to HCFA-imposed frequency limits and that are paid by Medicare on the basis of a fee schedule. We believe that under the terms of the exception the risk of abuse for these services is extremely low and that this exclusion is consistent with the statutory language and structure and the expressed Congressional intent to provide preventive care to Medicare beneficiaries.

In referring to drugs furnished in pediatric and family practices, we assume that the commenter was interested in the definition of outpatient prescription drugs under the Medicaid program. We intend to address the effects of the physician self-referral prohibition on the Medicaid program in Phase II of this rulemaking.

Comment: A commenter raised questions about our decision to exclude EPO and other drugs furnished as part of a dialysis treatment from the definition of "outpatient prescription

drugs." The commenter considered this exclusion ambiguous and requested clarification about whether a particular drug provided by a facility is "part of a dialysis treatment." The commenter pointed out that EPO and other pharmaceuticals are typically administered during the course of treatment to avoid the painful process of injecting the patient multiple times, but that it could be argued that these pharmaceuticals are not "part of" the treatment itself. Therefore, the commenter requested that we revise the exclusion of "other drugs furnished as part of the dialysis treatment" to instead apply to "other drugs furnished to an individual who dialyzes at home or in a facility, as part of an ESRD patient's plan of care."

Response: When we carved out of the definition of "outpatient prescription drugs, EPO and other drugs furnished as part of the dialysis treatment," we did not aim to carve out the far broader category of all "other drugs furnished * * * as part of an ESRD patient's plan of care." We regard "other drugs furnished as part of the dialysis treatment" to be those furnished so that the dialysis treatment can be effective and to counteract the problems that can be caused directly by dialysis. For example, dialysis makes some patients anemic, so EPO is provided to deal with this dialysis-related problem. In addition, iron therapy is covered to make EPO therapy effective and Vitamin D hormone therapy is covered to correct for bone density loss caused by dialysis. Other drugs furnished to an individual who dialyzes at home or in a facility may include drugs that a patient uses for reasons other than to make the dialysis treatment effective. In fact, these other drugs may have nothing whatsoever to do with a patient's renal problems.

Comment: Another commenter agreed with our proposal to exclude EPO in the January 1998 proposed rule because it would allow physicians who own a dialysis facility to prescribe Medicare-covered medications to patients of the dialysis facility on the basis that the drugs are an integral part of the dialysis procedure. The commenter asked that we clarify that self-administered medications for home dialysis such as EPO can only be furnished by the dialysis provider or a supplier that has an agreement with the dialysis provider (a Method II supplier) and cannot be provided through the referring physician's office. The commenter contended that teaching the home dialysis patients to self-administer medications and monitoring the effects

of self-administered medications is the responsibility of the dialysis facility.

Response: We agree with the commenter. As provided in § 414.335 (Payment for EPO furnished to a home dialysis patient for use in the home), medications for home dialysis can only be furnished by the dialysis provider or a Method II supplier that has an agreement with a provider. If a referring physician has a financial agreement with a Method II supplier, the arrangement must meet an exception.

Comment: A commenter asked that immunosuppressant drugs prescribed for patients following organ transplants and covered by Medicare be excluded from the definition of "outpatient prescription drugs." The commenter believes that the rationale for excluding these drugs is similar to the rationale for excluding EPO, since the use of these drugs is peripheral to the transplant surgery, but medically integral to the success of the surgery.

The commenter contended that excluding immunosuppressants from the definition will not provide an opportunity for program or patient abuse because their cost is an economically minor, though medically critical, part of a large and immensely complicated treatment. In addition, the commenter believes that physicians have no motivation to overprescribe these drugs, because the drugs are only used for transplant patients according to clinically accepted protocols that are designed to prevent organ rejection while avoiding unnecessarily high levels of toxicity. The commenter believes that the transplant community adheres to the prevailing standards of medical care with only minor deviations. In addition, each transplant center is required to report its transplant survival rates to an HHS contractor. Centers with survival rates below established thresholds can lose their certification.

Response: Immunosuppressant drugs furnished in an outpatient setting are "outpatient prescription drugs" under Phase I of this rulemaking. (They are inpatient or outpatient hospital services when furnished in a hospital setting.) We are not persuaded that an exception is appropriate or necessary. We believe that to the extent physicians provide transplant drugs to patients in their offices, they will generally be able to do so under the in-office ancillary services exception. If a referring physician has an ownership or investment interest in a free-standing transplant pharmacy or other pharmacy that provides transplant drugs to his or her patients pursuant to a referral, the financial relationship

would have to fit in an applicable exception.

M. Inpatient and Outpatient Hospital Services

In § 411.351 of the January 1998 proposed rule, we defined inpatient hospital services as services that a hospital provides for its patients that are furnished either by the hospital or by others "under arrangements" with the hospital. For outpatient services, we explained in the preamble of the January 1998 proposed rule (63 FR 1683) that we would consider all covered services (either diagnostic or therapeutic) performed on hospital outpatients that are billed by the hospital to Medicare (including arranged for services) as outpatient hospital services. We have revised the definition of outpatient hospital services in the regulations text to clarify that it includes services furnished "under arrangements." Inpatient services are not coded by HCPCS codes. Any outpatient hospital service, regardless of the HCPCS code, is a designated health service.

In the January 1998 proposed rule, we requested comment on whether we should exclude lithotripsy from the definition of inpatient or outpatient hospital services on the theory that it could not be overutilized, since the procedure itself apparently documents the medical necessity to prescribe it. Commenters were also concerned about physician services that are "bundled" into hospital payments and about services furnished by a hospital "under arrangements" with an outside facility. We discuss each of these topics below.

Comment: We received hundreds of comments on the subject of lithotripsy, mostly from urologists who have ownership interests in a lithotripter that a hospital rents. These commenters requested that lithotripsy be excluded from the definition of inpatient and outpatient hospital services so that they could continue to refer to the hospitals without being concerned about how the hospital compensates them. According to these commenters, urologist-owned lithotriptors increased quality of care and patient access without any risk of overutilization of lithotripsy. We also received comments on this topic from individual hospitals, a State and national hospital trade association, and nonphysicians who rented lithotriptors to hospitals in competition with physician owners. These commenters asserted that hospitals pay more for the use of physician-owned lithotriptors than hospitals pay for the use of their own lithotriptors or lithotriptors owned by nonphysicians and urged us to

include lithotripsy in the definition of inpatient and outpatient hospital services.

Response: We have determined that there is no reason to treat lithotripsy any differently than other inpatient or outpatient hospital services. As we have said elsewhere in the preamble, we believe the Congress did not intend that we make service-by-service decisions on whether a service is a designated health service based on the service's potential for overutilization. Even were we able to determine that there is no potential for overutilization of lithotripsy (including comparisons to alternative treatments), there is a substantial potential for urologists who own lithotriptors to extract higher than market rate rents for their equipment or for the financial arrangement between the lessor urologists and the lessee hospital to encourage overutilization of other hospital services. Commenters provided no evidence to support their claims that physician ownership of lithotriptors increased quality of care or access to treatment.

In any event, the exclusion of lithotripsy from the definition of inpatient and outpatient services would not obviate the need for the physician-owners to structure their rental arrangements to comply with section 1877 of the Act. Whether lithotripsy is a designated health service or not, the rental arrangement itself would create a financial relationship between the physician-owners and the hospital. Unless the financial relationship (that is, the lithotripter lease) fit into a compensation exception (such as the equipment rental exception), the physicians could not refer any Medicare patients to the hospital for any inpatient or outpatient services. In short, the relief sought by these commenters would be illusory.

We believe that the changes we have made in § 411.354(d) of these regulations to the volume or value standard (discussed in section V of this preamble) will enable hospitals and urologists to protect *bona fide* arrangements either under an equipment lease or a personal service arrangements exception or under the fair market value exception. Most importantly, Phase I of this rulemaking clarifies that "per service" or "per use" rental or services payments are permitted, even for services performed on patients referred by the urologist-owner, provided the rental or services payment is fair market value and does not take into account any Federal or private pay business generated between the urologist and the hospital (and provided all other conditions of an

exception are met). Because the prevalence of physician ownership of lithotriptors may distort pricing in the marketplace, we believe valuation methods that look to the prices charged by persons not in a position to refer to the hospital or that consider acquisition cost and rate of return are especially appropriate. We also are aware that some manufacturers of lithotriptors lease the machines to urologists on a "per use" basis with the urologists, in turn, leasing the lithotriptors to hospitals on a "per use" basis. In these circumstances, any disparity in the "per use" fee charged by the manufacturer to the urologists and the "per use" fee charged in turn by urologists to the hospital would call into question whether both sets of fees could be fair market value.

Comment: Several commenters suggested that section 1877 of the Act was only intended to address diagnostic procedures. Accordingly, they asked that we exclude therapeutic treatments such as lithotripsy from the definition of inpatient or outpatient hospital services in cases in which the referring urologist or a member of his practice actually treats the referred patient.

Response: The list of DHS in section 1877(h)(6) of the Act contains both therapeutic and diagnostic types of service (for example, physical therapy services are therapeutic and clinical laboratory services are diagnostic). This indicates that the Congress believed that both types of services could be subject to abuse. We have concluded that when a physician initiates a designated health service and personally performs it him or herself, that action would not constitute a referral of the service to an entity under section 1877 of the Act. However, in the context of inpatient and outpatient hospital services, there would still be a referral of any hospital service, technical component, or facility fee billed by the hospital in connection with the personally performed service. Thus, for example, in the case of an inpatient surgery, there would be a referral of the technical component of the surgical service, even though the referring physician personally performs the service. If the referring physician has a financial relationship with the hospital, that relationship must fit in an exception. Potentially available exceptions, depending on the circumstances, include, for example, the personal service arrangements exception, the employee exception, the space or equipment rental exception, the whole hospital exception, and the fair market value exception.

