THE ABA HEALTH LAW SECTION
THE HEALTH LAWYER
SPECIAL EDITION

STARK II - PHASE II - THE FINAL VOYAGE

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Introduction

On March 26, 2004, the Centers for Medicare and Medicaid Services ("CMS") issued the long awaited second phase of its final regulations implementing the Stark II ban on physician referrals to health care entities with which they have financial relationships. 69 Fed. Reg. 16054 (2004). Although many portions of the Phase II rule published on March 26th finalize portions of the January 1998 Stark II proposed rule, CMS did not publish Phase II as final but instead waived the notice of proposed rulemaking and published the rule as an interim final rule with a 90-day comment period. The March 26, 2004 Phase II interim final rule is effective on July 26, 2004. In accordance with Section 902 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), CMS is obligated to consider comments received on this interim final rule and publish a final rule addressing those comments within three years.

In response to numerous public comments received on the January 1998 proposed rule as well as the public comments received on Phase I, in Phase II, CMS continued its efforts to reduce the regulatory burden on the health care community as evidenced by the broadening of exceptions and the creation of new exceptions. These efforts are evidenced by:

- Broadening of the exception for academic centers;
- Revisions to the in-office ancillary services exception which ease the same building requirement by substituting a simpler more expansive set of alternative tests;
- Revisions to the physician recruitment exception;
- Creation of new exceptions for professional courtesy, intra-family referrals, charitable donations, anti-kickback safe harbors,

SPECIAL EDITION
APRIL 2004

THE HEALTH LAWYER

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The Health Lawyer (ISSN: 0736-3443) is published by the American Bar Association Health Law Section 750 N. Lake Shore Drive, Chicago, IL 60611. Address corrections should be sent to the American Bar Association, c/o Member Records.

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community-wide information systems, and temporary lapses in compliance;

- Revisions to the "set in advance" definition to permit certain common fluctuating compensation arrangements; and
- Elimination of the 1998 proposed restriction on productivity bonuses, thereby permitting employees to be paid based on personal productivity.

Notwithstanding the more flexible approach taken in both Phase I and Phase II, the health care community should stay vigilant as the physician self-referral prohibition is implicated in nearly every financial relationship between physicians and entities that furnish designated health services ("DHS"). Violations of the law have substantial financial consequences for all parties involved, regardless of the intent of the parties. Sanctions include denial of payment for DHS claims, civil monetary penalties, and exclusion from the Medicare program. The imposition of these sanctions can lead to multi-million dollar liability, and in some cases, violations could lead to liability under the False Claims Act. All providers of health care should pay close attention to the requirements of Stark, particularly in light of potential Qui Tam whistleblowers utilizing technical violations of Stark as a predicate for False Claims Act litigation.

Stark I and II - A Brief History

The original Stark self-referral prohibition was enacted in 1989 with the purpose of prohibiting physicians from referring patients for laboratory services to entities in which they had a financial interest. The self-referral ban, referred to as "Stark I" after Representative Pete Stark who introduced the legislation, went into effect on January 1, 1992. As of January 1, 1992, physicians were prohibited from referring Medicare beneficiaries for clinical laboratory services to entities with which they, or members of their immediate family, had a financial relationship. It also prohibited entities from making a claim for payment under the Medicare program for clinical laboratory services furnished pursuant to a prohibited referral.

In 1993, the Stark I ban was expanded to include additional health care services considered to be particularly susceptible to overutilization as a result of physician financial interests. The Stark II amendments also applied aspects of the ban to Medicaid beneficiaries. The 1993 amendments, now referred to as "Stark II", went into effect on January 1, 1995. Stark II prohibits physician referrals of Medicare or Medicaid beneficiaries to entities with which they, or members of their immediate family, have a financial relationship for DHS. DHS include: clinical laboratory services; physical therapy services; occupational therapy services; radiology services (including MRI, CAT scans,

and ultrasound services); radiation therapy services and supplies; durable medical equipment and supplies; parenteral and enteral nutrients, equipment and supplies; prosthetics, orthotics, and prosthetic devices and supplies; home health services; outpatient prescription drugs; and inpatient and outpatient hospitalization services. The Stark II ban also prohibits entities from making a claim for payment under the Medicare or Medicaid programs for the provision of a designated health service furnished pursuant to a prohibited referral. 42 U.S.C. 1395nn.

In August of 1995, The Health Care Financing Administration ("HCFA") published the Stark I final regulations. 60 Fed. Reg. 41923 (1995). While the Stark I final rule applied directly only to referrals for clinical laboratory services, it was expected that many of the interpretations in the Stark I final rule would apply to the other DHS as well. In January 1998, the Stark II proposed regulations were issued. Although many of the interpretations from the Stark I final rule were included in the proposed rule, the Stark II proposed rule contained significant changes. A number of these proposed changes were abandoned in Phase I of the rulemaking.

Phase I of the Stark II Final Regulations

On January 4, 2001, HCFA issued the first phase of its Stark II final regulations. 66 Fed. Reg. 856 (2001). Phase I of the rulemaking did not address all of the provisions set forth in the Stark law and it was intended that a second phase of the rulemaking would be published to address those provisions not addressed in Phase I. Phase I addressed the general prohibition and those general exceptions that are applicable to both ownership or investment interests and compensation arrangements. However, for the most part, Phase I did not address exceptions that are only applicable to ownership or investment interests and the exceptions that are only applicable to compensation arrangements. In addition to creating new general exceptions, Phase I also created new exceptions that are applicable only to compensation arrangements and also addressed the definition section of Stark. Phase I only applies to referrals of Medicare beneficiaries. With two exceptions (Section 424.22 (d), relating to home health services and Section 411.354 (d) (1) relating to the definition of set in advance), the Phase I final regulations went into effect on January 4, 2002, one full year after publication. The delayed effective date was selected in order to give individuals and entities time to restructure business arrangements in light of the Phase I requirements. For a comprehensive analysis of Stark II Final Rule-Phase I, see, *"Stark II Final Rule-Phase I A Kinder and Gentler Stark?", The Health Lawyer, Special Edition, January 2001.*

Phase II of the Stark II Interim Final Regulations

Phase II of the final regulations addresses the provisions in the Stark law not addressed in Phase I of the rulemaking process and covers additional regulatory definitions, new regulatory exceptions, and responses to the public comments on Phase I regulations. Although it was intended that Phase II would address section 1903 (s) of the Act, which applies section 1877 of the Act to referrals for Medicaid covered services, in the interest of expediting publication of Phase II, with one exception, CMS reserved the Medicaid issue for future rulemaking. The one exception is that Phase II amended the prepaid plans exception at Section 411.356(c) to cover Medicaid managed care plans.

Phase I and Phase II of the final regulations are intended to be integrated and read together as a whole. Modifications and revisions to Phase I are indicated in the Phase II preamble and corresponding regulations. The Phase I and the Phase II rules, together, supersede the 1995 final rule (60 Fed. Reg. 41914), which had been applicable to clinical laboratory services.

The General Prohibition

The Stark II self-referral ban prohibits physician referrals of Medicare or Medicaid beneficiaries to entities, with which they or members of their immediate family, have a financial relationship for DHS. Phase I of the rulemaking process implemented this general prohibition with respect to Medicare beneficiaries. Phase II contains clarifications and changes involving the interpretation of the general prohibition. For example, Phase II creates an exception for certain arrangements that have unavoidably and temporarily fallen out of compliance with other exceptions, creates an exception for intra-family referrals, modifies the group practice definition to address problems faced by group practices that fall out of compliance, and interprets the lease exceptions to permit holdover month-to-month leases for up to six months.

