For further information, contact:

Lisa Ohrin (410) 786-4565 or Joanne Sinsheimer (410) 786-4620 for issues related to physician self-referral rules.

David Walczak (410) 786-4475 for issues related to reassignment and physician self-referral rules for diagnostic tests and beneficiary signature for ambulance transport.

M. Physician Self-Referral Provisions

[If you choose to comment on issues in this section, please include the caption "PHYSICIAN SELF-REFERRAL PROVISIONS" at the beginning of your comments.]

1. Changes to Reassignment and Physician Self-Referral Rules Relating to Diagnostic Tests (Anti-Markup Provision)

Medicare rules currently prohibit the markup of the technical component of certain diagnostic tests that are performed by outside suppliers and billed to Medicare by a different individual or entity (§414.50). In addition, Medicare program instructions restrict who may bill for the professional component (the interpretation) of diagnostic tests (CMS Pub. 100-04, Chapter 1, 30.2.9.1).

In the CY 2007 PFS proposed rule (71 FR 48982), we stated that recent changes to our rules on reassignment concerning the right to receive Medicare payment may have led to some confusion as to whether the anti-markup and purchased interpretation requirements apply to certain situations where a reassignment has occurred under a contractual arrangement. In addition, we expressed concern about the existence of certain arrangements that we believe are not within the intended purpose of the physician

self-referral rules, which permit physician group practices to bill for certain services furnished by a contractor physician in a "centralized building." We also expressed concern that allowing physician group practices or other suppliers to purchase or otherwise contract for the provision of diagnostic testing services and to then realize a profit when billing Medicare may lead to patient and program abuse in the form of overutilization of services and result in higher costs to the Medicare program (71 FR 49054).

In the CY 2007 PFS proposed rule (71 FR 48982), we proposed to amend §424.80 to provide that if the TC of a diagnostic test (other than clinical diagnostic laboratory tests paid under section 1833(a)(2)(D) of the Act, which are subject to the special rules set forth in section 1833(h)(5)(A) of the Act) is billed by a physician or medical group (the "billing entity") under a reassignment involving a contractual arrangement with a physician or other supplier who performs the service, the amount billed to Medicare by the billing entity, less the applicable deductibles and coinsurance, may not exceed the lowest of the following amounts:

- The physician's or other supplier's net charge to the billing physician or medical group.
- The billing physician's or medical group's actual charge.
- The fee schedule amount for the service that would be allowed if the physician or other supplier billed directly.

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We also proposed that, to bill for the TC, the billing entity would be required to perform the interpretation. In addition, we considered imposing certain conditions on when a physician or medical group can bill for a reassigned PC of a diagnostic test. We

stated that we were considering the following conditions (which currently appear in manual provisions and are known as the purchased interpretation rules):

- The test must be ordered by a physician who is financially independent of the person or entity performing the test and also of the physician or medical group performing the interpretation.
- The physician or medical group performing the interpretation does not see the patient.
- The physician or medical group billing for the interpretation must have performed the TC of the test.

We stated that, although we welcomed comments on all aspects of our proposals, we were particularly interested in receiving comments on whether: diagnostic imaging tests should be excepted from any of our proposed provisions; the proposal in whole or in part should apply only to pathology services; any of the proposed provisions should apply to services performed on the premises of the billing entity and if so, how to define the premises appropriately. We also requested comments as to whether an anti-markup provision should apply to the reassignment of the PC of diagnostic tests performed under a contractual arrangement, and if so, how to determine the correct amount that should be billed to the Medicare program.

For our physician self-referral rules, we proposed to modify the definition of "centralized building" at §411.351 to require a centralized building to consist of at least 350 square feet. We further proposed that the proposed minimum square footage requirement would not apply to space owned or rented in a building in which no more than three group practices own or lease space in the "same building," as defined at

§411.351 (that is, in a building with the same street address) and share the same "physician in the group practice" (as defined at §411.351). We also proposed that a centralized building must contain, on a permanent basis, the necessary equipment to perform substantially all of the designated health services (DHS) that are performed in the space in order to meet the definition of a centralized building. We solicited comments as to whether a centralized building should have a minimum square foot requirement, and if so, whether the minimum should be 350 square feet or an amount more or less than that. In addition, we sought comments regarding whether there should be an exception to any minimum square foot requirement, and if so, the circumstances under which an exception should apply.

For our proposal that the centralized building permanently contain the necessary equipment to perform substantially all of the DHS that is furnished in the centralized building, we sought comments on whether this test should be imposed, and whether at least 90 percent or some other minimum percentage or measurement would be appropriate. We stated that we were also considering whether to require that, for space to qualify as a centralized building, the group practice must employ, in that space, a nonphysician employee or independent contractor who will perform services exclusively for the group for at least 35 hours per week. Finally, we sought comments on whether a group practice should be allowed to maintain a centralized building in a State different from the State(s) in which it has an office that meets the criteria in §411.355(b)(2)(i), and if so, whether space that is located in a different State must be within a certain number of miles from an office of the group practice that meets the criteria in §411.355(b)(2)(i) in order to qualify as a centralized building.

We received numerous comments on these proposals. As a result, we did not finalize our proposals in the CY 2007 PFS final rule with comment period. Based on the comments received and other information that we considered, we are proposing to impose an anti-markup provision on the TC and PC of diagnostic tests. We would apply the anti-markup provision irrespective of whether the billing physician or medical group outright purchases the PC or the TC, or whether the physician or other supplier performing the TC or PC reassigns his or her right to bill to the billing physician or medical group (unless the performing supplier is a full-time employee of the billing entity). To prevent gaming, whereby the performing physician's or other supplier's net charge to the billing entity is inflated to cover the cost of equipment or space that is leased to the performing physician or other supplier, we would define "net charge" as exclusive of any amount that takes into consideration such charges. For example, consider the following hypothetical:

- The fee schedule amount for the PC of a particular diagnostic test is $100.
- Performing Physician A rents office space and equipment from Group B for $50 per test interpretation performed.
- Physician A charges Group B $100 per test.