Comment: Several commenters stated that the only reason extracorporeal

shock wave lithotripsy (ESWL) is even subject to the physician self-referral provisions is because Medicare only pays for lithotripsy if it is billed through a hospital, thus forcing the procedure into the realm of inpatient or outpatient hospital services. Many commenters have cited debate language pertaining to adopting the Conference Report for OBRA '93, which language suggests that the sponsor of section 1877 of the Act, Representative Stark, did not intend for ESWL to come under the law.

Response: We believe that lithotripsy was meant to be a "designated health service" under the law, since the law does not exclude any particular hospital services, nor does the legislative history indicate that the Congress meant to exclude them. The House Report for the first version of the physician self-referral law mentioned a specific exception for a facility providing lithotripsy services performed personally by the referring physician. (See H. Rep. No. 101-247, 101st Cong. 1041 (1989).) This exception did not apply to the hospital services at issue, nor was it enacted. In adding hospital services to the list of DHS, the legislative history reveals that the Congress was concerned about increased admissions to hospitals, regardless of the reason for the admission. (We discuss this issue further below, where we address hospital services provided "under arrangements.")

Comment: Another commenter pointed out that we proposed excluding from the definition of inpatient hospital services those services performed by physicians and other providers who bill independently. The commenter asked us to clarify whether physician and individual professional services are excluded from the definition of inpatient hospital services when they are billed by a hospital. Hospitals bill for these services when they are part of a global fee that covers both the technical and professional components of a service or when they bill on an assignment (or reassignment) basis. This commenter argued that if these services are not excluded under section 1877 of the Act, a hospital may not be able to compensate a physician for services performed in, and billed by, the hospital, or to compensate a doctor who supervises a nurse practitioner in a hospital. The commenter also suggested that we clarify that we will treat both inpatient hospital services and outpatient hospital services the same way.

Response: Professional services that Medicare pays independently of an inpatient or outpatient hospital service

do not become DHS if they are billed by a hospital under assignment or reassignment; they remain physician services and are not considered hospital services. Any other service for which a hospital bills is a hospital inpatient or outpatient service, even though it may consist of both a technical and professional component. Therefore, these services constitute DHS under section 1877 of the Act. However, if a hospital is paying the physician for his or her professional services under either a personal services contract or an employment agreement, the physician can still refer to the hospital as long as the compensation arrangement meets an exception, such as the exception that applies to personal service arrangements or the exception for employment agreements. These exceptions require, among other things, that the hospital pay the physician an amount that is based on a fair market value standard.

Comment: Several commenters expressed concern with the effect the definitions of inpatient and outpatient hospital services may have when a hospital purchases services "under arrangements" from an entity owned in whole or in part by a referring physician. Commenters fear that if services are deemed to be inpatient or outpatient hospital services for the purposes of 1877 of the Act when furnished by a hospital "under arrangements" with an entity owned by a physician, physicians may be unwilling to invest in equipment using new technologies. One commenter specifically proposed an exception that would apply to any service that would be exempt from the physician self-referral prohibition if the physician referred directly to the entity, outside of the hospital context. According to several commenters, it is the nature of the service itself that should determine whether or not a referral may be made, not the inpatient or outpatient status of the patient. Commenters were concerned that a physician will not be able to refer a patient to a hospital if the hospital has an arrangement with an entity that the physician owns. The commenters believe that, as long as the actual services are compensated at fair market value, there should be no risk of program or patient abuse.

Response: The Congress specifically chose to include inpatient and outpatient services as DHS under section 1877(h)(6)(K) of the Act. Inpatient and outpatient hospital services include any services that a hospital provides to a hospital patient, whether it provides them itself or provides them by purchasing them from another entity under arrangements; any

other policy would encourage hospitals to purchase as many services as possible under arrangements in order to avoid the effects of the physician self-referral provision. In light of the description of "volume or value" in Phase I of this rulemaking, we believe that *bona fide* "under arrangements" relationships can easily be structured to comply with the personal service arrangements exception, or, in some cases, the fair market value exception. We believe this approach is consistent with section 1877(e)(7) of the Act, which provides a limited exception for certain "under arrangements" relationships that were established before 1989 and met several other requirements.

We are concerned that the provision of services "under arrangements" could be used to circumvent the prohibition in section 1877(c)(3) of the Act of physician ownership of parts of hospitals. We understand that some hospitals are leasing hospital space to physician groups, which the groups then use to provide services "under arrangements" that the hospital had previously provided directly. These arrangements, especially when they involve particularly lucrative lines of business, raise significant issues under section 1877 of the Act, as well as the anti-kickback statute.

However, we also recognize that "under arrangements" relationships are pervasive in the hospital industry and that many of the services being provided by physician groups "under arrangements" are services that the physicians provide in physician-owned facilities primarily to their own patients who are hospital inpatients. In these situations, an "under arrangements" relationship can avoid unnecessary duplication of costs and underutilization of expensive equipment.

While we believe section 1877 of the Act could reasonably be interpreted to prohibit "under arrangements" relationships as constituting prohibited ownership interests in a part of a hospital, we decline to do so at this time for several reasons. First, given the sheer number of these arrangements, we think prohibiting these arrangements would seriously disrupt patient care. Second, almost all these arrangements could be restructured to fit into a combination of the personal service arrangements and equipment lease exceptions (or fair market value exception), although this restructuring will in some cases be administratively burdensome. Third, we believe there is precedent in the statute for treating this situation solely as a compensation arrangement. In section 1877(e)(7) of the Act, the Congress

created a specific compensation exception for certain hospital services provided by physician groups "under arrangements." Since, by definition, all services protected under section 1877(e)(7) of the Act—and the resources used to produce them—were "owned" by the physician groups, the Congress would not have created a protected compensation relationship unless it had first determined that these arrangements did not create a prohibited ownership or investment interest in the hospitals. Simply stated, the Congress would not have excepted these relationships from the compensation arrangement restriction, if they were prohibited as an ownership or investment interest.

In sum, for purposes of section 1877 of the Act, we will treat "under arrangements" financial arrangements between hospitals and physician-owned entities as compensation and not ownership relationships. These arrangements can be protected provided they meet an appropriate compensation exception. We will, however, monitor these arrangements and may reconsider our decision if it appears that the arrangements are abused. We also caution physician groups and hospitals that these arrangements remain subject to the Federal anti-kickback statute.

Comment: One commenter requested that we clarify how the physician self-referral law applies in cases in which a financial relationship arises solely because of Medicare requirements. The commenter discussed a situation in which a radiation therapy group and a radiation therapy facility (owned by some or all of the group members) are located in a medical office building across the street from a hospital in a nonrural area. The closest comparable facility is over 35 miles away. Occasionally, the hospital sends an inpatient for radiation therapy to the radiation facility, which provides the services as "arranged for" inpatient hospital services. The hospital pays the facility for use of the radiation equipment from money it receives from Medicare for the inpatient hospital stay. (The group practice bills Medicare for the professional services of the radiation oncologists.) The commenter erroneously asserted that Medicare requires the hospital to pay the radiation facility for the amount that it would have received under Medicare Part B if the radiation therapy had been provided as an outpatient service. The commenter believes that the payment by the hospital to the radiation therapy facility creates a compensation arrangement with the facility and, in turn, the physicians.

Often, a radiation oncologist will refer a patient of the radiation facility to the hospital for certain tests and other services. The radiation oncologist receives no economic benefit for referring patients to the hospital and refers there for the patient's convenience, not because there is any requirement to do so. The commenter believes that, under our proposed rule, the "under arrangements" compensation arrangement would trigger the physician self-referral law, preventing the radiation oncologists from referring Medicare patients to the hospital for services, even though this financial relationship is not voluntary and not subject to abuse.

The commenter requested clarification whether the proposed § 411.355(d)(2), covering services furnished under composite types of payment rates that the Secretary determines provide no financial incentive for underutilization or overutilization, or any other risk of program or patient abuse, would apply. The commenter also wished to know whether we could include an additional described compensation arrangement exception under § 411.357(d) (the personal service arrangements exception) or clarify § 411.357(g) (the exception for remuneration from a hospital to a physician if the remuneration does not relate to the furnishing of DHS) to include the arrangements the commenter mentioned, or create some variation in the fair market value exception in § 411.357(l)(3) that would allow compensation determined on the basis of the volume of services (that is, fee-for-service payments as covered under Medicare Part B) in the type of situation the commenter described.

Response: As discussed above in section VIII.A of this preamble, we have determined not to include the proposed § 411.355(d)(2) in Phase I of this rulemaking for DHS other than clinical laboratory services. However, as discussed in the preceding response, the arrangement described by the commenter would be a compensation arrangement that could be structured to fit in one of the compensation exceptions, such as the equipment rental, personal service arrangements, or the new fair market value exceptions.

N. Other Definitions

1. Consultation

The definition of "consultation" is addressed in section III.B.2 of this preamble and in the regulations in § 411.351.