Indirect Financial Relationships Clarified

The existence of a financial relationship between the referring physician (or an immediate family member) and the entity furnishing DHS is the factual predicate triggering application of the general Stark prohibition. The statute expressly contemplates that financial relationships include both direct and indirect ownership and investment interests and direct and indirect compensation arrangements between referring physicians and entities furnishing DHS. Section 1877 (a) (2) and Section 1877 (h) (I) of the Social Security Act. Phase I of the rulemaking established a three-part test that defines the universe of indirect compensation arrangements that may potentially trigger disallowance of claims and penalties. Phase I also created an exception for the subset

of indirect compensation arrangements that will not trigger disallowances or penalties. 42 CFR Section 411.354 (c) (2) and 411.357 (p).

Definition of Indirect Compensation Arrangement

The first step for determining whether an arrangement is an indirect compensation arrangement is to determine whether the relationship meets the three-part indirect compensation arrangement test. Accordingly, an indirect compensation arrangement exists if the following three elements are met:

- Between the referring physician (or immediate family member) and the entity furnishing DHS there exists an unbroken chain of any number (but not fewer than one) of persons or entities that have financial relationships (either ownership or investment interests or compensation arrangements) between them;
- The referring physician (or immediate family member) receives aggregate compensation from the person or entity in the chain with which the physician (or immediate family member) has a direct financial relationship that varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician for the entity furnishing DHS, regardless of whether the individual unit of compensation satisfies the special rules on unit-based compensation;
- The entity furnishing DHS has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician (or immediate family member) receives aggregate compensation that varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS.

42 CFR 411.354 (c) (2).

Indirect Compensation Arrangement Exception

If a relationship meets the three-part indirect compensation arrangement definition, the second step is to determine whether the relationship falls within the indirect compensation arrangement exception. In order for an indirect compensation arrangement to meet this exception, the following requirements must be met:

- The compensation received by the referring physician (or immediate family member) described in 411.354 (c) (2) (ii) is fair market value for services and items actually provided and not determined in any manner that takes into account the value or volume of referrals or other business generated by the referring physician for the entity furnishing DHS;
- The compensation arrangement described in 411.354 (c) (2) (ii) is set out in writing, signed by the parties, and specifies the services covered by the arrangement, except in the case of a *bona fide* employment relationship between an employer and an employee, in which case the arrangement need not be set out in a written contract, but must be for identifiable services and be commercially reasonable even if no referrals are made to the employer;
- The compensation arrangement does not violate the anti-kickback statute, or any Federal or State law or regulation governing billing or claims submission.

42 CFR 411.357 (p).

The Definition of Indirect Compensation Arrangement Includes Time Based Or Per-Unit Compensation

Many who commented expressed confusion regarding the interplay between the definition of an indirect compensation arrangement (which looks at whether the referring physician's aggregate compensation varies with, or otherwise takes into account "the volume of value of referrals" generated by the referring physician) and Section 411.354 (d) (2) and (3) which both describe certain compensation, such as time based and unit-of service based payments, that will be deemed not to take into account "the volume or value of referrals," or " other business generated between the parties." In response to such confusion, Phase II modifies the language of the definition of indirect compensation arrangement to make clear that CMS intends to include any compensation including time-based or unit-of service based compensation where the aggregate compensation received by the referring physician varies with or, otherwise takes into account, "the volume or value of referrals" or "other business generated between the parties." This is true notwithstanding whether the individual unit of compensation qualifies under the special rules on unit-based compensation pursuant to Section 411.354 (d) (2) and Section 411.354 (d) (3). 66 Fed Reg. at 16059, 42 CFR Section 411.354 (c) (2) (ii).

The preamble explains that since time-based or unit-of-service based compensation will always vary with the volume or value of services when considered in the aggregate, these compensation arrangements can constitute "indirect compensation arrangements." However, these compensation arrangements would be excluded under the indirect compensation arrangement exception at Section 411.357(p) where the compensation is fair market value and does not reflect the volume or value of referrals or other business generated and the other conditions of the exception are satisfied. CMS explained that while the ultimate result may be the same (time based and unit-of-service based arrangements are generally permitted if they are fair market value without reference to referrals), this concept is more consistent with the statutory treatment of direct compensation arrangements. 69 Fed. Reg. at 16059.

In summary, in response to the confusion expressed after Phase I, Phase II modifies the definition of an indirect compensation arrangement to make clear that the special rules on unit-based compensation do not apply when analyzing whether a relationship is considered an indirect compensation arrangement. These rules, however, do apply when analyzing whether an indirect compensation arrangement fits within the indirect compensation arrangement exception.

Referring Physicians Stand in the Shoes of Their Wholly Owned PCs

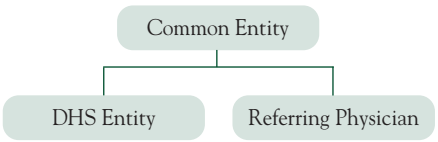
The definition of referring physician has been modified in Phase II to clarify that a referring physician may be treated as "standing in the shoes" of his wholly owned professional corporation (PC). 42 CFR 411.354. This clarification was made in response to commenters who noted that the fact that a physician practices through a wholly owned PC should not convert a direct financial relationship with a DHS entity into an indirect relationship. The preamble explains that the revised definition will make it simpler for physicians and others to evaluate their financial relationships and the application of exceptions under the Section 1877 of the Act. 69 Fed. Reg. at 16060.

The preamble comments also make clear that this modification does not apply in the group practice context. For example, when a hospital contracts with a group practice for services, an indirect compensation arrangement is created between the DHS entity and the referring physicians who are members of the group because the physicians do not stand in the shoes of their group practices. CMS believes that allowing group practice members to stand in the shoes of their group practices would be inconsistent with the compensation exceptions. 69 Fed. Reg. at 16060.

Common Ownership Does Not Create Indirect Ownership but May Create an Indirect Compensation Arrangement

Phase II modifies the language contained in the indirect ownership interest definition to make clear that common ownership or investment interest in an entity does not, by itself, establish an indirect ownership or investment interest by one common owner or investor in another common owner or investor. 42 CFR 411.354 (b)(5)(iii). The preamble comments do, however, note that common ownership in an entity may create an indirect compensation arrangement.

To illustrate this concept, the Phase II preamble states that if a DHS entity and a referring physician jointly own an entity, such co-ownership creates a link in the chain of financial relationships between the DHS entity and the referring physician.



CMS notes, however, that even if the unbroken chain element of the indirect compensation arrangement test exists, in order to meet the indirect compensation definition, the two other elements must be satisfied (i.e., knowledge, varying aggregate compensation with referrals). CMS does state that it would expect that most joint ownership of non-DHS entities would not meet the definition of an indirect compensation arrangement so long as the physician's aggregate return on investment in the co-owned entity did not vary with or otherwise take into account the volume or value of referrals to, or other business generated for, the DHS entity (not the co-owned entity).