In this example, pursuant to our proposal, Physician A's charge of $100 would be deemed to take into account the $50 rental fee imposed by Group B (simply by virtue of the rental arrangement). Therefore, Group B would not be allowed to bill the full fee schedule amount of $100, but rather, would be limited to the lesser of Physician A's net charge determined exclusive of the amount that is deemed to have taken into consideration the lease expense, that is $50, or Group B's actual charge for the PC. We

are also concerned that overutilization of diagnostic tests could continue despite our proposal to apply an anti-markup provision to TCs that are reassigned to, or outright purchased by, group practices. That is, our proposal in the CY 2007 PFS proposed rule to impose an anti-markup provision would not have addressed the situation in which the TC is performed by a part-time or leased employee of the group practice in a centralized building, and the group neither receives a reassignment from the employee technician (if the technician is not able to bill for the TC in his or her own right), nor purchases the TC outright from the technician. Therefore, we are proposing to apply an anti-markup provision to TCs that are performed in a centralized building, and are seeking comments on whether we should have such a provision and, if so, how we should effect such a provision (for example, through amending the definition of "centralized building" or through some other means). We would except the anti-markup provision for PCs ordered by independent laboratories because we do not believe that PCs ordered by independent laboratories pose a significant risk of program abuse because the independent lab is not ordering the TC. In States where the corporate practice of medicine doctrine is in effect, independent labs that are organized as corporations are prevented from hiring physicians as employees to perform PCs of diagnostic tests.

In addition, we are proposing in §414.50 that--(1) the PC of a purchased test be subject to an anti-markup provision; (2) the anti-markup provision for the TC and PC apply to all arrangements not involving a reassignment from a full-time employee of the billing entity; (3) the performing physician's or other supplier's net charge be calculated exclusive of any charge that reflects the cost of space or equipment leased to the

performing physician or other supplier by the billing entity; and (4) the anti-markup provision not apply to independent labs that have not ordered the TC.

At this time, we are not proposing to make changes to the definition of "centralized building" (with the one possible exception noted below in this section). We believe that changes to the definition may be unnecessary in light of our proposals for an anti-markup provision on the TC and PC of diagnostic tests (although if we decide to impose an anti-markup provision for TCs performed by technicians in a centralized building, we may accomplish that through amending the definition of "centralized building"). If an anti-markup provision is finalized, we may evaluate at a later time whether to make any revisions to the definition of "centralized building." We also are not proposing to adopt the purchased test interpretation rules in the context of reassignments because this provision may be unnecessary if we impose an anti-markup provision and because the purchased test interpretation rules may be problematic for multi-specialty group practices. Finally, in the CY 2007 PFS proposed rule, we proposed that, in order to bill for the TC of the diagnostic test, the billing physician or medical group must directly perform the PC. However, we believe this provision may be unnecessary if we impose an anti-markup provision and also would be problematic for independent labs that cannot employ physicians due to corporate practice of medicine restrictions.

2. Burden of Proof

We are proposing to add §411.353(g) to clarify that, consistent with our policy with respect to claims denials, in any appeal of a denial of payment for a designated health service that was made on the basis that the service was furnished pursuant to a

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prohibited referral, the burden is on the entity submitting the claim for payment to establish that the service was not furnished pursuant to a prohibited referral. That is, the burden of proof is not on CMS or our contractors to establish that the service was furnished pursuant to a prohibited referral.

3. In-Office Ancillary Services Exception

One of the most important exceptions to the physician self-referral prohibition, applicable to services furnished by group practices and sole practitioners, is the in-office ancillary services exception. Section 1877(b)(2) of the Act sets forth an exception for certain services (other than durable medical equipment and parenteral and enteral nutrients) that are provided ancillary to medical services provided by a physician or group practice and that meet certain conditions. The in-office ancillary services exception is codified in §411.355(b).

Among other things, the exception allows patients of a sole practitioner or physician in a group practice to receive ancillary services in the same building in which the referring physician or his or her group practice furnishes medical services, including some services unrelated to the furnishing of DHS. The exception provides additional flexibility for patients seen by a physician in a group practice by allowing these patients to receive a test or procedure in another building in space owned or leased on a full-time, exclusive basis by a group practice (that is, a "centralized building" as defined at §411.351).

The in-office ancillary services exception does not contain certain requirements that are found in other compensation exceptions. For example, the exception for personal

service arrangements in §411.357(d), like many of the compensation exceptions, requires that compensation be set in advance, consistent with fair market value, and not determined in a manner that takes into account the volume or value of referrals or other business generated by the referring physician. These requirements are not present in the in-office ancillary services exception. Also, under the "special rule for productivity bonuses and profit shares" in §411.352(i), a physician in a group practice may receive a share of profits or a productivity bonus for referred ancillary services, provided that the payment is not directly related to the volume or value of referrals.

We believe that the Congress included an exception for in-office ancillary services to allow for the provision of certain services necessary to the diagnosis or treatment of the medical condition that brought the patient to the physician's office. At the time of enactment, a typical in-office ancillary services arrangement might have involved a clinical laboratory owned by physicians located on one floor of a small medical office building. Under such an arrangement, a staff member would take a urine or blood sample to the clinical laboratory, create a slide, perform the test, and obtain the results for the physician while the patient waited.