2. Entity

In § 411.351 of the August 1995 final rule covering referrals for clinical laboratory services, we defined the term "entity" broadly to cover a sole proprietorship, trust, corporation, partnership, foundation, not-for-profit corporation, or unincorporated association. We revised this definition in the January 1998 proposed rule to make it clear that the definition covers a physician's sole practice or a practice of multiple physicians that provides for the furnishing of DHS, or any other sole proprietorship, trust, corporation, partnership, foundation, not-for-profit corporation, or unincorporated association. We explained in the preamble to the January 1998 proposed rule at 63 FR 1706 that we regard an "entity" for purposes of the referral prohibition as the business organization, or other association that actually furnishes, or provides for the furnishing of, a service to a Medicare or Medicaid patient and bills for that service (or receives payment for the service from the billing entity as part of an "under arrangements" or similar agreement). We explained that we meant that the referral prohibition applies to a physician's referrals to any entity that directly furnishes services to program patients, or to any entity that arranges for the furnishing of these services under arrangements. We are clarifying in Phase I of this rulemaking that, for purposes of section 1877 of the Act, a person or entity is considered to be furnishing DHS if it is the person or entity to which we make payment for the DHS, directly or upon assignment on the patient's behalf, except that if the person or entity has reassigned its right to payment to (i) an employer pursuant to § 424.80(b)(1); (ii) a facility pursuant to § 424.80(b)(2); or (iii) a health care delivery system, including clinics, pursuant to § 424.80(b)(3) (other than a health care delivery system that is a health plan (as defined in § 1000.952(l)), and other than any MCO, PSO, or IPA with which a health plan contracts for services provided to plan enrollees), the person or entity furnishing DHS is the person or entity to which payment has been reassigned. Provided further, that a health plan, MCO, PSO, or IPA that employs a supplier or operates a facility that could accept reassignment from a supplier pursuant to §§ 424.80(b)(1) and (b)(2) is the entity furnishing DHS for any services provided by such supplier.

A number of commenters pointed out, in various contexts, that they did not believe a physician could make a "referral" to himself or herself. We agree and discuss this issue in section III.B of

this preamble, which covers the definition of a referral. In our analysis of this issue, we also concluded that when a physician is referring to himself or herself, that act is not a referral to an "entity," as we have defined it in § 411.351. However, when the physician requests a service from another member of his or her group practice or from the practice's staff, that would be a referral to the practice for purposes of the physician self-referral law. These concepts are discussed in more detail in our responses to specific comments on the definition of a "referral" and on some of the DHS.

In the preamble to the January 1998 proposed regulation (63 FR 1710), we addressed the question of when the owner of a DHS provider is considered to be equivalent to the entity providing DHS. We had proposed to equate a referring physician with the entity when the physician (or a family member) has a significant ownership or controlling interest that allows the physician to determine how the entity conducts its business and with whom. We used two examples to illustrate this concept. Commenters found both our analysis and those examples to be confusing. As a result, we have abandoned this analysis and will simply apply the rules related to indirect financial relationships and indirect referrals as described in detail in section III of this preamble, which covers the general referral prohibition under section 1877(a) of the Act. Section III.A of this preamble includes a discussion about when there is a financial relationship between a physician and an entity.

Comment: A commenter suggested that we clarify in both the preamble and regulations text that a medical device manufacturing company is not an "entity" for the purposes of section 1877 of the Act, and that the manufacturer does not receive payments from billings "under arrangements." Another commenter requested that we clarify that drug manufacturers are not "entities" for purposes of section 1877 of the Act, and that a referral for outpatient prescription drugs only occurs when a physician sends a patient to a particular entity that actively furnishes drugs, such as a pharmacy.

Response: We generally do not regard manufacturers as entities that furnish items or services directly to patients, or as entities that furnish services "under arrangements." Thus, the commenters are correct in stating that a medical device manufacturer or a drug manufacturer is unlikely to be an entity furnishing DHS for purposes of section 1877 of the Act, while a pharmacy, which delivers outpatient prescription

drugs directly to patients, would be one. (We discuss this issue in more detail in section VIII.B of this preamble.) A person or entity is considered to be furnishing DHS if it is the person or entity to which we make payment for the DHS, directly or upon assignment on the patient's behalf, except that if the person or entity has reassigned its right to payment to (i) an employer pursuant to § 424.80(b)(1); (ii) a facility pursuant to § 424.80(b)(2); or (iii) a health care delivery system, including clinics, pursuant to § 424.80(b)(3) (other than a health care delivery system that is a health plan (as defined in § 1000.952(l)), and other than any MCO, PSO, or IPA with which a health plan contracts for services provided to plan enrollees), the person or entity furnishing DHS is the person or entity to which payment has been reassigned. Provided further, that a health plan, MCO, PSO, or IPA that employs a supplier or operates a facility that could accept reassignment from a supplier pursuant to §§ 424.80(b)(1) and (b)(2) is the entity furnishing DHS for any services provided by such supplier.

Comment: A commenter asked us to clarify that State governments and their instrumentalities are not "entities" for purposes of section 1877 of the Act. The commenter noted that many State and local governments create integrated delivery systems and payment arrangements in order to increase access to and decrease the cost of publicly provided care. If the governments or their instrumentalities were to be considered "entities," the commenter argued that State-sponsored clinics and programs may cease to exist, thus restricting access to, and raising the costs of, public programs.

Response: The referral prohibition applies whenever a physician has an unexcepted financial relationship with "an entity" that furnishes DHS. The statute makes no distinction between private and governmental entities, nor do we believe that we have the authority to make such a distinction. We have no basis for concluding that referrals to governmental entities are always free from potential patient or program abuse, so we see no grounds for creating an additional exception under section 1877(b)(4) of the Act. However, we would assume that many governmental entities have compensation arrangements with physicians, rather than being owned in any way by physicians. If this is the case, there are a number of compensation related exceptions in the statute and regulations that are designed to allow physicians who receive fair compensation to continue making referrals.

3. Fair Market Value

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

In the January 1998 proposed rule, we discussed what constitutes a value that is "consistent with the general market value." We drafted the definition as follows so that it applies to any arrangements involving items or services, including, but not limited to, employment relationships, personal service arrangements, and rental agreements:

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

The definition of "fair market value" in the proposed rule continued to include the additional requirements in section 1877(h)(3) of the Act for rentals or leases. Among other things, the statute defines the fair market value of rental property as its value for general commercial purposes, not taking into account its intended use. Most of the comments we received addressed the question of how to establish the fair market value of an asset or agreement and how to value rental property "for general commercial purposes." We have tried to clarify these concepts in our responses.

Comment: Several commenters asked that we clarify the documentation that will sufficiently establish a transaction as consistent with fair market value (and general market value) for the exceptions that apply to compensation arrangements. The proposed definition of fair market value states that "usually the fair market price is the price at

which *bona fide* sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition or the compensation that has been included in *bona fide* service agreements with comparable terms at the time of the agreement." One commenter stated that using the word "usually" may create ambiguities and suggested making clear in the definition of fair market value that the standard of comparable transactions is only one potential means of establishing fair market value.

Another commenter stated that the January 1998 proposed rule is unclear about the steps that must be taken to confirm fair market value. The commenter asked that we adopt the position that a valuation from an independent person experienced in the valuation of health care operations is sufficient as one approach (but not the only approach) to establishing fair market value. However, the commenter further stated that, because sales of medical practices are private and not reported to any central data base, and because there is often a lack of a representative pool upon which to draw comparisons, we should adopt the position that confirmation of fair market value does not necessarily require the finding of comparable entities for comparison. Another commenter stated that the Internal Revenue Service (IRS) guidelines for determining fair market value with respect to tax exempt organizations are too restrictive and are inappropriate for application to for-profit entities.

Response: To establish the fair market value (and general market value) of a transaction that involves compensation paid for assets or services, we intend to accept any method that is commercially reasonable and provides us with evidence that the compensation is comparable to what is ordinarily paid for an item or service in the location at issue, by parties in arm's-length transactions who are not in a position to refer to one another. (As discussed in section V of this preamble, in most instances the fair market value standard is further modified by language that precludes taking into account the "volume or value" of referrals, and, in some cases, other business generated by the referring physician. Depending on the circumstances, the "volume or value" restriction will preclude reliance on comparables that involve entities and physicians in a position to refer or generate business.) The amount of documentation that will be sufficient to confirm fair market value (and general market value) will vary depending on the circumstances in any given case;

that is, there is no rule of thumb that will suffice for all situations. The burden of establishing the "fairness" of an agreement rests with the parties involved in the agreement. Depending on the circumstances, parties may want to consider obtaining good faith, written assurances as to fair market value from the party paying or receiving the compensation, although such written assurances are not determinative.

For example, a commercially reasonable method of establishing fair market value (and general market value) for the rental of office space can include providing us with a list of comparables. We would also find acceptable an appraisal that the parties have received from a qualified independent expert. Although some transactions are not subject to public scrutiny, we believe generally that there should be sufficient documentation of similar public transactions that the parties can use as a basis of comparison. In regions with inadequate direct comparables, such as rural areas, a reasonable alternative may involve comparing institutions or entities located in different, but similar, areas where property is zoned for similar use. For example, a hospital affiliated with a university in one part of the country could be comparable to other hospitals affiliated with universities that are located in similar types of communities. In other cases, all the comparables or market values may involve transactions between entities that are in a position to refer or generate other business. For example, in some markets, physician-owned equipment lessors have driven out competitive third-party lessors of similar equipment. In such situations, we would look to alternative valuation methodologies, including, but not limited to, cost plus reasonable rate of return on investment on leases of comparable medical equipment from disinterested lessors.

In contrast, there may be cases in which finding a commercially reasonable representation of fair market value (or general market value) could be as simple as consulting a price list. As for using the IRS guidelines for determining fair market value that applies to tax exempt organizations, we recognize that in some cases they may not be appropriate for for-profit entities. Nonetheless, it is our view that some elements of the IRS guidelines could be applied under certain circumstances, depending upon the specifics of any particular agreement. We do not wish to either mandate their use or rule them out if they can be appropriately used to demonstrate fair market value.

Comment: One commenter noted that, as part of our definition of "fair market

value,” we include the term “general market value,” which applies to any arrangement involving items and services, including employment relationships, personal service arrangements, and rental agreements. The commenter pointed out that in the January 1998 proposed rule we do not address the specific documentation requirements necessary to verify and document that the price of an asset or the compensation for certain services actually reflects the market rate. The commenter requested that we confirm that internally generated surveys are sufficient for establishing the market rate, and that there is no requirement to use an independent valuation consultant.

Response: We agree that there is no requirement that parties use an independent valuation consultant for any given arrangement when other appropriate valuation methods are available. However, while internally generated surveys can be appropriate as a method of establishing fair market value in some circumstances, due to their susceptibility to manipulation and absent independent verification, such surveys do not have strong evidentiary value and, therefore, may be subject to more intensive scrutiny than an independent survey.