Additionally, the preamble commentary provides an example of a common venture that could meet the indirect compensation arrangement definition, which would then need to meet the indirect compensation arrangement exception. The example given is that of a co-ownership arrangement in an imaging equipment leasing company between a hospital (DHS entity) and a referring physician. The preamble provides that the common ownership of the venture may create an indirect compensation arrangement if the physician's aggregate payout from the leasing company varies with, or otherwise takes into account, the volume of imaging business that the physician generates for the hospital. According to the Phase II preamble, in general, if the rental payment (commonly a "per click" payment) by the hospital to the leasing company is fair market value and the "per click" fee does not vary over the term of the agreement and does not otherwise reflect the volume or value of referrals, the indirect compensation arrangement would be excepted. Parties structuring these relationships, however, should still be mindful that such arrangements may run afoul of the anti-kickback statute, as noted in the preamble commentary. 69 Fed. Reg. at 16061.

Definition of Referral Remains Untouched

Phase I of the rulemaking excluded from the definition of "referral", services personally performed by the referring physician. However, the definition includes services provided by a physician's employees, co-workers, or independent contractors. CMS solicited comments in Phase I of the rulemaking on whether, and under what circumstances, services performed by a physician's employee could be treated as the physician's personally performed services. 66 Fed. Reg. at 872. After consideration of this issue, CMS adhered to its original determination that "incident to" services, as well as services performed by the physician's employees, are referrals within the meaning of Section 1877 of the Act. 69

Fed. Reg. at 16063. Although Phase II declined to narrow the definition of "referral", many other aspects interpret the statutory and regulatory exceptions broadly.

In addition, the Phase II preamble clarifies that a referral will be imputed to a physician if he/she has controlled or influenced the person who makes the referral (for example, nurse practitioners or physician assistants). 66 Fed. Reg. at 16064.

Physician Compensation

Section 1877 of the Act provides various exceptions for physician compensation, which vary based upon whether the physicians are physicians in a group practice, employees, or independent contractors. Phase I of the rulemaking also created new regulatory exceptions for fair market value compensation paid to employees or independent contractors and compensation for academic medical center physicians. In response to the Phase I regulations, CMS received many comments regarding physician compensation with a common theme that there should only be one set of conditions applicable to physician compensation. That is, the commenters felt that the same set of rules should apply to group practices, employees, independent contractors, and compensation arrangements that are structured under the fair market value and academic medical center exceptions. In response to these commenters, the Phase II preamble makes clear that the statute itself favors group practices by allowing group practices to divide revenues among their physicians in ways that are very different from the ways in which other DHS entities are allowed to share revenues with employed and independent contractor physicians. 69 Fed. Reg. at 16066. Specifically, with regard to "incident to" services, the statute allows group practices to compensate physicians regardless of status of owner, employee, or independent contractor. Moreover, the statute allows group practices to compensate indirectly for other DHS referrals. Section 1877 (h) (4) (B) (i). In an attempt to equalize the other aspects of physician compensation, with respect to physician compensation outside of the group practice context, Phase II sets forth several modifications and clarifications in the regulations and preamble commentary. Notwithstanding these attempts, caution should still be taken when analyzing physician compensation, as the specific terms and conditions of each exception continue to differ in some respects.

Modifications and clarifications were made in Phase II to equalize, to the extent possible, the important conditions in the other main physician compensation exceptions. As a result, under the employment, personal services, fair market value, and academic medical centers exceptions, physician compensation can be based on the following:

- A percentage of revenues or collections for personally performed services;
- Productivity bonuses on any personally performed services; and
- Risk sharing payments made pursuant to participation in a physician incentive plan related to health plan enrollees.

66 Fed. Reg. at 16066-16067.

Percentage Compensation - Set In Advance

Both the personal service arrangement exception and fair market value exception, the two main exceptions utilized by independent contractors, require that the compensation that the physician receives is "set in advance." 42 CFR 411.357(d) and 42 CFR 411.357(l). Phase I interpreted "set in advance" to prohibit most percentage compensation arrangements, thereby restricting compensation structures for physicians practicing as independent contractors relying upon these compensation exceptions. Phase II modifies this interpretation to permit some percentage compensation arrangements. As a result, like their group practice and employee counterparts, independent contractors can now receive limited forms of percentage compensation. Accordingly, the definition of set in advance has been tailored to allow certain percentage compensation payments and has been modified to clarify that the formula for calculating percentage compensation must be established with specificity prospectively, must be objectively verifiable, and may not be changed based on the volume or value of referrals or other business generated by the referring physician over the course of the agreement between the parties. 42 CFR 411.354(d)(1). As a result of the changes to the "set in advance" definition, academic physicians receiving payment pursuant to the academic medical center exception (which also contains the "set in advance" requirement), can also receive certain limited forms of percentage compensation. 69 Fed. Reg. at 16066.

Productivity Bonuses - Other Business Generated

In response to Phase I, commenters also expressed concern regarding the availability of physicians to receive productivity bonuses, outside of the group practice/in-office ancillary context. In Phase I, CMS thought it addressed the issue by defining "referral" to include only DHS referrals, excluding personally performed DHS. However, because CMS also interpreted "other business generated" to include any health care business, including private pay business (which many commenters construed to encompass personally performed services), many commenters believed that this meant that independent contractors (or academic physicians) could not be paid productivity bonuses based upon their personally performed services. Phase II modifies the regulations to clarify that it was not the intent to of Congress or CMS to include personally performed services in the definition of "other business generated." Physicians, however, must keep in mind that any technical component of a service corresponding

to the personally performed service is considered "other business generated." 42 CFR 411.354 (d) (3). Importantly, Phase II now makes clear that all physicians, whether employees, independent contractors, or academic medical center physicians, can be paid productivity bonuses based on work they personally perform. 69 Fed. Reg. at 16067-16068.

Physician Incentive Plans and Other Risk-Sharing Arrangements

Another area of concern raised by commenters involved the perceived inconsistency relating to payments made to physicians pursuant to risk-sharing arrangements. After Phase I, commenters were confused because the statutory personal service arrangement exception contains an express provision allowing independent contractor physicians to be compensated under a physician incentive plan. However, the group practice, employee, fair market value, and academic medical center exceptions do not contain this same language. In response to this confusion, Phase II clarifies that the regulatory exception created in Phase I for compensation under a risk-sharing arrangement can be used by all physicians, regardless of whether the physician is a member of a group, employed, an independent contractor, or an academic physician. 69 Fed. Reg. at 16067, 42 CFR 411.357 (n).

Exceptions Applicable to Ownership and Compensation Arrangements

The In-Office Ancillary Services Exception

The in-office ancillary services exception has arguably been the single most important exception in the Stark law. This exception prompted numerous comments in response to the 1998 Stark II proposed rule as well as several comments in response to Phase I of the rulemaking. The exception is designed to protect the in-office provision of certain DHS that are genuinely ancillary to the medical services provided by the practice. The in-office ancillary exception exempts services personally provided by the referring physician, a physician who is a member of the same group practice as the referring physician, an individual that is supervised by the referring physician, or if the referring physician is in a group practice, by another physician in the group practice, provided that the supervision complies with all of the Medicare payment and coverage rules for the services. In addition, the exception contains a location and a billing requirement. The in-office ancillary services exception covers nearly all DHS except durable medical equipment (other than a few carve outs for certain types of infusion pumps, blood glucose monitors, and certain other devices that provide assistance to patients leaving the physician's office), and parenteral and enteral nutrients, equipment and supplies. 42 CFR 411.355 (b).

Although Phase I of the rulemaking made several significant changes to the in-office ancillary exception, the significant changes made in Phase II focus only on the "same building" test contained in the location requirement. Phase II did not make any changes to the scope of DHS applicable to the in-office ancillary services exception, or any changes to the supervision or billing requirements, apart from the clarification that solo practitioners can furnish DHS through a shared facility in the same building as long as all of the other requirements of the in-office ancillary services exception are met. 69 Fed. Reg. at 16071.