However, services furnished today purportedly under the in-office ancillary services exception are often not as closely connected to the physician practice. For example, pathology services may be furnished in a building that is not physically close to any of the group practice's other offices, and the professional component of the pathology services may be furnished by contractor pathologists who have virtually no relationship with the group practice (in some cases, the technical component of the pathology services is furnished by laboratory technologists who are employed by an

entity unrelated to the group practice). In other words, the core members of the group practice and their staff are never physically present in the contractor pathologist's office. Similarly, the contractor pathologists do not participate in any group practice activities; they attend no meetings (except for phone calls about individual patients), and do not obtain retirement or health benefits from the group practice. In sum, these types of arrangements appear to be nothing more than enterprises established for the self-referral of DHS.

Even in the case of ancillary services furnished in the same building, there may be very little interaction between the physicians who treat patients and the staff that provide the ancillary services. For example, an entity with its own staff located in a large medical office building next to a hospital may furnish an array of diagnostic services, including clinical laboratory services and radiology services, to patients of physicians who practice in the building and own either the equipment or the entity.

Comments received on the Phase I and Phase II physician self-referral rules (66 FR 856 and 69 FR 16055, respectively) stated that the in-office ancillary services exception is susceptible to abuse. For example, in response to the 1998 physician self-referral proposed rule (66 FR 892), a commenter asserted that the Congress did not intend for a group practice to have multiple centralized office locations, except for the provision of clinical laboratory services. This sentiment was reiterated in response to the Phase I final rule when several commenters objected to the decision to allow group practices to have more than one centralized facility (69 FR 16075). In response to Phase II, we received hundreds of letters from physical therapists and occupational therapists stating that the in-office ancillary services exception encourages physicians to create physical

and occupational therapy practices. In addition, we have been informed by a number of physician specialists that the in-office ancillary services exception enables physicians to order and then subsequently perform ancillary services instead of making a referral to a specialist.

In the CY 2007 PFS proposed rule (71 FR 48982), we stated our intent to address certain types of potentially abusive arrangements in which group practice physicians make a referral for a designated health service to a specialist who is an independent contractor of the group practice. The specialist then performs the service for the group practice in a "centralized building" and reassigns his or her right to Medicare payment to the group (which then bills Medicare at a profit).

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Comments received on the CY 2007 PFS proposed rule stated that, although our proposal addressed potential abuses arising from referrals to independent contractors who perform services in a centralized building, it failed to address abusive arrangements within the physician's office. Our review of industry trade articles and discussions with trade associations has heightened our awareness of the proliferation of in-office laboratories and the migration of sophisticated and expensive imaging or other equipment to physician offices. "Turn-key" operations, such as the arrangements described in this section for in-office laboratories and other ventures, are being marketed to physicians over the internet.

At this time, we decline to issue a specific proposal for amending the in-office ancillary services exception. Rather, we are soliciting comments as to whether changes are necessary and, if so, what changes should be made. We are interested in receiving comments on: (1) whether certain services should not qualify for the exception (for

example, any therapy services that are not provided on an incident to basis, and services that are not needed at the time of the office visit in order to assist the physician in his or her diagnosis or plan of treatment, or complex laboratory services); (2) whether and, if so, how we should make changes to our definitions of same building and centralized building; (3) whether nonspecialist physicians should be able to use the exception to refer patients for specialized services involving the use of equipment owned by the nonspecialists; and (4) any other restrictions on the ownership or investment in services that would curtail program or patient abuse.

4. Obstetrical Malpractice Insurance Subsidies

We are concerned that our exception for obstetrical malpractice insurance subsidies is unnecessarily restrictive; that is, that our exception does not allow for certain obstetrical malpractice insurance subsidies that may be provided without a risk of program or patient abuse. The exception in §411.357(r) incorporates by reference the conditions in the anti-kickback safe harbor in §1001.952(o). We have received accounts, through advisory opinion requests and anecdotally, of patient difficulty obtaining obstetrical care in some communities in States in which obstetrical malpractice insurance premiums are relatively high. We have also been informed that obstetricians have left these States for other practice locations where obstetrical malpractice insurance premiums are less expensive, requiring patients to drive long distances to receive obstetrical care. We are seeking comments describing such problems and recommendations for how the exception should be changed without creating a risk of program or patient abuse. For example, the exception requires that the physician practice

in a primary care HPSA and that 75 percent of the physician's obstetrical patients treated under the coverage of the malpractice insurance will either reside in a HPSA or a medically-underserved area or be part of a medically-underserved population. We are interested in whether the exception would more effectively ensure beneficiary access to obstetrical care without risking program abuse if any of the requirements were changed. In addition, to the extent possible, we would like to establish bright-line requirements in the exception.

We are proposing to revise the exception in §411.357(r) to specifically list the conditions that we believe are appropriate to safeguard against program or patient abuse when remuneration is provided by a hospital to a physician in the form of an obstetrical malpractice insurance subsidy. As noted previously, the current exception incorporates the conditions in the anti-kickback safe harbor in §1001.952(o). We are seeking comments with respect to requirements, such as the following, that would be appropriate to include in the exception for obstetrical malpractice insurance subsidies:

- A requirement for a written agreement between the parties.
- Physician certification (or, in subsequent years, actual data indicating) that a specified percent of the physician's obstetrical patients treated under the coverage of the subsidized malpractice insurance will either reside in a HPSA or medically-underserved area or be part of a medically-underserved population.
- Location of the entity making the malpractice insurance premium subsidy payment.
- Location of the medical practice of the physician receiving the malpractice insurance subsidy payment.