Special Rule for Rental Property. Under section 1877(h)(3) of the Act, fair market value means the value of rental property for general commercial purposes (not taking into account its intended use). In the case of a lease of space, this value may not be adjusted to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor where the lessor is a potential source of patient referrals to the lessee. We incorporated this provision into the August 1995 final rule covering referrals for clinical laboratory services and into the January 1998 proposed rule at § 411.351. Commenters raised questions about the meaning of the statutory provision.

Comment: With respect to the rental of property, commenters questioned our definition of fair market value as “the value of rental property for general commercial purposes (not taking into account its intended use).” The commenters believe this language is problematic for appraising a medical office building because it requires the appraiser to compare the property to the broad category of properties that are “used for general commercial purposes.” This latter category can include properties that are highly dissimilar in character and value. For example, the appraisal for medical

office property could include retail or industrial rates. Such an approach conflicts with the fundamental principle that appraisals should be based on comparing properties with similar attributes.

Response: We believe that a rental property meets the requirement that a payment reflect the “value of property for general commercial purposes, not taking into account its intended use” when the payment takes into account any costs that were incurred by the lessor in developing or upgrading the property, or maintaining the property or its improvements, regardless of why the improvements were added. That is, the rental payment can reflect the value of any similar commercial property with improvements or amenities of a similar value, regardless of why the property was improved. On the other hand, we also believe that rental payments would specifically take into account the intended use of the property if the lessee paid inflated amounts solely to enhance his or her medical practice. For example, rental payments by a physical therapist would not be fair market value for purposes of section 1877 of the Act if the physical therapist agreed to pay an inflated rate that was not justified by improvements or other amenities and was higher than the rate paid by other, similarly situated medical practitioners in the same building just because the building was occupied by several orthopedic practices.

A rental payment cannot be adjusted to reflect the *additional* value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor where the lessor is a physician and a potential source of patient referrals to the lessee. We interpret this requirement to allow rental payments that reflect the fair market value of the area in which the property is located, even if a lease is for medical property in a “medical community.” To qualify, the payments should not reflect any *additional* value, such as an amount that is above that paid by other medical practitioners in the same building or in the same or in a similar location, just because the lessor is a potential source of referrals to the lessee. That is, the rental payments should be roughly equivalent to those charged to similarly situated parties in arrangements in which referrals are not an issue.

Also, the statute requires that the rental payments not reflect the additional value either party attributes to the proximity or convenience to the lessor where the *lessor* is a potential source of patient referrals to the lessee. The definition of a “referral” by a

“referring physician” in section 1877(h)(5) of the Act focuses only on actions and requests for services that are initiated by physicians; it does not include any requests for services initiated by entities or other providers or suppliers, nor does the referral prohibition itself apply to anything but physician referrals. Thus, we believe that it is fair to interpret the limitation in the fair market value definition as confined to situations in which a physician is the lessor and a potential source of referrals to an entity lessee. That limitation does not appear to us to apply when an entity, such as a hospital, is the lessor that rents space to physicians, even if the hospital is in a position to refer to the physicians. As a result, we believe a hospital should factor in the value of proximity when charging rent to lessee physicians.

4. Group Practice

The definition of a group practice under section 1877(h)(4) of the Act is addressed in this preamble at section VI.C and in the regulations at § 411.352.

5. Health Professional Shortage Areas

The existing regulations covering referrals for clinical laboratory services define a health professional shortage area (HPSA) for purposes of section 1877 of the Act as “an area designated as a health professional shortage area under section 332(a)(1)(A) of the Public Health Service Act for primary medical care professionals (in accordance with the criteria specified in 42 CFR part 5, appendix A, part I—Geographic Areas)” and, in addition, “an area designated as a health professional shortage area under section 332(a)(1)(A) of the Public Health Service Act for dental professionals, mental health professionals, vision care professionals, podiatric professionals, and pharmacy professionals. We proposed no changes to the existing rule.

The definition of a HPSA for purposes of Phase I of this rulemaking is intended to track the definition of a HPSA as promulgated by the Health Resources Services Administration (HRSA), which administers the HPSA designation process. HRSA has proposed revising the existing HPSA regulations. (See 63 FR 46538; 64 FR 29831.) We have modified the definition of a HPSA in these regulations to track current HRSA interpretations of the HPSA regulations and to make clear that the definition incorporates any future changes or amendments to HRSA’s definition of a HPSA, which is codified in 42 CFR part 5.

6. Employee

We defined an "employee" in the existing regulation and in the January 1998 proposed regulation in § 411.351 by reiterating the statute. Section 1877(h)(2) of the Act specifically defines an "employee" of an entity as an individual who would be considered to be an employee under the usual common law rules that apply in determining the employer-employee relationship, as applied for purposes of section 3121(d)(2) of the Internal Revenue Code of 1986.

Comment: Two commenters recommended an expansion of the proposed definition of "employee" to include "leased employees" to better reflect the realities of the market place. The current definition, which references income tax law, limits an employee to an individual who meets the definition of a "common law" employee. But the definition of a common law employee does not include leased employees, who are defined by State law and have a quasi-common law status.

Response: We do not believe we have the authority to expand the definition of employee that appears in the law. It is our understanding that leased employees are essentially regarded by the courts, the IRS, and Federal legislators as "contingent employees." Contingent workers are generally described as workers who are not part of the employer's regular work force, but are hired to meet certain needs. These workers are technically employed by an entity other than the one for whom the services are performed. Other types of contingent workers include independent contractors and consultants.

A leased employee is defined in section 414(n) of the Internal Revenue Service Code as an individual who performs services under an agreement between the service recipient and a leasing/staffing organization; performs services under the primary direction or control of the service recipient; and performs services for the service recipient on a substantially full-time basis for a 12-month period. The labeling of a worker as a leased employee under a leasing/staffing arrangement does not mean that the worker will be defined as a "leased employee" under section 414(n) of the Internal Revenue Code for employee benefit plan purposes. The IRS determines the common law employment relationship between a worker and an organization by analyzing the facts and circumstances of each particular situation. The IRS uses guidelines, in the form of a list of

factors, for classifying workers as either employees or independent contractors, in order to determine whether there is actually an employer/employee relationship. We would regard any leased employee that qualifies as an "employee" under the IRS test as an employee for purposes of section 1877 of the Act.

7. Immediate Family Members

The referral prohibition in section 1877(a) of the Act states that if a physician, or immediate family member, has a financial relationship with an entity, the physician cannot refer a Medicare patient to that entity for the furnishing of DHS, unless an exception applies. In the August 1995 final rule, we listed in § 411.351 the individuals who qualify as a physician's "immediate" family members. These individuals include a husband or wife; natural or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild. We adopted this definition without any changes in the January 1998 proposed rule.

We did not receive any comments on this definition. We did receive comments that relate to whether physicians should be precluded from referring to people who qualify as members of their immediate family. We have addressed these comments in section VI.B of this preamble. To conform to common usage, we have amended the definition to substitute the term "birth" for "natural" parent.

8. Referral

The definition of "referral" is addressed in this preamble in section III and in § 411.351 of the regulations.

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

The definition of "remuneration" in section 1877(h)(1)(B) of the Act is drafted broadly to include "any remuneration, directly or indirectly, in cash or in kind." However, a "compensation arrangement" is defined in paragraph (h)(1)(A) of section 1877 of the Act to specifically exclude various kinds of remuneration that are listed in paragraph (h)(1)(C) of section 1877 of the Act. These are arrangements involving only the following remuneration:

(i) the forgiveness of amounts owed for inaccurate tests or procedures, mistakenly performed tests or procedures, or the correction of minor billing errors;

(ii) the provision of items, devices, or supplies that are used solely to—

(I) collect, transport, process, or store specimens for the entity furnishing the item, device, or supply, or

(II) to order or communicate the results of tests or procedures for such entity.

(iii) a payment made by an insurer or a self-insured plan to a physician to satisfy a claim, submitted on a fee for service basis, for the furnishing of health services by that physician to an individual who is covered by a policy with the insurer or by the self-insured plan, if—

(I) the health services are not furnished, and the payment is not made under a contract or other arrangement between the insurer or the plan and the physician,

(II) the payment is made to the physician on behalf of the covered individual and would otherwise be made directly to the individual,

(III) the amount of the payment is set in advance, does not exceed fair market value, and is not determined in a manner that takes into account directly or indirectly the volume or value of any referrals, and

(IV) the payment meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.

We incorporated these exclusions from the definition of "remuneration" into the August 1995 final rule and into the January 1998 proposed rule in § 411.351. We interpreted the exclusions in the January 1998 proposed rule at 63 FR 1693 through 1694 to mean that the portion of any business arrangement that consists of the remuneration listed in paragraph (h)(1)(C) of section 1877 of the Act alone does not constitute a compensation arrangement. The final regulation adopts our proposed regulations text and incorporates expressly the interpretation applicable to arrangements that include portions of remuneration that meet the exclusions in section 1877 (h)(1)(C) of the Act.

a. Minor Billing Errors.

Comment: One commenter, in referring to the exclusion from remuneration of forgiveness for amounts due to corrections of minor billing errors, stated that even a "minor" billing error might have large dollar consequences, particularly if the same minor mistake were repeated on numerous bills. This could easily happen because virtually all bills are now computer-generated. The commenter stated that the term "minor" should refer to the type of error, rather than the sum of money that may be involved.

Response: We agree with the commenter's suggestion that a "minor" billing error could have large dollar consequences, particularly in situations in which bills are computer generated. We also agree that the term "minor"

should refer to the kind of billing error rather than the sum of money involved. Therefore, we are interpreting “minor billing errors” to cover isolated or infrequent instances in which an administrative error, such as a typographic, keying, or other transcribing error, results in an incorrect charge or bill. On the other hand, a pattern of similar or consistent billing error “corrections” may suggest improper remuneration and subject the business arrangement to scrutiny.

b. Medicare as an Insurer.