Same Building Requirement – Affords Greater Flexibility

Under the in-office ancillary services exception, DHS must be furnished to patients in the same building where the referring physicians provide their regular medical services, or in the case of a group practice, in a centralized building. 42 CFR 411.355 (b) (2) (i) and (ii). These location rules were designed to give physicians and group practices an important opportunity to provide *bona fide* in-office ancillary DHS to their patients, while at the same time preventing group practices from using the exception to operate self-referred DHS enterprises. A group practice can satisfy the location requirement by either meeting the "same building" test or the "centralized building" test. Although many commenters objected to components of the "centralized building" test, which require full-time, exclusive ownership or occupancy of the centralized space (to prevent abuse of off-site DHS arrangements such as part time MRI or CAT scan rentals), Phase II did not make any changes to this requirement. 42 CFR 411.351.

Phase II of the regulations develops three (3) new alternative "same building" tests to replace the Phase I three-part test in its entirety. Only one of the three (3) tests must be satisfied to meet the "same building" requirement and all three (3) tests are available to both solo practitioners and group practice physicians. 69. Fed. Reg. at 16072, 42 CFR 411.355 (b) (2). According to the preamble, the new tests were developed to provide greater flexibility for physicians and were established to provide a more sufficient "bright line" approach. CMS contends that virtually all legitimate arrangements that complied with the Phase I three-part test should also qualify under one of the new tests, however, arrangements that may have complied with the Phase I test, but that do not meet any of the new tests, should be restructured (or unwound) before July 26, 2004. 69 Fed. Reg. at 16072. Under all three (3) tests, referring physicians or group practices must have offices in the building that are normally open to their patients a requisite number of hours per week. All three (3) tests also require that the physician regularly practices medicine and furnishes physician services for a minimum number of hours per week in that office (unfilled appointments cancellations and occasional gaps are permitted).

Alternative Test 1– Relief for Radiologists and Oncologists

Under the first new alternative test, a DHS is furnished in the "same building" if:

1. The referring physician or his/her group practice has an office that is normally open to their patients at least 35 hours per week; and
2. The referring physician or one or more members of his or her group regularly practices medicine and furnishes physician services to patients in that office at least 30 hours per week. The 30 hours must include *some* physician services that are unrelated to the furnishing of DHS, whether Federal or private pay, even if the unrelated physician services may lead to the ordering of DHS.

42 CFR 411.355(b)(2)(i)(A).

In response to Phase I, CMS recognized that the "same building" requirement did not adequately take into account the nature of certain specialty practices like radiology and oncology that inherently consist of the furnishing of a substantial amount of DHS. Accordingly, CMS expects that this new test should address the concerns raised by these groups as this test does not require that the physician services unrelated to the furnishing of DHS be "substantial". The new test provides a lower threshold (i.e., providing "some" unrelated services). The preamble notes that interpretations or reads of tests are generally considered DHS and therefore will not count as "some" physician services unrelated to the furnishing of DHS. 69 Fed. Reg. at 16075. CMS declined to define the term "some" but noted that it should be interpreted in its common sense meaning. 69 Fed. Reg. at 16073.

Alternative Test 2

Under the second alternative test, a DHS is furnished in the "same building" if:

1. The patient receiving the DHS usually receives physician services from the referring physician or members of his or her group practice; and
2. The referring physician or the referring physician's group practice owns or rents an office that is normally open to the physician's or group's patients for medical services at least 8 hours per week; and
3. The referring physician regularly practices medicine and furnishes physician services at least 6 hours per week. The 6 hours must include *some* physician services that are unrelated to the furnishing of DHS, whether Federal or private pay, even if the unrelated physician services may lead to the ordering of DHS.

42 CFR 411.355(b)(2)(i)(B).

Under this alternative, the services provided by members of the referring physician's group do not count toward the six (6) hour threshold. This test also mandates that the building must be one in which the patient receiving the DHS usually sees the referring physician (or a member of his or her group). According to the preamble commentary, this test is generally designed to describe a building where a referring physician practices medicine at least one (1) day per week and it is the principal place in which the patient receives services. 69 Fed Reg. at 16073.

Alternative Test 3–Presence in the Building Test

Under the third alternative test, a DHS is furnished in the "same building" if:

1. The referring physician is present and orders the DHS during a patient visit on the premises (as set forth in 2 below) or the referring physician or member of the referring physician's group practice is present while the DHS is furnished during occupancy of the premises (as set forth in 2 below);
2. The referring physician or the referring physician's group practice owns or rents an office that is normally open to the physician's or group's patients for medical services at least 8 hours per week; and
3. The referring physician or one or more members of the referring physician's group practice regularly practices medicine and furnishes physician services to patients at least 6 hours per week. The 6 hours must include *some* physician services that are unrelated to the furnishing of DHS, whether Federal or private pay, even if the unrelated physician services may lead to the ordering of DHS.

42 CFR 411.355(b)(2)(i)(C).

Theoretically, this test describes buildings that referring physicians, or group practice members, provide physician services to patients at least 1 day a week and the DHS are ordered during a patient visit or the physicians are present during the furnishing of DHS. This test requires presence in the building but, as the preamble notes, the presence does not have to be in the same space or part of the building. 69 Fed. Reg. at 16073.

Same Building - Special Rule for Home Services Remains Narrow

Phase I of the rulemaking created a special rule under the in-office ancillary services exception for home care physicians. Specifically, this special rule allows home care physicians whose principal medical practice consists of treating patients in their private homes (a private home does not include nursing, long-term care, or other facility or institution) to meet the same building requirement if the physician (or accompanying staff member) provides a DHS contemporaneously with a physician service that is not a DHS. 42 CFR 411.355(b)(6). In Phase I, CMS

solicited comments on whether home care physicians require additional special rules. 66 Fed. Reg. at 888. In Phase II, CMS declined to relax the standards as the exception was intended to create a narrow rule for a particular group of physicians who otherwise would be precluded from utilizing the in-office ancillary services exception because they would have no qualifying building. The preamble does clarify that independent living facilities and assistant living facilities could qualify as a private residence if the patient occupies the premises as his or her residence though ownership or lease and has the right to exclude others from the premises. 69 Fed. Reg at 16074, 42 CFR 411.355 (b)(6).

Purchased Diagnostic Tests Allowed

The Phase II regulations modify the definition of "entity" to exclude physicians or group practices that bill for purchased diagnostic tests in accordance with Medicare's purchased diagnostic testing rules. 42 CFR 411.351. This modification was made by CMS as Phase I of the regulations did not adequately provide for the furnishing of these services, which was an unintended outcome. As a result of this modification, physicians and group practices may purchase the technical component of mobile services, which are not buildings for purposes of the in-office ancillary services exception, so long as they are billed pursuant to Section 414.50 and the purchased diagnostic testing rules at section 3060 of the Medicare Carriers Manual. 69 Fed. Reg. at 16073.

Group Practice Definition - Slightly Modified

Although the group practice definition contained in 42 CFR 411.352 is not an exception to the self-referral prohibition in and of itself, it has significant meaning to any group of physicians that want to take advantage of the in-office ancillary services and physician services exceptions. After the publication of the Stark II proposed rule, many commenters expressed great concern that CMS was trying to micromanage group practices. In response to these concerns, Phase I of the final regulations revised many of the standards in an attempt to minimize the impact on common group practices. 66. Fed. Reg. at 860-861. CMS has made no major changes in Phase II of the final regulations, however, slight modifications and clarifications were made providing a little more flexibility for groups.