- A requirement that the payment not be conditioned on the physician making referrals to, or otherwise generating business for, the entity.
- No restriction on the physician establishing staff privileges at, referring any service to, or otherwise generating any business for any other entity.
- A requirement that the amount of the payment may not vary based on the volume or value of any previous or expected referrals to or business otherwise generated for the entity by the physician.
- A requirement that the physician must treat obstetrical patients who receive medical benefits or assistance under any Federal health care program in a nondiscriminatory manner.
- A requirement that the insurance is a bona fide malpractice insurance policy or program, and the premium, if any, is calculated based on a bona fide assessment of the liability risk covered under the insurance.

In addition, we would include the requirement that the arrangement not violate the anti-kickback statute (section 1128B(b) of the Act) or any Federal or State law or regulation governing billing or claims submission (which is a requirement of our other compensation exceptions issued under our authority under section 1877(b)(4) of the Act).

5. Unit-of-service (Per-Click) Payments in Space and Equipment Leases

Section 1877(e)(1) of the Act provides an exception to the prohibition on physician referrals for space and equipment leases, provided that certain requirements are met. Among the requirements, which are incorporated in our regulations in §411.357(a) and (b), are that the lease be commercially reasonable even if no referrals were made

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between the parties, and that the rental charges be set in advance, be consistent with market value, and not be determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties. The statute also requires that the lease arrangement meet such other requirements as the Secretary may impose by regulation as needed to safeguard against program or patient abuse. We are concerned with lease arrangements that are structured so that a physician is rewarded for each referral he or she makes for DHS. Such arrangements could take the form of a physician leasing equipment that he or she owns to a hospital, and receiving a per-use (per-click) fee each time a patient is referred by the physician-owner to the hospital for the use of the equipment. We are also concerned about arrangements where the physician is the lessee and rents space or equipment from a hospital or other DHS entity on a per-click basis. For example, if a physician rents an MRI machine from a hospital only when the physician refers a patient for an MRI and then provides the facility portion of the MRI service under arrangements with the hospital, the physician benefits financially and the arrangement could provide an incentive for overutilization or other program abuse.

In the 1998 proposed rule (63 FR 1714), we noted that we had been asked about situations in which a physician rents equipment (such as an MRI machine) to an entity that furnishes a DHS, such as a hospital, with the physician receiving rental payments on a per-click basis (that is, total rental payments increase each time the machine is used). We stated that we believed that this arrangement would not prohibit the physician from otherwise referring to the entity, provided that these kinds of arrangements were typical and complied with the fair market value and other requirements included under the rental

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exception. However, we added that, because a physician's compensation under this exception may not reflect the volume or value of the physician's own referrals, the rental payments may not reflect per-click payments for patients who are referred for the service by the lessor physician.

In the Phase I rulemaking, we stated that we were substantially revising the proposed rule with respect to "the volume or value standard." We stated:

> Most importantly, we are permitting time-based or unit-of-service-based payments, even when the physician receiving the payment has generated the payment through a DHS referral. We have reviewed the legislative history with respect to the exception for space and equipment leases and concluded that the Congress intended that time-based or unit-of-service-based payments be protected, so long as the payment per unit is at fair market value at inception and does not subsequently change during the lease term in any manner that takes into account DHS referrals. (66 FR 876)

After reconsidering the issue, we are proposing that space and equipment leases may not include unit-of-service-based payments to a physician lessor for services rendered by an entity lessee to patients who are referred by a physician lessor to the entity lessee. We believe that such arrangements are inherently susceptible to abuse because the physician lessor has an incentive to profit from referring a higher volume of patients to the lessee, and we would disallow such per-click payments, using our authority under section 1877(e)(1) of the Act, even if the statute does not expressly forbid per-click payments to a lessor for patients referred to the lessee.

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Finally, we are soliciting comments on whether, using our authority under section 1877(e)(1) of the Act, we should prohibit time-based or unit-of-service-based payments to an entity lessor by a physician lessee, to the extent that such payments reflect services rendered to patients sent to the physician lessee by the entity lessor.

6. Period of Disallowance for Noncompliant Financial Relationships

In response to the Phase II interim final rule with comment period (69 FR 16054), we received several comments that questioned what the period would be for which the physician could not refer DHS to the entity and the entity could not bill Medicare for the situation in which a financial arrangement between a referring physician and an entity failed to satisfy the requirements of an exception to the general prohibition on self-referrals.

At this time, we are not making proposals for prescribing the period of disallowance for various types of noncompliance, but rather are seeking comments on how we might, to the extent practicable, set forth the period of disallowance for arrangements that implicate, but fail to satisfy the requirements of, one or more of the various exceptions. As a general matter, we believe that the statute contemplates that the period of disallowance should begin with the date that a financial arrangement failed to comply with the statute and the regulations and end with the date that the arrangement came into compliance or ended. However, in some instances it may not be clear when a financial arrangement has ended. For example, where an entity leases space to a physician at a rental price that is substantially below fair market value, it may raise the inference that the below market rent was in exchange for future referrals, including referrals made beyond the expiration of the lease. We are seeking comment whether, with respect to types of noncompliance for which it is not clear when a financial relationship ended, we should always employ a case-by-case approach, or deem certain types of financial relationships to continue for a prescribed period of time.