Section 1877(h)(1)(C)(iii) of the Act “excepts” from the definition of a compensation arrangement situations involving payments made by an insurer or self-insured plan to a physician. The payments must satisfy a physician’s fee-for-service claim for furnishing health services to an individual who is covered by a policy with the insurer or the self-insured plan.

Comment: One commenter asked whether the term “insurer” includes the Medicare program. The commenter believes that Medicare is included within the meaning of the term “insurer,” and cited for support references in the preamble, as well as the designation of Medicare in the Act as “Health Insurance for the Aged and Disabled.”

Response: In the preamble to the January 1998 proposed rule at 63 FR 1694, we pointed out that we believed this provision was designed for situations in which an insurer is also involved in the delivery of health care services. If the insurer owns a health care facility, a physician might otherwise be precluded from referring to that facility just because the physician receives compensation from the insurer in the form of payments that satisfy the physician’s claims.

The Medicare program is not directly involved in the delivery of services, but is simply a payer of services; that is, Medicare never actually furnishes services to program patients but pays for claims from providers and suppliers or makes payments to managed care organizations. The physician self-referral law is only implicated if a physician refers a patient to an entity for DHS and the physician has an ownership or investment interest in the entity or receives direct or indirect remuneration from the entity. Since a physician would never refer a patient to the Medicare program to receive a designated health service, these payments from Medicare to a physician are totally irrelevant under this law.

c. Items, Devices, or Supplies Used Solely To Collect Specimens.

Comment: One commenter thought there was a possible inconsistency in the preamble to the January 1998 proposed rule in the section discussing whether biopsy needles are excluded from the definition of remuneration under section 1877(h)(1)(C)(ii) of the Act. Section 1877(h)(1)(C)(ii) of the Act covers items, devices, or supplies that are used solely to collect, transport, process, or store specimens for the entity providing the items, devices, or supplies. First, the commenter noted our conclusion at 63 FR 1693 through 1694 that biopsy needles do not function solely as specimen collection devices and therefore are categorically excluded from “items, devices, or supplies that are used solely” for specimen collection purposes. In other words, biopsy needles may constitute remuneration under section 1877 of the Act. This discussion is followed in the preamble by a statement that any items, supplies, or devices provided to a physician must be used solely in connection with specimens sent by the physician to the entity that supplied the items, devices, or supplies. Accordingly, the preamble indicates that the number of items, supplies, or devices furnished should not exceed the number of specimens sent to the laboratory for processing. The commenter suggested that the proximity and sequence of these discussions in the preamble has caused confusion in the industry; some have concluded that, regardless of the first discussion and conclusion, biopsy needles might not constitute remuneration if the number of biopsy needles provided by a laboratory were to correlate to the number of biopsy specimens sent to the laboratory.

The commenter urged us to adopt the view that biopsy needles are surgical or medical devices, rather than items, devices, or supplies solely used for specimen collection purposes in all cases. The commenter noted that this interpretation would be consistent with statements made by the OIG that the free provision of biopsy needles from a laboratory to a physician would be suspect under the anti-kickback statute because the needles have independent value to the physician as a surgical device used in surgical procedures. (See the letter dated August 4, 1997, available on the OIG website at <http://www.dhhs.oig.gov>.) A second commenter concurred with this conclusion, and suggested that the same analysis should apply to other surgical or medical devices that may be used during a procedure to collect specimens, but have independent value to

physicians, such as snares and reusable aspiration and injection needles.

Response: We agree with the first commenter that the proximity and sequence of our discussion of this topic in the preamble might have been confusing. We wish to clarify our views on the “items, devices, and supplies” provision here. First, in enacting section 1877(h)(1)(C)(ii) of the Act, we believe that the Congress did not intend to allow laboratories to supply physicians with surgical instruments for free or below fair market value prices. Rather, we believe the Congress intended to include in this section items, supplies, and devices of low value, such as single use needles, vials, and specimen cups, that are primarily provided by laboratories to physicians to ensure proper collection of specimens for processing at the laboratory and that have little, if any, independent economic value to the physicians who receive them. In many cases, the cost of these items may already be included in the practice expense portion of the Medicare payment made to the physician. In addition, to the extent the items are reusable, they may have value unrelated to the collection of specimens for processing by the laboratory providing the items. The provision of such items for free or below fair market value poses a risk that the items may constitute compensation from the laboratories for the physician’s referrals and increase the risk of overutilization. Accordingly, biopsy needles and like devices, such as snares and reusable aspiration and injection needles, are categorically excluded from the items, devices, and supplies covered by section 1877(h)(1)(C)(ii) of the Act, although arrangements for providing such items may be structured to fit into the exception for payments by a physician for items and services to an entity if the items or services are furnished at a price that is consistent with fair market value. (See section 1877(e)(7) of the Act and § 411.357(i).) This view is consistent with the guidance published by the OIG noted in the preceding comment.

The discussion of the correlation of the number of supplies to the number of specimens sent to the laboratory has no application to biopsy needles and other devices that fall outside section 1877(h)(1)(C)(ii) of the Act. As to those single use, low value items, devices, and supplies that come within the scope of section 1877(h)(1)(C)(ii) of the Act, the fact that the number of supplies provided to a physician approximates the number of specimens sent by the physician to the laboratory providing

the supplies is merely one indicator that the supplies have been provided in connection with specimen collection for the entity providing the supplies. The numerical correlation is not a statutory or regulatory requirement. However, the provision of an excessive number of supplies creates an inference that the supplies are not provided solely to collect, transport, process, or store specimens for the entity providing them.

Comment: A commenter noted that certain supplies that are used in connection with the collection of specimens, such as gloves, can also be used by a physician for other purposes. Since the laboratory cannot guarantee that the gloves it supplies are used by the physician only for collecting specimens, the commenter recommended that the laboratory monitor the volume of the items supplied. The commenter asserted that if the number of gloves supplied equals, or is close to, the number needed for the collection of specimens by this physician, we should consider the conditions in the exception in section 1877(h)(1)(C)(ii) of the Act to have been met.

Response: While we recognize that sterile gloves are essential to the proper collection of specimens, we believe they are not items, devices, or supplies used solely to collect, transport, process, or store specimens. To be sure, sterile gloves are essential to the specimen collection process, but their main function is to prevent infection or contamination. Also, sterile gloves are fungible, general purpose supplies typically found in a physician's office and used for a wide range of examinations and procedures. We believe it would be impractical for physicians' offices to monitor and regulate the use of gloves so as to limit their use to the collection of specimens for the laboratory that provided them. Accordingly, we believe the provision of free gloves is remuneration subject to the general prohibition of section 1877 of the Act, in the absence of an applicable exception.

Comment: A commenter questioned how a laboratory should measure the volume of specimen collection supplies it provides to a new physician or group client with whom it has no experience. In such a situation, the commenter believes the laboratory should be allowed to rely on the anticipated volume of services, until an actual pattern of referral can be established, to meet the requirement that items furnished by the laboratory be consistent with the number of tests referred to the laboratory.

Response: As noted above, there is no explicit requirement in the statute that the volume of supplies provided by a laboratory correlate with the volume of specimens sent to the laboratory for processing. Rather, a correlation is one indicator that the provision of the supplies meets the requirement that they be used to collect, transport, process, or store specimens for the laboratory that provided them and that the supplies are not for the physician's general office use. We understand that a laboratory may not have a pattern of referrals on which to base the provision of items, devices, and supplies to a new physician or group practice client. In these instances, the laboratory may elect to provide supplies based on the number of tests typically ordered by physicians or group practices of like type and size in that community until the physician or group practice establishes a pattern of referrals with the laboratory sufficient to determine the appropriate number of supplies. The laboratory or physician should be prepared to demonstrate that the items, devices, or supplies were furnished based on a community standard and to describe the standard.

Comment: One commenter asked that we clarify how section 1877 of the Act applies to a clinical laboratory's provision of a phlebotomist to a physician, group practice, or ESRD facility without charge to the physician, group, or ESRD facility.

Response: Under section 1877(h)(1)(B) of the Act, remuneration includes "any remuneration, directly or indirectly, overtly or covertly, in cash or in kind," with the exception of certain items of potential value listed in section 1877(h)(1)(C) of the Act. The provision of personnel, such as a phlebotomist, does not fit in any category listed in section 1877(h)(1)(C). Thus, the provision of a phlebotomist, as described by the commenter, may constitute remuneration, and therefore create a compensation arrangement, for purposes of section 1877 of the Act. Whether a particular phlebotomist arrangement confers a benefit on a physician or group practice depends on the specific facts and circumstances. (The provision of a phlebotomist to an ESRD facility would not implicate section 1877 of the Act, unless the arrangement conferred a direct or indirect benefit on a physician or physician group; such laboratory-ESRD facility arrangements may implicate the anti-kickback statute.)

The OIG has issued a special fraud alert addressing the provision of free goods and services to physicians under the anti-kickback statute, 59 FR 242

(December 9, 1994). We believe the fraud alert is instructive here. Discussing the issue of laboratory phlebotomists placed in physicians' offices, it observes:

When permitted by State law, a laboratory may make available to a physician's office a phlebotomist who collects specimens from patients for testing by the outside laboratory. While the mere placement of a laboratory employee in the physician's office would not necessarily serve as an inducement prohibited by the anti-kickback statute, the statute is implicated when the phlebotomist performs additional tasks that are normally the responsibility of the physician's office staff. These tasks can include taking vital signs or other nursing functions, testing for the physician's office laboratory, or performing clerical services. Where the phlebotomist performs clerical or medical functions not directly related to the collection or processing of laboratory specimens, a strong inference arises that he or she is providing a benefit in return for the physician's referrals to the laboratory. In such a case, the physician, the phlebotomist, and the laboratory may have exposure under the anti-kickback statute. This analysis applies equally to the placement of phlebotomists in other health care settings, including nursing homes, clinics and hospitals. Furthermore, the mere existence of a contract between the laboratory and the health care provider that prohibits the phlebotomist from performing services unrelated to specimen collection does not eliminate the OIG's concern, where the phlebotomist is not closely monitored by his [or her] employer or where the contractual prohibition is not rigorously enforced.