Primary Purpose and Single Legal Entity Test - Clarified

In Phase II, modifications were made to the "primary purpose" test to make clear that the relevant inquiry in the single legal entity requirement is whether the group practice is a single legal entity operating primarily for the purpose of being a physician group practice, not whether this was the purpose at the time of formation. 42 CFR 411.352(a). CMS, however, emphasizes that an entity that has a substantial purpose other than operating a physician group practice, such as operating hospital, will not qualify under the test. Accordingly, hospitals that employ two or more physicians are not physician group practices for purposes of Stark. A hospital, however, may own or acquire a separate physician group practice that qualifies as a group practice and would be eligible for the in-office ancillary services exception. 69 Fed. Reg. at 16077.

The Phase II regulations also make modifications to the single legal entity test in order to accommodate group practices that operate across State lines. The regulations now allow groups that use multiple legal entities solely to comply with jurisdictional licensing laws in contiguous States to be considered a single legal entity if the entities are identical as to ownership, governance, and operation. CMS also notes that the States in which the group operates need to be contiguous, but each State need not be contiguous with every other State. 69 Fed. Reg. at 16076, 42 CFR 411.352(a).

Two or More Physicians Test - Clarified

Among other requirements, in order for a group of physicians to qualify for the group practice definition, the group practice must have at least two physicians who are members of the group. 42 CFR 411.352(b). Members of the group are defined as direct or indirect owners, employees, locum tenens physicians, or, in certain circumstances, on call physicians. Independent contractors are not considered members of the group. 42 CFR 411.351. In response to commenters that discerned no reason to require the second physician to be a full-time employee for purposes of the "two part test", CMS makes clear that physicians who are counted for the "two or more physicians" test can be part-time employed physicians. 69 Fed. Reg. at 16077.

New Grace Period - Created

As part of the group practice definition, section 411.352(d) (5) establishes a 12-month grace period for start-up groups to come into compliance with the group practice definition. The grace period does not apply when an existing group practice adds new members or reorganizes its practice. Several physician practice organizations commented that the application of this rule could cause group practices that add a new member to lose their group practice designations for a period of time after the new member joins the group because the new physician could skew the "substantially all" test. This test requires that at least 75 percent of patient care services provided by group members be provided through the group and billed under a number assigned to the group. The commenters noted that there are frequent delays in obtaining Medicare billing numbers for newly employed physicians. The physician organizations complained that the current rule discouraged existing group practices from bringing in younger physicians. 69 Fed. Reg. at 16078.

In response to such commenters, CMS concurred that some accommodation should be made for group practices

that add new members, as long as the group practice continues to fit squarely within the definition. In order to make this accommodation, a new exception was created to provide that if the addition of a new member who has relocated his or her practice to an existing group practice would cause the existing group to fall out of compliance with the requirements of the "substantially all" test, the group practice will be afforded 12 months to come back into full compliance. In order for groups to use this new exception, for the extra 12-month period, the group practice must be fully compliant with the "substantially all" test if the new member is not counted as a member and the new physician's employment with, or ownership or investment interest in, the group practice must be documented in writing before commencement of the new employment or ownership relationship. 42 CFR 411.352 (d) (6). Notably, in order to prevent abuse by groups adding members thru mergers, this new rule is limited to new members who have relocated their medical practices. 69 Fed. Reg. at 16078.

The Unified Business Test is Softened Again

The group practice definition also contains a requirement that a group practice be a "unified business." The "unified business" test is intended to be somewhat flexible, accommodating a myriad of group practice arrangements, but at the same time ensuring that a group practice is organized and operated on a *bona fide* basis as single intergraded business enterprise. Phase I of the rulemaking dramatically revised the Stark II proposed rule for the "unified business" requirement because it was thought to discourage beneficial integration of group practices as many felt it invalidated many *bona fide* and common group practice structures. Under Phase I, the "unified business test" incorporated a three part test which required that groups (1) engage in centralized decision making by a body that maintains effective control over the group's assets and liabilities; (2) consolidate billing, accounting, and financial reporting; and (3) centralize utilization review. 66 Fed. Reg. at 906. In response to the Phase I three part "unified business" test, several commenters asked that the third requirement of centralized utilization review either be modified or deleted because many group practices do not perform utilization review. Once again, CMS responded favorably to commenters and deleted the "centralized utilization review" requirement. 69 Fed. Reg. at 16080, 42 CFR 411.352 (f). This change will provide relief for those groups that otherwise satisfied the "unified business" test but that did not engage in utilization review activities.

Documentation of Compliance With Group Practice Requirements

Group practices that choose to take advantage of the special treatment that the Stark law affords them must be prepared to demonstrate compliance with relevant statutory and regulatory standards. In this regard, if requested by the Secretary, group practices are required to provide documentation of the total time each member spends on patient care services, and to maintain documentation supporting compliance with the "substantially all" test. 42 CFR 411.352 (d) (2). The "substantially all" test is intended to guarantee that the group practice members are providing a substantial amount of their services through the group. Groups can document compliance by any reasonable means, including without limitation, time cards, appointment schedules, personal diaries, or other reasonable means that are fixed in advance of the performance of the services being measured, uniformly applied over time, and verifiable. Groups are also required to document, in writing, a new member's employment with, or ownership or investment in, the group practice before the new relationship commences. 42 CFR 411.352 (d) (2). In light of the fact that technical Stark violations have been the impetus in recent Federal False Claims Act litigation, all group practices should comply with these documentation requirements. Group practices that actively engage in compliance may want to consider incorporating Stark's documentation requirements into their existing compliance plans.

Clarification That Physicians in the Group May Be Paid a Bonus or Profit Share Based Directly on "Incident To" Services

In response to Phase I, many commenters expressed confusion with regard to the ability of physicians in the group to be paid a bonus or profit share based upon "incident to" services. Accordingly, in Phase II, CMS modified the regulatory language contained in Section 411.352 (i) to now make clear that a physician in the group practice may receive a profit share or productivity bonus based *directly* on services that he or she personally performs *and* services that are "incident to" his or her personally performed services. 69 Fed. Reg. at 16080, 42 CFR 411.352 (i). CMS does caution, however, that if a group practice instead uses the *bona fide* employment, personal services arrangements, or fair market value exceptions to protect referrals from an independent contractor to the group practice, the compensation applicable under those exceptions must be satisfied. 69 Fed. Reg. at 16080

The Prepaid Plans Exception Expanded to Include Medicaid Organizations

Although it was intended that Phase II of the final regulations would address referrals for Medicaid covered services, in the interest of expediting publication of Phase II, with one notable exception, CMS reserved the Medicaid issue for future rulemaking. Phase II amends the prepaid plans exception to now cover Medicaid managed care plans. CMS expanded this exception because it recognized the prevalence of managed care in the Medicaid program and believed it would be useful and appropriate to expand the prepaid plans exception to

include referrals of Medicaid enrollees in Medicaid managed care plans. In effect, this exception makes clear that such referrals will not result in denial of payment. 69 Fed. Reg. at 16081, 42 CFR 411.355(c).