We are also soliciting comment as to whether we should allow the period of disallowance to terminate where a party has returned, or paid back the value of, the consideration. For example, if we were to impose a period of disallowance for a prescribed period of time because it would not be clear when a noncompliant compensation arrangement ended, the period of disallowance may terminate sooner than the prescribed period if the prohibited compensation were returned. We caution that we do not envision allowing such an option where the parties knew or, in our judgment, reasonably should have known that the arrangement did not satisfy the requirements of an exception.

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We are also seeking comment as to whether we should impose a period of disqualification from using an exception where an arrangement has failed to satisfy the requirements of that exception. For example, suppose non-monetary compensation is given by an entity to a physician that greatly exceeds the permissible limit prescribed in §411.357(k). In addition to whatever period of disallowance that would apply, we are considering whether the parties should be disqualified, for a period of time, from relying on this exception. For example, if an entity gives a piece of equipment to a physician that has a fair market value of $900, we may--

- Prohibit one or both of the parties from relying on this exception for a period of time;
- Require the parties to "spend down" in order to use the exception again (for example, if the permissible year limit is $300 (not taking into account adjustment for inflation) and the parties exceeded this limit by $600, the parties would be

precluded from using the exception during the next 2 years (not taking into account adjustment for inflation); or

- Require the physician to return or pay back the value of the excess compensation in order for one or both of the parties to use the exception again.

7. Ownership or Investment Interest in Retirement Plans

In the 1998 proposed rule (63 FR 1708), we noted that we had received questions concerning whether stock options and other nonvested interests (such as an interest in retirement funds that vests after a certain number of years worked) in an entity constitutes ownership in that entity. We replied that it was our view that options and nonvested interests are inchoate or partial ownership interests that qualify as "ownership" for purposes of the physician self-referral law. In response to a comment to the 1998 proposed rule, however, we stated in the Phase I final rule with comment period that we were withdrawing the statement in the 1998 proposed rule that an interest in a retirement plan might be treated as an ownership or investment interest for purposes of section 1877 of the Act and that, instead, we would consider contributions (including employer contributions) to retirement plans to be part of an employee's overall compensation arrangement with his or her employer (66 FR 870). As part of the Phase I rule, we promulgated §411.354(b)(3)(i), which excludes "[a]n interest in a retirement plan" from the definition of ownership and investment interests. We made no changes to this provision in Phase II (69 FR 16054).

We received a comment in response to the Phase II interim final rule (69 FR 16054) concerning the exclusion from an ownership or investment interest for retirement

plans as specified in §411.354(b)(3)(i). The commenter stated that, contrary to our intent, some physicians are using retirement plans to purchase DHS entities to which they refer patients for DHS. We agree with the commenter that it was not our intent to exclude from the definition of an ownership or investment interest an interest in a DHS entity that results from a physician's (or family member's) participation in a retirement plan that purchases an interest in that DHS entity. That is, where a physician has an interest in a retirement plan offered by Entity A, through the physician's (or an immediate family member's) employment with Entity A, we intended to except from the definition of ownership or investment interests any interest the physician would have in Entity A by virtue of his or her interest in the retirement plan; we did not intend to exclude from the definition of ownership or investment interests any interest the physician may have in Entity B through the retirement plan's purchase of an interest in Entity B.

Accordingly we are proposing to revise §411.354(b)(3)(i) to provide that ownership and investment interests do not include an interest in a retirement plan offered by the entity to the physician or immediate family member as a result of the physician's or immediate family member's employment with the entity.

8. "Set in Advance" and Percentage-based Compensation Arrangements

Several of the compensation exceptions in section 1877 of the Act require that the compensation be "set in advance" (or "fixed in advance"). This requirement has been carried over in our regulations implementing those statutory exceptions, and we have also included a "set in advance" requirement in some of our regulatory exceptions (that is, exceptions promulgated pursuant to our authority in section 1877(b)(4) of the Act to

create additional exceptions that pose no risk of program or patient abuse). In §411.354(d), Special Rules on Compensation, we state that compensation will be considered "set in advance" if the aggregate compensation, a time-based or per unit-of – service-based amount, or a specific formula for calculating the compensation, is set forth in an agreement between the parties before the furnishing of the items or services for which the compensation is to be paid. Under Phase I (66 FR 959), the last sentence of §411.354(d)(1) stated:

> Percentage compensation arrangements do not constitute compensation that is 'set in advance' in which the percentage compensation is based on fluctuating or indeterminate measures or in which the arrangement results in the seller receiving different payment amounts for the same service from the same purchaser.

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We had explained in that rule, in response to a public comment, that "[p]ercentage compensation that is determined by calculating a percentage of a fluctuating or indeterminate amount, such as revenues, collections or expenses, is not fixed in advance" (66 FR 878). Following publication of the Phase I rule, however, we received anecdotal accounts about contracts for physician services under which payment was calculated based on a percentage of the revenue raised by a physician's own professional services. Therefore, we delayed the effective date of the final sentence of §411.354(d)(1) through four **Federal Register** notices, to allow us to revise the provision "to avoid unnecessarily disrupting existing contractual arrangements for physician services" (68 FR 74491, December 24, 2003; 68 FR 20347, April 25, 2003; 67 FR 70322, November 22, 2002; 66 FR 60154 and 60155, December 3, 2001).

In the Phase II interim final rule with comment period, in the section on physician compensation, we explained that percentage compensation arrangements were of

particular concern to academic medical centers and to hospitals "which argued that percentage compensation is commonplace in their physician compensation arrangements" (69 FR 16068). We were persuaded that our original position was overly restrictive, and accordingly, we deleted the last sentence in §411.354(d)(1) and clarified that the specific formula must be set forth in sufficient detail before the furnishing of the items or services and the formula may not be modified within the time period in any manner that reflects the volume or value of referrals or any other business generated between the parties.