Like the OIG, we believe that if the phlebotomist is purely performing laboratory functions for the laboratory that places the phlebotomist, then there would be no remuneration to the physician or group practice (that is, no compensation arrangement). Put another way, there would be no services to the physician or group for which they should pay. However, if the phlebotomist performs services that are not directly related to the collection or processing of laboratory specimens for the laboratory that has provided the phlebotomist, he or she may be providing a benefit to the physician or group practice, thus creating a compensation arrangement between the physician and the clinical laboratory that furnished the phlebotomist. Such arrangements may be structured to fit in an exception to section 1877 of the Act, such as the personal service arrangements exception, the fair market value exception, or the exception for payments by physicians for items or services.

Comment: Another commenter asked that we establish a clear standard governing the use by ESRD facilities of

personnel from a clinical laboratory. The commenter recommended that employees of clinical laboratories only be allowed to perform duties directly associated with collecting and preparing specimens, and making test results available to the ESRD facility. Activities involved in ESRD facility administration, patient care, or handling of specimens or data from other laboratories would not be allowed.

Response: As noted above, the provision of a phlebotomist to an ESRD facility would not implicate section 1877 of the Act unless the arrangement benefits a physician or physician group.

Comment: One commenter inquired whether a laboratory may provide medical waste disposal supplies and services to physicians free of charge. The commenter asserted that the services would be provided only for medical waste generated in connection with the collection, transportation, processing, or storage of specimens.

Response: Section 1877(h)(1)(C)(ii) of the Act excludes from the definition of a compensation arrangement remuneration that consists of “the provision of items, devices, or supplies that are used solely to—(I) collect, transport, process, or store specimens for the entity providing the item, device, or supply * * *.” The provision does not specifically allow laboratories to furnish physicians and group practices with medical waste disposal supplies and services at no charge. However, we believe that supplies and the disposal of items used solely in connection with the collection of specimens for this clinical laboratory are part of the process the laboratory engages in when it collects, transports, and processes specimens. If a laboratory can provide a needle for collection and it can take away the specimen, we believe that the laboratory can also take away the needle and other items that are used in the process. However, we do not believe this exception covers the disposal of needles or other waste items that have been used by the physician practice for other purposes.

IX. Collection of Information Requirements

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

we solicit comments on the following issues:

- Whether the information collection is necessary and useful to carry out the proper functions of the agency;
 - The accuracy of the agency’s estimate of the information collection burden;
 - The quality, utility, and clarity of the information to be collected; and
 - Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.
- Therefore, we are soliciting public comment on each of these issues for the information collection requirements discussed below.

Section 411.352 Group Practice

Paragraph (d) requires that, except as provided in paragraphs (d)(2) and (d)(3) of this section, substantially all of the patient care services of the physicians who are *members of the group* (that is, at least 75 percent of the total patient care services of the group practice members) must be furnished through the group and billed under a billing number assigned to the group; the amounts received must be treated as receipts of the group; and “patient care services” must be measured and documented by any reasonable means (including, but not limited to, time cards, appointment schedules, or personal diaries) or any alternative measure that is reasonable, fixed in advance of the performance of the services being measured, uniformly applied over time, verifiable, and documented.

While this requirement is subject to the PRA, the burden associated with it is exempt from the PRA because it meets the requirements set forth in 5 CFR 1320.3(b)(2) and/or (b)(3) and 5 CFR 1320.4(a).

Paragraph (i) requires that supporting documentation verifying the method used to calculate the profit shares or productivity bonus under paragraphs (i)(2) and (i)(3) of this section, and the resulting amount of compensation, must be made available to the Secretary upon request.

While this requirement is subject to the PRA, the burden associated with it is exempt from the PRA because it meets the requirements set forth in 5 CFR 1320.3(b)(2) and/or (b)(3) and 5 CFR 1320.4(a).

Section 411.354 Financial Relationship, Compensation, and Ownership or Investment Interest

Paragraph (d) requires that, when special rules are applied to compensation under section 1877 of the

Act and under these regulations in subpart J of this part, the compensation will be considered “set in advance” if the aggregate compensation or a time-based or per unit of service-based (whether per-use or per-service) amount is set in advance in the initial agreement, in writing, between the parties in sufficient detail so that it can be objectively verified, and meets the terms and conditions of this section.

While this requirement is subject to the PRA, the burden associated with it is exempt from the PRA because it meets the requirements set forth in 5 CFR 1320.3(b)(2) and/or (b)(3) and 5 CFR 1320.4(a).

Section 411.355 General Exceptions to the Referral Prohibition Related to Both Ownership/Investment and Compensation

Paragraph (e) requires that the relationship of the components of the academic medical center must be set forth in a written agreement that has been adopted by the governing body of each component.

While this requirement is subject to the PRA, the burden associated with it is exempt from the PRA because it meets the requirements set forth in 5 CFR 1320.3(b)(2) and/or (b)(3) and 5 CFR 1320.4(a).

Section 411.357 Exceptions to the Referral Prohibition Related to Compensation Arrangements

Paragraph (l) requires that compensation resulting from an arrangement between an entity and a physician (or an immediate family member) or any group of physicians (regardless of whether the group meets the definition of a group practice set forth in § 411.351) for the provision of items or services by the physician (or an immediate family member) or group practice to the entity, must be set forth in an agreement, be in writing, and meet the conditions of the section.

While this requirement is subject to the PRA, the burden associated with it is exempt from the PRA because it meets the requirements set forth in 5 CFR 1320.3(b)(2) and/or (b)(3) and 5 CFR 1320.4(a).

Paragraph (p) requires that, for indirect compensation arrangements, as defined in § 411.354(c)(2), the compensation described in § 411.354(c)(2)(ii) is part of an arrangement that is set out in writing and meets all of the conditions and requirements set forth in this section.

While this requirement is subject to the PRA, the burden associated with it is exempt from the PRA because it meets the requirements set forth in 5

CFR 1320.3(b)(2) and/or (b)(3) and 5 CFR 1320.4(a).

We have submitted a copy of this final rule to OMB for its review of the information collection requirements in §§ 411.352, 411.354, 411.355, and 411.357. These requirements are not effective until they have been approved by OMB.

If you have any comments on any of these information collection and record keeping requirements, please mail the original and 3 copies within 30 days of this publication date directly to the following:

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Allison Heron Eydt, HCFA Desk Officer; and Health Care Financing Administration, Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards, Room N2-14-26, 7500 Security Boulevard, Baltimore, MD 21244-1850, Attn: John Burke HCFA-1809.

X. Regulatory Impact Statement

A. Overall Impact

We have examined the impacts of Phase I of this rulemaking as required by Executive Order 12866 (September 1993, Regulatory Planning and Review) and the Regulatory Flexibility Act (RFA) (Pub. L. 96-354, enacted September 19, 1980). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more annually). We do not believe that Phase I of this rulemaking is a major rule that will have an economically significant effect. We have no way of determining with any certainty the aggregate amount of savings or costs Phase I of this rulemaking will impose, but do not believe it will approach \$100 million or more annually.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$5 million or less

annually. For purposes of the RFA, most physician practices are considered to be small entities. Individuals and States are not included in the definition of a small entity.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds. We do not believe Phase I of this rulemaking will have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in an expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$100 million. Phase I of this rulemaking will not have such an effect on the governments mentioned, and we do not believe the private sector costs will meet the \$100 million threshold.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We do not anticipate that Phase I of this rulemaking will have a substantial effect on State or local governments.

B. Anticipated Effects

We stated in the impact analysis in the January 1998 proposed rule that any estimate of the individual or aggregate economic impact of the provisions of the final rule would be purely speculative. We explained that we could not gauge with any certainty the number of physicians and entities that would be affected, or the extent of any changes they would have to make to comply with the rule. As we noted in the January 1998 proposed rule at 63 FR 1716, various studies have indicated that the degree of conflict of interest presented by a physician's investment in entities to which he or she refers patients is unknown. We pointed out that ownership information or information on the compensation arrangements between physicians and all of their immediate family members and the entities that furnish any of 11 DHS constitutes an enormous amount of

data that is continually subject to change. We also expected that the American Medical Association's declaration that self-referrals are unethical outside of a physician's practice, in conjunction with State laws restricting or qualifying self-referrals and the referral prohibition under section 1877 of the Act itself, have already led to a decline in self-referral activity and financial relationships between physicians and entities. However, we lack the data necessary to either confirm or refute this supposition. We also lack data that would tell us how many of the financial relationships that physicians have with a furnishing entity would already be exempted under the statute.

We stated that, although the provisions in the rule do not lend themselves to a quantitative impact estimate, we did not anticipate that they would have a significant economic impact on a substantial number of small entities. We based this assessment on the many exceptions in the rule (including a broad exception for ownership in rural entities), as well as the actions parties can take to revise their business arrangements to avoid the referral prohibition. We still believe this to be the case. In fact, we expect that Phase I of this rulemaking will have a much smaller impact than the provisions that we proposed. However, because Phase I of this rulemaking may have significant effects on some health care practitioners, or be viewed as controversial, we wish to inform the public of what we regard as the possible major effects of Phase I of this rulemaking.