General Exceptions Related Only to Ownership or Investments in Publicly Traded Securities and Mutual Funds

For the most part, Phase I of the rulemaking did not address the general exceptions contained in Act, which relate to ownership or investment interests in publicly traded securities and mutual funds. Under the Act, an ownership in certain publicly traded securities and mutual funds will be excepted from the self-referral prohibition. To qualify for this exception: (1) the securities must be securities that may be purchased on terms generally available to the public; (2) the securities must be listed on the New York Stock Exchange, or any regional exchange in which quotations are published on a daily basis, or be foreign securities listed on comparable exchanges or traded under the National Association of Securities Dealers automated quotation system; and (3) the ownership must be in a corporation that had shareholder equity exceeding $75 million at the end of the corporation's most recent year or the average of the last three fiscal years. Section 1877 (c) (1). Additionally, the Act permits ownership of investments in mutual funds with total assets exceeding $75 million at the end of the most recent fiscal year or the average of the last three fiscal years. Investment securities include shares or bonds, debentures, notes, or other debt instruments. Section 1877 (c) (2).

The 1998 proposed rule interpreted the requirement that the investment securities be those that "may be purchased on terms generally available to the public" to mean that at the time the physician (or immediate family member) obtained the interest, the interest could have been purchased on the open market, even if the physician (or immediate family member) acquired the interest in another manner. 69 Fed. Reg. at 16081. Phase II revises the proposed interpretation to mean that the ownership interest must be in securities that are generally available to the public at the time of the DHS referral. That is, securities acquired by a referring physician (or his or her immediate family member) prior to a public offering will fit into the exception if they are available to the public at the time of any DHS referral. 69 Fed. Reg. at 16081, 42 CFR 411.356 (a).

In addition, for purposes of the $75 million test, the 1998 proposed regulations defined stockholder equity to mean the difference in the value between corporation's total assets and total liabilities. The Phase II interim final rule adopts this interpretation. 69 Fed. Reg. at 16081.

Phase II also modifies the definition of ownership and investment interest to reflect that stock options and convertible securities will be treated as compensation, rather than ownership, if they are received as compensation for services and will remain compensation until the time that they are exercised, at which time they convert to an ownership or investment interest. 42 CFR 411.354 (b), 69 Fed. Reg. at 16062-16063, 69 Fed. Reg. at 16081. Physicians with stock options or convertible securities should make sure that their referral relationships are reviewed in the event that they exercise these options to ensure that their new ownership interests do not trigger an unexcepted relationship under the Act.

Additional Exceptions Related Only to Ownership or Investment Prohibition of the Act

Phase II of the rulemaking process makes no changes to the 1998 proposed regulations regarding ownership interests in hospitals located in Puerto Rico. Under the Act and Phase II regulations, an ownership or investment interest in a hospital located in Puerto Rico is not considered a financial relationship for purposes of Section 1877. Section 1877 (d) (1), 42 CFR 411.356(c) (2).

Rural Hospital Exception Incorporates the 18-Month Moratorium on Specialty Hospitals

With respect to DHS furnished in rural areas, section 1877 (d) (2) of the Act permits referring physicians to have ownership or investment interests in rural providers that furnish DHS in a rural area, if substantially all of the DHS are furnished to individuals residing in the rural area. Section 507 of the recently enacted Medicare Prescription Drug, Improvement, and Modernization Act ("MMA"), however, amended section 1877 (d) (2) to specify that, for the 18-month period beginning on December 8, 2003, the rural provider may not be a specialty hospital. The MMA also defined the term "specialty hospital" in a new subsection under section 1877 (h) (7).

Except for the codification of changes made by MMA, Phase II of the regulations adopts the 1998 proposed rule that defined a "rural provider" as an entity that furnishes at least 75 percent of its total DHS to residents of a rural area. The proposed regulations defined a "rural area" as an area that is not an urban area. 42 CFR 411.356(c) (2). Some commenters stated that the 1998 rural provider proposed exception was too broad and unfairly benefited physician-owned DHS entities in rural areas, particularly in the home health services arena. CMS responded that the statutory exception clearly applies to rural providers of DHS regardless of whether other DHS entities already operate in a particular rural area or serve a particular rural patient base. As a result, CMS recognized that the exception may benefit physician-owned DHS entities to the detriment of competing non-physician owned DHS entities. 69 Fed. Reg. at 16083.

With respect to the 18-month "specialty hospital" moratorium incorporated into the rural provider exception, a specialty hospital means a subsection (d) hospital, as defined in section 1886 (d) (1) (B), that is primarily or exclusively engaged in the care and treatment of one of the following: (1) patients with a cardiac condition; (2) patients with a orthopedic condition; (3) patients receiving a surgical procedure; (4) or any other special category that the Secretary designates as inconsistent with the purpose of permitting physician ownership and investment interest in a hospital. 42 CFR 411.351. The specialty hospital definition, however, does contain a so-called grandfather provision that excepts certain specified hospitals from the 18-month moratorium. 42 CFR 411.351.

Hospital Ownership Exception

With respect to DHS provided by a hospital, an ownership or investment interest in a hospital is not a financial relationship within the meaning of the Act as long as the referring physician is authorized to perform services at the hospital. This exception, however, is strictly limited to ownership in the hospital, not merely a subdivision of the hospital. Section 1877 (d) (3), 42 CFR 411.356 (c) (3). In the 1998 proposed rule, CMS interpreted the requirement that DHS be "provided by the hospital" to mean that the services had to be provided at the hospital and not by another hospital-owned entity, such as a skilled nursing facility or home health agency. In addition, the proposed rule also provided that the exception only protected referrals provided by an entity that is a "hospital" under the Medicare conditions of participation. 63 Fed. Reg. at 1713. In Phase II of the rulemaking, CMS adopts the 1998 proposed rule for the hospital ownership exception, except that the specialty hospital 18-month moratorium contained in 507 of MMA was also incorporated into the exception as well. 42 CFR 411.356 (c) (3).

Exceptions Related to Other Compensation Arrangements

Rental of Office Space and Equipment

Phase II of the regulations makes several minor changes to the 1998 proposed regulations regarding rental of office space and equipment. In order for an office space or equipment lease to meet the exceptions, the following requirements must be met: (1) the lease is in writing, signed by the parties, and specifies the space or equipment covered by the lease; (2) the term of the agreement is at least one year; (3) the space or equipment rented or leased does not exceed what is reasonable and necessary for the legitimate business purposes of the lease, and is used exclusively by the lessee when being used by the lessee (except that prorated payments for common areas are allowed); (4) the rental charges over the term of the lease are set in advance and are consistent with fair market value; (5) the rental charges over the term of the agreement are not determined in manner that takes into account the volume or value of any referrals or other business generated between the parties; and (6) the agreement would be commercially reasonable even if no referrals were made between the parties. 42 CFR 411.357 (a) and 411.357 (b). For purposes of these exceptions, "fair market value" means the value of the rental property for general commercial purposes (not taking into account the property's intended use). In addition, for rentals or leases where the lessor is a potential source of patient referrals to the lessee, fair market value means general commercial value not taking into account the intended use or the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor. 42 CFR 411.351.

In the 1998 proposed regulations, CMS made several interpretations with respect to these lease arrangements. First, the one-year term requirement was interpreted to permit leases to be terminated for cause, provided that the parties did not enter into another lease until after the expiration of the original term. The one-year term was also interpreted as precluding hold-over month-to-month leases. Second, the exclusive use provision was interpreted to prohibit subleases, unless the sublease met all of the conditions of the exception. Third, these exceptions applied only to operating, not capital leases. Moreover, CMS noted that "per-click" equipment rental payments would qualify for the equipment rental exception, unless the payments were for the use of the equipment on patients referred by the lessor-physician. 63 Fed. Reg. at 1713-1714.