Despite our intent that percentage compensation arrangements could be used only for compensating physicians for the physician services they perform, it has come to our attention that percentage compensation arrangements are being used for the provision of other services and items, such as equipment and office space that is leased on the basis of a percentage of the revenues raised by the equipment or in the medical office space. We are concerned that percentage compensation arrangements in the context of equipment and office space rentals are potentially abusive. We note that section 1877(e)(1)(A)(vi) of the Act, with respect to office space rentals, and section 1877(e)(1)(B)(vi) of the Act, with respect to equipment rentals, allow us to impose requirements on office space and equipment rental arrangements as needed to protect against program or patient abuse. Although we are concerned primarily with percentage compensation arrangements in the context of equipment and office space rentals, we believe there is the potential for percentage compensation to be utilized in other areas as well. Therefore, relying on our authority in sections 1877(e)(1)(A)(vi), 1877(e)(1)(B)(vi), and 1877(b)(4) of the Act, we are proposing to clarify that percentage compensation arrangements: (1) may be used only for paying for personally performed physician services; and (2) must be based on the

revenues directly resulting from the physician services rather than based on some other factor such as a percentage of the savings by a hospital department (which is not directly or indirectly related to the physician services provided).

9. Stand in the Shoes

Commenters to the Phase I final rule with comment period proposed that we permit physicians to stand in the shoes of their group practices, thereby requiring analysis of certain indirect compensation arrangements as direct compensation arrangements. In the Phase II interim final rule, we solicited comments on this issue, and we may be addressing this issue in an upcoming final rule. In this proposed rule, we are focusing on the DHS entity side of physician-DHS entity financial relationships. We propose to amend §411.354(c) to provide that, where a DHS entity owns or controls an entity to which a physician refers Medicare patients for DHS, the DHS entity would stand in the shoes of the entity that it owns or controls and would be deemed to have the same compensation arrangements with the same parties and on the same terms as does the entity that it owns or controls. For example, a hospital would stand in the shoes of a medical foundation that it owns or controls (such as where the hospital is the sole member of a non-profit corporation). Thus, if a hospital owns or controls a medical foundation that contracts with a physician to provide physician services at a clinic owned by the medical foundation, the hospital would stand in the shoes of the medical foundation, and would be deemed to have a direct compensation relationship with the contractor physician.

We believe that it is necessary to collapse the type of relationship discussed above to safeguard against program abuse by parties who endeavor to avoid the application of the physician self-referral requirements by simply inserting an entity or contract into a chain of financial relationships linking a DHS entity and a referring physician. We are soliciting comments as to whether and how we would employ a stand in the shoes approach for the type of relationship discussed above, as well as for other types of financial relationships. In submitting comments, commenters should be mindful that we may finalize (or may already have finalized) a provision that treats physicians as standing in the shoes of their group practices or other physician practices.

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10. Alternative Criteria for Satisfying Certain Exceptions

We received several comments in response to the Phase II rulemaking that asserted that even innocent and trivial violations of the physician self-referral statute may result in huge penalties to an entity that submits claims to Medicare. For example, the failure of a hospital to obtain a signature on a lease or a personal service arrangement with a physician could result in the hospital being required to make repayment for all services for which it billed Medicare as a result of prohibited referrals from the physician. One commenter stated that we should exercise our discretion in pursuing minor violations and any violations involving a failure to meet the procedural or form requirements of an exception (such as obtaining all required signatures prior to commencement of the agreement for personal services). Another commenter stated that we should consider adding an exception that would permit physicians to refer for DHS, and entities to submit and receive payment for DHS, if, in our sole discretion, we determined that there was no

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abuse. The commenter suggested that such an exception be available only after (1) receipt by the entity of a favorable advisory opinion, or (2) a voluntary disclosure by the entity or upon audit or investigation by the government.

Although we do not have discretion to waive violations of the physician self-referral statute, we are considering whether to amend certain of the exceptions that appear in §411.355 through §411.357 to provide an alternate method for satisfying the exception. We caution that our proposal is intended to address only inadvertent violations in which an agreement fails to satisfy the procedural or "form" requirements of an exception in the statute or regulations. We do not intend to apply the alternative method for compliance to other requirements such as compensation that is fair market value, not related to volume or value of referrals, or set in advance, etc. What we have in mind, for example, is a situation in which parties are missing a signature but every other requirement of the exception for personal service arrangements is satisfied. In such a case, provided that there is full disclosure, the missing signature is inadvertent, and other conditions for alternative compliance described here are satisfied, the alternative method for compliance would be met and the parties would comply with the exception.

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The alternative method for compliance with the physician self-referral prohibition would provide that, if an arrangement does not meet all of the existing prescribed criteria of an exception, the arrangement nevertheless would meet the exception if: (1) the facts and circumstances of the arrangement are self-disclosed by the parties to us; (2) we determine that the arrangement satisfied all but the prescribed procedural or "form" requirements of the exception at the time of the referral for DHS at issue and at the time of the claim for such DHS; (3) the failure to meet all the prescribed criteria of the

exception was inadvertent; (4) the referral for DHS and the claim for DHS were not made with knowledge that one or more of the prescribed criteria of the exception were not met (consistent with other exceptions, we would apply the same knowledge standard as that applicable under the False Claims Act); (5) the parties have brought (or will bring as soon as possible) the arrangement into complete compliance with the prescribed criteria of the exception or have terminated (or will terminate as soon as possible) the financial relationship between or among them; (6) the arrangement did not pose a risk of program or patient abuse; (7) no more than a set amount of time had passed since the time of the original noncompliance with the prescribed criteria; and (8) the arrangement at issue is not the subject of an ongoing Federal investigation or other proceeding (including, but not limited to, an enforcement matter). We would consider there to be an "inadvertent" failure to meet all of the prescribed criteria in an exception only where there was an innocent or unintentional mistake. We would rely on our authority under section 1877(b)(4) of the Act to implement an alternative compliance policy, and we would include requirements that are contained in all exceptions that we promulgate under that authority (including, but not limited to, the requirement that the arrangement not violate the anti-kickback statute).