We stated in the January 1998 proposed rule that we expected that physicians who refer Medicare patients for DHS and entities that furnish DHS, including hospitals, would be the parties that are primarily affected by this rule. In response to comments on the January 1998 proposed rule, we have liberalized a wide variety of the provisions that could affect these parties. We have tried to create a more manageable regulation that includes "bright line" rules to help the health care community determine more easily when a physician's referrals are in compliance with the law. We have made numerous changes to the rule to try to mold it around existing business practices, and have attempted to reinterpret the law so that it has a more practical and realistic effect on physicians and the entities that provide DHS. The result, we believe, is an overall approach that should have far less impact on the business relationships of individuals and entities

than the provisions of the January 1998 proposed rule. We discuss below some of the major issues affecting physicians and furnishing entities. We also briefly discuss the effects of the rule on Medicare beneficiaries.

1. Effects on Physicians

A physician can be financially related to an entity either through an ownership or investment interest in the entity, or through a compensation arrangement with the entity. A physician who has (or whose immediate family member has) a financial relationship with an entity that does not qualify for an exception is prohibited from referring Medicare patients to that entity for the provision of DHS. Also, when a physician with such a relationship makes a prohibited referral, there is a risk that the entity will receive no Medicare payment for those DHS. These provisions can have a significant effect on the business arrangements in which a physician will participate and the manner in which the physician will structure his or her practice.

The potential impact of the regulation on physicians and other individual parties was revealed to us by the voluminous comments from the public and health care community we received in response to the January 1998 proposed rule. In addition to specific complaints and objections, the commenters expressed a number of general concerns, including that the proposed regulation inappropriately intruded into the organization and delivery of medical care within physicians' offices; that the regulation in many respects was counter to our other longstanding policies on coverage and similar issues; that the rule was unclear in many areas and that in light of the severe penalty (that is, payment denial), "bright line" rules were essential; and that some aspects of the proposed rule, such as its treatment of indirect financial relationships, were administratively impractical or would have been prohibitively costly in terms of monitoring compliance.

We believe Phase I of this rulemaking substantially addresses the concerns raised by the commenters and yet is consistent with the statute. Phase I of this rulemaking clarifies the definitions of DHS; substantially broadens the in-office ancillary services exception (which allows physicians to refer within their own practices) by easing the criteria for qualifying as a group practice and conforming the supervision requirements to our coverage and other payment policies; permits shared facilities in the same building where physicians routinely provide services

that are neither Federal nor private pay DHS; excludes from the definition of "referral" services personally performed by the referring physician; expands the in-office ancillary services exception to cover certain DME provided to patients in physicians' offices; creates a new exception for compensation of faculty in academic medical centers; and clarifies when a managed care organization (MCO) is an entity furnishing DHS. All of these issues are described in greater detail elsewhere in the preamble, along with a number of lesser issues that could affect physicians.

2. Effects on Other Providers

As we stated above, Phase I of this rulemaking affects entities that furnish DHS by preventing them from receiving payment for services that they furnish as the result of a physician's prohibited referral. Entities can also be subject to various other sanctions, including fines and exclusion from Federal health care programs if they knowingly submit a claim in violation of the prohibition. We lack the data to determine the number of entities that could be affected by Phase I of this rulemaking. However, we believe they will be fewer in number than we had anticipated in the January 1998 proposed rule because, as we described above, physicians will have far more leeway to refer.

3. Effects on the Medicare and Medicaid Programs

Section 1877 of the Act was enacted primarily to address overutilization of health care services covered by Medicare. We have tried to focus Phase I of this rulemaking on financial relationships that may result in overutilization. We expect that Phase I of this rulemaking will result in savings to the program by providing physicians and entities with "bright line" rules on how to avoid the prohibited referrals that can result in overutilization of covered services. We cannot gauge with any certainty the extent of these savings to the program at this time. (We will discuss the effects on the Medicaid program in Phase II of this rulemaking.)

4. Effects on Beneficiaries

Some commenters thought the January 1998 proposed regulations exceeded our statutory authority and imposed unnecessary and costly burdens on physicians that would harm patient access to health care facilities and services. In Phase I of this rulemaking, we have tried to ensure that the rule will not adversely impact the medical care of Federal health care beneficiaries or other patients. Where we have determined that Phase I of this

rulemaking may impact current arrangements under which patients are receiving medical care, we have attempted to verify that there are other ways available to structure the arrangement, so that patients could continue to receive the care in the same location. In almost all cases, we believe Phase I of this rulemaking should not require substantial changes in delivery arrangements, although it may affect the referring physician's or group practice's ability to bill for the care.

In addition, we have significantly expanded the scope of services potentially included in the in-office ancillary services exception and thus readily available to a referring physician's patients by: (1) Making clear that outpatient prescription drugs may be "furnished" in the office, even if they are used by the patient at home; (2) explicitly permitting external ambulatory infusion pumps that are DME to be provided under the in-office ancillary services exception; (3) making clear that chemotherapy infusion drugs may be provided under the in-office ancillary services exception through the administration or dispensing of the drugs to patients in the physician's office; and (4) creating a new exception for certain items of DME furnished in a physician's office for the convenience of the physician's patients.

C. Alternatives Considered

In drafting the January 1998 proposed rule covering a physician's referrals for DHS, we attempted to interpret the statute strictly and literally. After reviewing the voluminous number of comments we received, we have considered many alternative ways to interpret the statute to accommodate the practical problems that commenters raised, while still fulfilling the intent of the law. For example, we revised the "same building" requirements in the in-office ancillary services exception to address commenters' concerns. Under section 1877(b)(2)(A)(ii)(I) of the Act, services qualify for the in-office ancillary services exception if they are furnished "in a building in which the referring physician (or another physician who is a member of the same group practice) furnishes physician services unrelated to the furnishing of designated health services." In the January 1998 proposed rule, we made it clear that we regarded the building requirement of the in-office ancillary services exception, in combination with the supervision and billing requirements, as the Congress's attempt to circumscribe the exception so that it applies only to services provided within the referring physician's actual sphere

of practice. Without these requirements, physicians could refer to, and profit from, almost any entity, with the claim that somehow the referred services are "in-office" services that are being supervised from some remote place.

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

We have also responded to the commenters' numerous concerns that the space in the building in which the DHS are provided must be adjacent to the space in which services that are not DHS are provided. We have revised the regulation so that an adjacent space is no longer necessary (subject to the dictates of any Medicare or Medicaid payment or coverage supervision rules). Shared facilities in the same building are now permitted to the extent they comply with the supervision, location, and billing requirements of the in-office ancillary services exception. However, because of the increased risk of abuse in this expansion, we felt that we could not protect DHS provided by mobile vans or other mobile facilities under the in-office ancillary services exception, except in very limited circumstances.

As these examples demonstrate, our approach in Phase I of this rulemaking was to address as many of the industry's concerns as possible. We considered a variety of suggestions and alternatives, selecting only those that were consistent with the statute's goals and directives, and that would protect Federal health care program beneficiaries' access to services.

D. Conclusion

For the reasons stated above, we are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined, and we certify, that Phase I of this rulemaking will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

In accordance with the provisions of Executive Order 12866, Phase I of this rulemaking was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 411

Kidney diseases, Medicare, Physician referral, Reporting and recordkeeping requirements.

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare.

For the reasons set forth in the preamble, HCFA amends 42 CFR chapter IV as set forth below:

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

A. Part 411 is amended as follows:

1. The authority citation for part 411 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart A—General Exclusions and Exclusions of Particular Services

2. In § 411.1, paragraph (a) is revised to read as follows:

§ 411.1 Basis and scope.

(a) *Statutory basis.* Sections 1814(a) and 1835(a) of the Act require that a physician certify or recertify a patient's need for home health services but, in general, prohibit a physician from certifying or recertifying the need for services if the services will be furnished by an HHA in which the physician has a significant ownership interest, or with which the physician has a significant financial or contractual relationship. Sections 1814(c), 1835(d), and 1862 of the Act exclude from Medicare payment certain specified services. The Act provides special rules for payment of services furnished by the following: Federal providers or agencies (sections 1814(c) and 1835(d)); hospitals and physicians outside of the U.S. (sections 1814(f) and 1862(a)(4)); and hospitals and SNFs of the Indian Health Service (section 1880 of the Act). Section 1877

of the Act sets forth limitations on referrals and payment for designated health services furnished by entities with which the referring physician (or an immediate family member of the referring physician) has a financial relationship.

* * * * *

Subpart J—Physician Ownership of, and Referral of Patients or Laboratory Specimens to, Entities Furnishing Clinical Laboratory or Other Health Services

3. Section 411.350 is revised to read as follows:

§ 411.350 Scope of subpart.

(a) This subpart implements section 1877 of the Act, which generally prohibits a physician from making a referral under Medicare for designated health services to an entity with which the physician or a member of the physician's immediate family has a financial relationship.

(b) This subpart does not provide for exceptions or immunity from civil or criminal prosecution or other sanctions applicable under any State laws or under Federal law other than section 1877 of the Act. For example, although a particular arrangement involving a physician's financial relationship with an entity may not prohibit the physician from making referrals to the entity under this subpart, the arrangement may nevertheless violate another provision of the Act or other laws administered by HHS, the Federal Trade Commission, the Securities and Exchange Commission, the Internal Revenue Service, or any other Federal or State agency.

(c) This subpart requires, with some exceptions, that certain entities furnishing covered services under Medicare Part A or Part B report information concerning their ownership, investment, or compensation arrangements in the form, manner, and at the times specified by HCFA.

4. Section 411.351 is revised to read as follows:

§ 411.351 Definitions.

As used in this subpart, unless the context indicates otherwise:

Centralized building means all or part of a building, including, for purposes of this definition only, a mobile vehicle, van, or trailer that is owned or leased on a full-time basis (that is, 24 hours per day, 7 days per week, for a term of not less than 6 months) by a group practice and that is used exclusively by the group practice. Space in a building or a

mobile vehicle, van, or trailer that is shared by more than one group practice, by a group practice and one or more solo practitioners, or by a group practice and another provider (for example, a diagnostic imaging facility) is not a centralized building for purposes of this rule. This provision does not preclude a group practice from providing services to other providers (for example, purchased diagnostic tests) in the group practice's centralized building. A group practice may have more than one centralized building.