Without Cause Provisions and Holdovers Allowed

In Phase II, several minor changes were made to these interpretations. A number of commenters requested that the one-year term requirement be interpreted to allow "without cause" provisions to avoid costs of litigation. Commenters also disagreed with the proposed position that holdover month-to-month leases should be prohibited. In response to such comments, Phase II modifies the regulations to allow "without cause" terminations, provided that the parties do not enter into a new lease during the first year of the original term and the new agreement complies with the exception. 42 CFR 411.357 (a) (2), 411.357 (b) (3). CMS also concurred with commenters that there was little risk if a holdover month-to-month tenancy proceeds on the same terms as the original agreement. As a result, Phase II also modifies the regulations to permit hold-over tenancies for a period of not more than six months. 42 CFR 411.357(a) (7), 411.357 (b) (6), and 69 Fed. Reg. at 16086.

Subleases Allowed

Moreover, Phase II modifies the exclusive use language to permit subleases. Many commenters objected to the 1998 proposed rule interpretation that the exclusive use requirement in the lease exceptions prohibit subleases. In response to such comments, CMS

concurred with commenters that Congress did not intend for the lease exceptions to preclude lessees from subletting leased space or equipment. The Phase II preamble provides that a fair reading of the exclusive use provision in the context of the lease exceptions is that the rented space or equipment cannot be shared with the lessor when it is being used or rented by the lessee. For example, if a DHS entity rents examination rooms from a physician practice, the physician practice may not use those same examination rooms while the lessee (or a sublessee) is using or renting them. 69 fed. Reg. at 16086.

Further, to preclude referring physicians or groups from circumventing the rules by setting up separate holding companies to act as the "lessor", the regulations were modified to preclude sharing of rented space with the lessor or any person or entity related to the lessor. 69 Fed. Reg. at 16086, 42 CFR 411.357 (a) (3), and 411.357 (b) (2). Although subleasing is permitted, parties should be aware that, depending on the circumstances, a sublease could create an indirect compensation arrangement between the original lessor and the sublessee. 69 Fed. Reg. at 16086.

Per Use or Per Unit Payments Allowed

With respect to equipment leases, Phase II modifies the original interpretation by permitting "per-click" payments for DHS referred by the referring physician as long as the payments are fair market value and do not take into account the volume or value of referrals or other business generated by the referring physician as defined in 411.351 and 411.354. 69 Fed. Reg. at 16085. Parties entering into these relationships, however, should keep in mind that "other business generated" includes private pay health care business (excluding personally performed services). 42 CFR 411.354 (d) (3). Finally, in Phase II, CMS also changed its original interpretation regarding lease types to reflect that the lease exceptions apply to both operating and capital leases. 69 Fed. Reg. at 16086.

Bona Fide Employment

Payments made by an employer to a physician (or immediate family member) pursuant to a *bona fide* employment relationship are excepted from Stark's prohibition, if certain conditions are met. Specifically, the employment must be for identifiable services, the amount of compensation must be fair market value and not determined in manner that takes into account (directly or indirectly) the volume or value of referrals, and the employment agreement must be commercially reasonable, absent the referrals. Section 1877 (e) (2) and 42 CFR 411.357 (c). The 1998 proposed rule added additional limitations to the statutory requirements to restrict a physician's ability to receive a productivity bonus based on his/her own productivity of DHS referrals, and to restrict compensation related to other business generated between the parties. Of particular importance to physicians, Phase II eliminates the 1998 added restrictions. In Phase II, CMS did not adopt the limitation placed upon productivity bonuses as it is no longer relevant given the determination that personally performed DHS are not considered "referrals" for purposes of the Act. The Phase II preamble notes that the statute contemplates that employed physicians can be compensated based on their own personal labor, including labor in the provision of DHS. Additionally, the exception does not preclude a productivity bonus based solely on personally performed supervision of services that are not DHS, as this type of bonus would not take into account the volume or value of DHS referrals. 69 Fed. Reg. at 16087 and 42 CFR 411.357 (c).

Notably, the preamble provides that productivity bonuses based on supervising DHS raise concerns because the payment for supervision may merely be a proxy payment for having generated the DHS being supervised. In this regard, Phase II notes that any payment for supervision services must meet the fair market value standard. Similarly, commenters asked whether an employer could pay an employed physician a flat fee for each mid-level provider he/she supervises to compensate the physician for time spent on supervision. In response, CMS notes that nothing in the exception would bar flat fee compensation based on the number of mid-level providers under the physician's supervision, provided that the compensation is fair market value for actual time dedicated to supervision and is not determined in any manner that takes into account (directly or indirectly) the volume or value of referrals generated by the physician. 69 Fed. Reg. at 16088.

Several commenters raised concerns regarding exclusivity provisions in employment contracts. These commenters noted that the exclusivity provision could be viewed as taking into account the volume or value of referrals, even if the payments made to the physician were unvaried. In response to these concerns, Phase II recognizes that exclusive contracting agreements between hospitals and traditional hospital-based physicians (radiologists, pathologists, anesthesiologists, and emergency room physicians) can, in certain cases, serve legitimate business purposes. Phase II provides that to the extent that these payments are for personally performed services, they do no raise substantial concerns. However, CMS cautions that to the extent the payments reflect or take into account non-personally performed services, they may merit case-by-case determination, regardless of a fixed payment structure. 69 Fed. Reg. at 16088.

Personal Service Arrangements

In Phase II, CMS made minor modifications to the 1998 proposed rule regarding the personal service arrangements exception. Specifically, these modifications include clarifying the treatment of the termination provisions, clarifying that downstream subcontractors are included in the physician incentive plan exception, modifying the requirement that other contracts be

incorporated by reference, and clarifying the "set in advance standard" as applied to physician compensation. Notably, Phase II also creates a "safe harbor" provision under the definition of fair market value for hourly payments made to physicians for their personal services.

Phase II modifies the one-year term provision to reflect that "without cause" provisions are permitted, provided that the parties do not enter into the same or substantially the same agreement during the first year of the original term. Moreover, any subsequent agreement between the parties must fit into the exception. 42 CFR 411.357(d) (1) (iv).

The personal services exception contains an express provision allowing independent contractor physicians to be compensated under a physician incentive plan ("PIP") with respect to services provided to individuals enrolled with the entity making the payments. 42 CFR 411.357 (d) (2). Phase II modifies this PIP exception to clarify that it applies to downstream contractor arrangements related to health plan enrollees. 42 CFR 411.357(d) (2).

Incorporation by Reference Rule - Modified

In 1998, CMS proposed interpreting the requirement that " the arrangement cover all services to be provided by the physician (or immediate family member)" to permit multiple agreements between the physician and the entity if each individual agreement fits in an exception and all of the agreements incorporate one another by reference. 63 Fed. Reg. at 1701. In response to such interpretation, several commenters complained that requiring multiple agreements to incorporate one another by reference imposes an undue administrative burden on providers, especially large providers. 69 Fed. Reg. at 16090. CMS agreed with these commenters and alleviated the burden in Phase II by requiring either incorporation of other agreements or cross-referencing to a master list of contracts that is maintained and updated centrally. 42 CFR 411.357(d). The preamble commentary notes that the master list alternative will be satisfied if more than one master list is maintained and cross-referenced, so long as the several master lists, taken together, cover all of the contracts with the referring physician (or immediate family member). Additionally, annual or other financial statements that clearly provide parties, dates, payments, and purposes of payments separately for each personal services contract can qualify as a master list. 69 Fed. Reg. at 16091. These changes should minimize the administrative burden placed on large providers, such as hospitals. However, providers that take advantage of this new alternative must be prepared to properly maintain the list(s) in a manner that preserves the historical record if requested by the Secretary. 42 CFR 411.357 (d) (1) (ii).