We believe that if we were to adopt an alternative compliance method policy for certain exceptions, with the criteria specified above, the determination of whether an arrangement meets the terms of an exception despite not meeting all of the prescribed criteria of an exception should be at our sole discretion and not subject to further administrative or judicial review. We caution that we would retain the discretion as to whether to make such a determination; parties would have no right to receive such a

determination and no time period by which we would be required to issue a determination. We further caution that, because we would retain sole authority to determine that an arrangement that failed to satisfy all of the prescribed procedural or "form" criteria of an exception meets the conditions for the alternative method for compliance, and because of the proposed requirements that: (1) the failure to meet all of the prescribed criteria of the exception was inadvertent; and (2) the referral for DHS and the claim for DHS were not made with knowledge that one or more of the prescribed criteria of the exception were not met, parties to an arrangement would not be able to refer or bill for DHS with the knowledge that the arrangement did not comply with all of the prescribed criteria of an exception and then later claim in response to an enforcement action that they believed that their conduct was proper because, in their view, the arrangement would have met the criteria for the alternative method for compliance with the prescribed criteria of an exception. In fact, if our proposal were to be adopted and a DHS entity were to submit a claim for Medicare payment with the knowledge that its financial relationship with the referring physician (or his or her immediate family member) did not meet the prescribed criteria of any exception, and did so in advance of any determination from us that the arrangement met the alternative method for compliance, it could be found liable under the False Claims Act.

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We are especially interested in comments regarding: whether we should adopt an alternative compliance method policy, and if so, the exceptions for which the policy should be applicable; the conditions that must be met in order to obtain a favorable determination that an arrangement that does not meet all of the prescribed criteria of an exception nevertheless satisfies the alternative method of compliance with the exception;

the manner (for example, advisory opinion) for making such a determination; the length of time during which the alternative method option would be available (that is, the length of time that a party would have to discover that an arrangement was out of compliance with the prescribed criteria of an exception and seek protection under the alternative compliance method policy); and, whether, having received a favorable determination that an arrangement satisfied the alternative method of compliance (essentially, that the arrangement was deemed to have met the prescribed criteria of an exception), an entity should be precluded for a period of time from receiving another favorable determination with respect to an arrangement that (1) failed to meet the prescribed criteria of the same exception (or similar criteria of another exception) and (2) that was entered into after the date the arrangement that received the favorable determination was entered into by the entity. We are also interested in comments as to whether each eligible exception should specify which criterion or criteria an arrangement can fail to meet and nevertheless still qualify under the alternative method as satisfying the exception (for example, specifying in several exceptions that an arrangement that is missing a signature can nevertheless qualify for the alternative compliance method), or whether, in addition to or in lieu thereof, we should provide that an arrangement may qualify for the alternative compliance method if we make a determination that the arrangement substantially complied with the prescribed criteria and met all of the other alternative criteria. We are specifically seeking comment on what, if any, additional requirements or standards should be met where an arrangement fails to satisfy a procedural or "form" requirement of an exception. For example, we would like comments on whether we should require other documentary proof of the parties' intent to contract (through memoranda, electronic

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mail, or otherwise) in the case where the parties failed to obtain a necessary signature to effect the contractual arrangement.

We reiterate that we do not have the authority to waive violations of the physician self-referral statute or regulations. We do not mean to suggest that, for financial relationships that implicate the general prohibition, anything less than full compliance with one or more of the exceptions is sufficient; rather, we are proposing to provide additional and alternative criteria for some of the exceptions themselves so that some arrangements that otherwise would be noncompliant as a result of an inadvertent mistake might satisfy an exception. In effect, we are merely proposing to expand the scope of some exceptions to provide more flexibility.

Finally, we note that our proposal for an alternative compliance method policy is intended to complement, and not replace, the provisions in §411.353(f) for certain arrangements involving temporary noncompliance. Among other requirements, in order to qualify for protection under §411.353(f), the financial relationship between the entity and the referring physician must have been in compliance with an exception for at least 180 consecutive calendar days immediately preceding the date on which the financial relationship became noncompliant, and the financial relationship must have fallen out of compliance due to reasons beyond the control of the entity. In addition, claims are payable only for DHS rendered during a maximum of 90 consecutive calendar days following the date on which the financial relationship became noncompliant; the exception may be used by an entity only once every 3 years for the same referring physician; and the exception may not be used for temporary noncompliance with the exception for nonmonetary compensation or medical staff incidental benefits.