Clinical laboratory services means the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings, including procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body, as specifically identified by the CPT and HCPCS codes posted on the HCFA web site, <http://www.hcfa.gov>, (and in annual updates published in the **Federal Register** and posted on the HCFA web site), except as specifically excluded on the HCFA web site and in annual updates. All services identified on the HCFA web site and in annual updates are clinical laboratory services for purposes of these regulations. Any service not specifically identified on the HCFA web site, as amended from time to time and published in the **Federal Register**, is not a clinical laboratory service for purposes of these regulations.

Consultation means a professional service furnished to a patient by a physician if the following conditions are satisfied:

(1) The physician's opinion or advice regarding evaluation and/or management of a specific medical problem is requested by another physician.

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

(3) After the consultation is provided, the physician prepares a written report of his or her findings, which is provided to the physician who requested the consultation.

(4) With respect to radiation therapy services provided by a radiation oncologist, a course of radiation treatments over a period of time will be considered to be pursuant to a consultation, provided the radiation oncologist communicates with the

referring physician on a regular basis about the patient's course of treatment and progress.

Designated health services (DHS) means any of the following services (other than those provided as emergency physician services furnished outside of the U.S.), as they are defined in this section:

- (1) Clinical laboratory services.
- (2) Physical therapy, occupational therapy, and speech-language pathology services.
- (3) Radiology and certain other imaging services.
- (4) Radiation therapy services and supplies.
- (5) Durable medical equipment and supplies.
- (6) Parenteral and enteral nutrients, equipment, and supplies.
- (7) Prosthetics, orthotics, and prosthetic devices and supplies.
- (8) Home health services.
- (9) Outpatient prescription drugs.
- (10) Inpatient and outpatient hospital services.

Except as otherwise noted in these regulations, the term "designated health services (DHS)" means only DHS payable, in whole or in part, by Medicare. DHS do not include services that are reimbursed by Medicare as part of a composite rate (for example, ambulatory surgical center services or SNF Part A payments), except to the extent the services listed in paragraphs (1) through (10) of this definition are themselves payable through a composite rate (that is, all services provided as home health services or inpatient and outpatient hospital services are DHS).

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

Employee means any individual who, under the common law rules that apply in determining the employer-employee relationship (as applied for purposes of section 3121(d)(2) of the Internal Revenue Code of 1986), is considered to be employed by, or an employee of, an entity. (Application of these common law rules is discussed in 20 CFR 404.1007 and 26 CFR 31.3121(d)-1(c).)

Entity means a physician's sole practice or a practice of multiple physicians or any other person, sole proprietorship, public or private agency or trust, corporation, partnership, limited liability company, foundation, not-for-profit corporation, or unincorporated association that furnishes DHS. For purposes of this definition, an entity does not include the referring physician himself or herself, but does include his or her medical practice. A person or entity is

considered to be furnishing DHS if it is the person or entity to which HCFA makes payment for the DHS, directly or upon assignment on the patient's behalf, except that if the person or entity has reassigned its right to payment to an employer pursuant to § 424.80(b)(1) of this chapter; a facility pursuant to § 424.80(b)(2) of this chapter; or a health care delivery system, including clinics, pursuant to § 424.80(b)(3) of this chapter (other than a health care delivery system that is a health plan (as defined in § 1000.952(l) of this title), and other than any managed care organization (MCO), provider-sponsored organization (PSO), or independent practice association (IPA) with which a health plan contracts for services provided to plan enrollees), the person or entity furnishing DHS is the person or entity to which payment has been reassigned. Provided further, that a health plan, MCO, PSO, or IPA that employs a supplier or operates a facility that could accept reassignment from a supplier pursuant to §§ 424.80(b)(1) and (b)(2) of this chapter is the entity furnishing DHS for any services provided by such supplier.

Fair market value means the value in arm's-length transactions, consistent with the general market value. "General market value" means the price that an asset would bring, as the result of *bona fide* bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for the other party; or the compensation that would be included in a service agreement, as the result of *bona fide* bargaining between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party, on the date of acquisition of the asset or at the time of the service agreement. Usually, the fair market price is the price at which *bona fide* sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition, or the compensation that has been included in *bona fide* service agreements with comparable terms at the time of the agreement. With respect to the rentals and leases described in § 411.357(a) and (b), "fair market value" means the value of rental property for general commercial purposes (not taking into account its intended use). In the case of a lease of space, this value may not be adjusted to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor when the lessor is a potential source of patient referrals to the lessee. For purposes of

this section, a rental payment does not take into account intended use if it takes into account costs incurred by the lessor in developing or upgrading the property or maintaining the property or its improvements.

Home health services means the services described in section 1861(m) of the Act and part 409, subpart E of this chapter.

Hospital means any entity that qualifies as a "hospital" under section 1861(e) of the Act, as a "psychiatric hospital" under section 1861(f) of the Act, or as a "rural primary care hospital" under section 1861(mm)(1) of the Act, and refers to any separate legally organized operating entity plus any subsidiary, related entity, or other entities that perform services for the hospital's patients and for which the hospital bills. However, a "hospital" does not include entities that perform services for hospital patients "under arrangements" with the hospital.

HPSA means, for purposes of this subpart, an area designated as a health professional shortage area under section 332(a)(1)(A) of the Public Health Service Act for primary medical care professionals (in accordance with the criteria specified in part 5 of this title).

Immediate family member or member of a physician's immediate family means husband or wife; birth or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild.

"Incident to" services means those services that meet the requirements of section 1861(s)(2)(A) of the Act and section 2050 of the Medicare Carriers Manual (HCFA Pub. 14-3), Part 3—Claims Process. (Those wishing to subscribe to program manuals should contact either the Government Printing Office (GPO) or the National Technical Information Service (NTIS) at the following addresses: Superintendent of Documents, Government Printing Office, ATTN: New Orders, P.O. Box 371954, Pittsburgh, PA 15250-7954, Telephone (202) 512-1800, Fax number (202) 512-2250 (for credit card orders); or National Technical Information Service, Department of Commerce, 5825 Port Royal Road, Springfield, VA 22161, Telephone (703) 487-4630. In addition, individual manual transmittals and Program Memoranda can be purchased from NTIS. Interested parties should identify the transmittal(s) they want. GPO or NTIS can give complete details on how to obtain the publications they sell. Additionally, all manuals are

available at the following Internet address: <http://www.hcfa.gov/pubforms/progman.htm>.)

Inpatient hospital services means those services as defined in section 1861(b) of the Act and § 409.10(a) and (b) of this chapter and includes inpatient psychiatric hospital services listed in section 1861(c) of the Act and inpatient rural primary care hospital services, as defined in section 1861(mm)(2) of the Act. "Inpatient hospital services" do not include emergency inpatient services provided by a hospital located outside of the U.S. and covered under the authority in section 1814(f)(2) of the Act and part 424, subpart H of this chapter, or emergency inpatient services provided by a nonparticipating hospital within the U.S., as authorized by section 1814(d) of the Act and described in part 424, subpart G of this chapter. These services also do not include dialysis furnished by a hospital that is not certified to provide end-stage renal dialysis (ESRD) services under subpart U of part 405 of this chapter. Inpatient hospital services include services that a hospital provides for its patients that are furnished either by the hospital or by others under arrangements with the hospital. "Inpatient hospital services" do not include professional services performed by physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse midwives, and certified registered nurse anesthetists and qualified psychologists if Medicare reimburses the services independently and not as part of the inpatient hospital service (even if they are billed by a hospital under an assignment or reassignment).

Laboratory means an entity furnishing biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body. Entities only collecting or preparing specimens (or both) or only serving as a mailing service and not performing testing are not considered laboratories.

List of CPT/HCPCS Codes Used to Describe Certain Designated Health Services Under the Physician Referral Provisions (Section 1877 of the Social Security Act) means the list of certain designated health services under section

1877 of the Act initially posted on the HCFA web site and updated annually thereafter in an addendum to the physician fee schedule final rule and on the HCFA web site.

Member of the group means, for purposes of this rule, a direct or indirect physician owner of a group practice (including a physician whose interest is held by his or her individual professional corporation or by another entity), a physician employee of the group practice (including a physician employed by his or her individual professional corporation that has an equity interest in the group practice), a *locum tenens* physician (as defined in this section), or an on-call physician while the physician is providing on-call services for members of the group practice. A physician is a member of the group during the time he or she furnishes "patient care services" to the group as defined in this section. An independent contractor or a leased employee is not a member of the group. "*Locum tenens* physician" means a physician who substitutes (that is, "stands in the shoes") in exigent circumstances for a regular physician who is a member of the group, in accordance with applicable reassignment rules and regulations, including section 3060.7 of the Medicare Carriers Manual (HCFA Pub. 14-3), Part 3—Claims Process.

Outpatient hospital services means the therapeutic, diagnostic, and partial hospitalization services listed under sections 1861(s)(2)(B) and (C) of the Act; outpatient services furnished by a psychiatric hospital, as defined in section 1861(f) of the Act; and outpatient rural primary care hospital services, as defined in section 1861(mm)(3) of the Act. Emergency services covered in nonparticipating hospitals are excluded under the conditions described in section 1835(b) of the Act and subpart G of part 424 of this chapter. "Outpatient hospital services" includes services that a hospital provides for its patients that are furnished either by the hospital or by others under arrangements with the hospital. "Outpatient hospital services" do not include professional services performed by physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse midwives, certified registered nurse anesthetists, and qualified psychologists if Medicare reimburses the services independently and not as part of the outpatient hospital service (even if they are billed by a hospital under an assignment or reassignment).