11. Services Furnished "Under Arrangements"

Our physician self-referral rules prohibit a physician from making referrals for DHS to an entity with which the physician (or an immediate family member) has a financial relationship, and prohibit the entity from billing Medicare for the DHS, unless an exception applies. In the 1998 proposed rule, we stated that we had received questions about which entities are the relevant ones for purposes of the prohibition on referrals, given that some entities only bill for services, whereas others actually directly "furnish" the services. We noted that, for example, in an "under arrangements" situation, a hospital, rural primary care hospital, SNF, HHA, or hospice program contracts with a separate provider to furnish services to the hospital's, SNF's, or other contracting entity's patients, for which the hospital, SNF or other contracting entity ultimately bills. Sections 1832, 1835(b)(1), 1861(e), and 1861(w)(1) of the Act and §413.65(i) provide for Medicare payment to providers for services furnished "under arrangements." The CMS Internet-Only Manual (IOM), publication 100-01, Medicare General Information, Eligibility and Entitlement Manual, Chapter 5, section 10.3 requires that the provider must exercise professional responsibility over an arranged-for service, using the same quality controls as applied to services furnished by the provider's salaried employees. Under §413.65(i), a provider-based hospital department may not provide all of its services under arrangements. Therefore, a hospital department may not contract out all of its patient care services.

We stated in the 1998 proposed rule that, absent an exception, the referral prohibition applies to a physician's DHS referrals to any entity that directly furnishes

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DHS to Medicare or Medicaid patients. We stated that a physician can have an incentive to overutilize services if he or she has a financial relationship with the entity that directly furnishes DHS, even if this is not the entity ultimately billing for the services. In these situations, the physician can potentially realize a profit from each referral based on the fact that the DHS will, in essence, be sold to the entity that bills (63 FR 1707).

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Notwithstanding our statements in the 1998 proposed rule, we have interpreted the definition of "entity" at §411.351 as including only the person or entity that bills Medicare for the DHS, and not the person or entity that performs the DHS (where the person or entity performing the DHS is not the person or entity billing for it).

We continue to have concerns with services provided under arrangements to hospitals and other providers. We believe that the risk of overutilization that we identified in the 1998 proposed rule has continued, particularly with hospital outpatient services for which Medicare pays on a per-service basis. That is, we pay a hospital separately for each clinical laboratory test, for each therapy service, and for the vast majority of radiology and other imaging services. We have received anecdotal reports of hospital and physician joint ventures that provide hospital imaging services formerly provided by the hospital directly. There appears to be no legitimate reason for these arranged for services other than to allow referring physicians an opportunity to make money on referrals for separately payable services. Many of the services furnished by the joint venture were previously furnished directly by the hospitals, and in most cases, could continue to be furnished directly by hospitals. We are also concerned that the services furnished under arrangements to a hospital are furnished in a less medically-intensive setting than the hospital, but billed at higher outpatient hospital PPS rates, which not only costs the

Medicare program more, but also costs Medicare beneficiaries more in the form of higher deductibles and coinsurance. Often, physician specialists who order services for their hospital patients set up joint ventures, frequently including as an owner a hospital to which the physicians refer patients. The joint venture often owns an entity that furnishes medically less intensive services than a hospital, such as an ASC, an IDTF, or a physician office. The entity may even be located in a hospital building in space leased by the hospital to the joint venture, whether owned by physicians alone or with the hospital. It appears that the use of these arrangements may be little more than a method to share hospital revenues with referring physicians in spite of unnecessary costs to the program and to beneficiaries.

We believe that more and more procedures are being performed as arranged for hospital services. The provider community is well aware that, effective for services furnished on or after January 1, 2008, Medicare may pay more for all hospital outpatient surgical procedures than for the same procedures billed by ASCs under the revised ASC payment system required by section 626(b) of the MMA. (In the CY 2007 OPPS/ASC proposed rule (71 FR 49635), we proposed that payment for an ASC surgical procedure would be made at 62 percent of the payment for the same procedure under the OPPS (71 FR 49656).)

After the close of the Phase II comment period, the Medicare Payment Advisory Commission (MedPAC), in its March 2005 Report to Congress, recommended that the Secretary "should expand the definition of physician ownership in the physician self-referral law to include interests in an entity that derives a substantial proportion of its revenue from a provider of designated health services." Specifically, MedPAC wrote:

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

(See http://www.medpac.gov/publications/congressional_reports/Mar05_EntireReport.pdf, at page 170.) We agree with the concerns of MedPAC and a commenter to the Phase II interim final rule that arrangements structured so that referring physicians own leasing, staffing, and similar entities that furnish items and services to entities furnishing DHS but do not submit claims, raise significant concerns under the fraud and abuse laws. We believe such arrangements to be contrary to the plain intent of the physician self-referral law. Arrangements so structured are particularly problematic because referrals by physician-owners of leasing, staffing, and similar entities to a contracting DHS entity can significantly increase the physician-owned entity's profits and investor returns, creating incentives for overutilization and corrupting medical decision-making.

We are attempting to determine the best approach to prohibit certain arrangements under which physicians supply items and services to DHS entities. We note that some of the arrangements described by MedPAC are subject to the physician self-referral prohibition and more may become subject to the physician self-referral prohibition through provisions we may implement in the upcoming Phase III final rule.

Although MedPAC recommended that the definition of physician ownership subject to the physician self-referral prohibition be expanded to include any entity that derives a substantial proportion of its revenue from a provider of DHS, we are proposing

what we believe is a more straightforward approach to addressing the issue. That is, we propose to revise our definition of entity at §411.351 so that a DHS entity includes both the person or entity that performs the DHS, as well as the person or entity that submits claims or causes claims to be submitted to Medicare for the DHS. Our proposal is not meant to exclude any persons or entities that presently are considered to be DHS entities. (In this regard, we note that we propose to reorganize and delete some of the material in the current definition and are seeking comment on our proposed changes to the regulatory text.) Although we believe our proposed approach is sufficient to address abusive arrangements, we solicit comments on whether we should implement the MedPAC approach, either in some combination with our proposed approach or instead of our proposed approach. We would be particularly interested in comments related to what should constitute a "substantial" proportion of revenue derived from providing DHS.