Moreover, with respect to compensation paid under a personal services arrangement, Phase II also clarifies that the aggregate compensation does not need to be set in advance. As noted earlier, this allows physicians to be paid based upon a percentage, provided that the requirements set forth in the "set in advance" standard are met. 69 Fed. Reg. at 16090, 42 CFR 411.357 (d) (1)(v), and 42 CFR 411.354 (d) (1).

Fair Market Value - Safe Harbor Added

In a continued effort to provide "bright line" rules, Phase II creates a safe harbor provision for DHS entities making payments to a physician for his/her personal services. Notably, this safe harbor provision provides that an hourly payment for a physician's personal services (not services performed by employees, contractors, or others) shall be considered fair market value if the hourly payment is established using either of the following two methods:

- The hourly rate is less than or equal to the average hourly rate for emergency room physician services in the relevant physician market, provided that there are at least three (3) hospitals providing emergency room services in the market; or
- The hourly rate is determined by averaging the 50th percentile national compensation level for physicians with the same physician specialty (or if a specialty is not identified, for general practice) in at least four surveys (as identified in the regulations), divided by 2,000 hours.

42 CFR 411.351.

Although compliance with these safe harbor methodologies is entirely voluntary, DHS entities that choose to use either of these bright line methods will be assured that their compensation will be deemed fair market value. The preamble commentary does caution, however, that DHS entities will still need to make sure their arrangements comply with all other conditions of an applicable exception. 69 Fed. Reg. at 16092.

Remuneration Unrelated to the Provision of DHS - Interpreted Narrowly

Remuneration that is provided by a hospital to a physician that does not relate to the furnishing of DHS does not constitute a prohibited financial relationship for purposes of Stark. 42 CFR 411.357 (g). In Phase II, CMS interprets this exception to be extremely narrow and available only if the remuneration is wholly unrelated to the furnishing of DHS, such as the rental of residential property. In general, any item, or service, or cost that could be allocated in whole or in part to Medicare or Medicaid under applicable cost reporting will not qualify for this exception. Moreover, CMS will consider the remuneration to be related to the furnishing of DHS if it is furnished directly or indirectly, explicitly or implicitly, to medical staff or other physicians in a position to make or influence referrals in any manner

that is selective, targeted, preferential, or conditional. 69 Fed. Reg. at 16093. As a result of this narrow interpretation, for all practical purposes, this exception will have extremely limited use.

Physician Recruitment

Under Stark, a hospital is permitted to pay a physician to relocate to the hospital's geographic area in order for the physician to be a member of the hospital's medical staff. Specifically, the recruitment arrangement must meet the following requirements: (1) the arrangement is set out in writing and signed by both parties; (2) the arrangement cannot be conditioned on the physician's referrals; (3) the amount of remuneration under the agreement may not be determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the physician; and (4) the physician must be allowed to establish staff privileges at any other hospital and to refer business to other entities. 42 CFR 411. 357(e)

In the 1998 proposed rule preamble, CMS interpreted the recruitment rule to require that the recruited physician reside in an area outside the hospital's geographic area and actually relocate into the hospital area. Phase II makes significant changes to this interpretation. In particular, CMS agreed with commenters that the physician should not be required to relocate his residence. As a result, the final rule looks to the relocation of the recruited physician's medical practice, rather than the physician's residence. In order to meet the relocation requirement, the physician must: (1) relocate his/her practice a minimum of twenty-five (25) miles; or (2) at least seventy-five percent (75%) of the physician's revenues must come from care provided to new patients. 69 Fed. Reg. at 16094, 42 CFR 411.357 (e). Phase II also modifies the regulations by affording special treatment to residents and new physicians (physicians who have been in practice less than one year). These physicians will be eligible for the physician recruitment exception regardless of whether they actually move their practices. 42 CFR 411.357 (e) (3).

Although commenters requested that the exception be expanded to protect recruitment payments from DHS entities other than hospitals, CMS declined to make a wholesale expansion to other DHS entities. However, CMS did use its authority to expand the exception to cover federally qualified health centers (FQHCs). 69 Fed. Reg. at 16095 and 42 CFR 411.357 (e) (5). The Phase II preamble comments provide that such an extension was not only consistent with the statute, but would ensure that FQHCs would be able to provide substantial services to underserved populations. 69 Fed. Reg. at 16094-16095.

Recruitment Exception Expanded to Include Payments to Groups

CMS also responded favorably to comments that the recruitment exception be expanded to include hospital payments to medical groups in connection with the recruitment of new physicians to join the group. Specifically, CMS agreed with commenters that many physicians prefer to join existing groups and that such arrangements save the cost and labor of setting up a new practice and provide cross-coverage and peer review. 69 Fed. Reg. at 16096. However, because CMS was concerned about potential abuses, the accommodation for recruitment payments to group practices is narrowly tailored. 69 Fed. Reg. at 16096. Accordingly, remuneration provided by a hospital (or FQHC) to a physician indirectly through payments to another physician or physician practice are permitted if the following criteria are met: (1) the arrangement between the hospital and physician practice is in writing and signed by the parties; (2) the remuneration is passed directly through to, or remains with, the recruited physician; (3) in the case of an income guarantee made by the hospital to a physician who joins a local physician practice, costs allocated by the physician practice to the recruited physician may not exceed the actual additional incremental costs to the practice attributable to the recruited physician; (4) the new physician must establish a medical practice in the hospital's geographic area and join the hospital's medical staff; (5) the practice's arrangement with the recruited physician must be set out in writing and signed by the parties; (6) the new physician may not be required to refer patients to the hospital and is allowed to establish staff privileges at any other hospital and to refer business to other entities; (7) the remuneration from the hospital is not determined in any manner that takes into account (directly or indirectly) the volume or value of any referrals (actual or anticipated) by the recruited physician or by the physician practice receiving the direct payments from the hospital (or any physician affiliated with that physician practice); and (8) the physician practice receiving the hospital payments may not impose additional practice restrictions on the recruited physician (e.g. a covenant not to compete), but may impose conditions related solely to quality considerations. Additionally, the arrangement must not violate the anti-kickback statute and must comply with all relevant billing laws and regulations. The Phase II comments also provide that in the event the physician practice receiving the payments from the hospital is a DHS entity to which the recruited physician will refer (e.g. a practice that submits claims to Medicare for DHS), any separate or additional financial relationship it has with the recruited physician must fit within an applicable exception. 69 Fed. Reg. at 16097.

Retention Payment Exception Created for Underserved Areas

In response to several commenters that requested that the recruitment exception be expanded to permit hospitals to provide incentives to retain physicians already on staff (particularly in rural or inner city areas), Phase II establishes a narrow retention exception

for certain remuneration paid to physicians with practices in health professional shortage areas ("HPSAs"). 69 Fed. Reg. at 16097 and 42 CFR 411.357 (t). This exception applies to retention payments made to a physician with a practice located in a HPSA who has a firm written recruitment offer from an unrelated hospital (or FQHC) that specifies the remuneration being offered and that would require the physician to move the location of his or her practice at least 25 miles and outside of the geographic area served by the hospital (or FQHC). Additionally, the retention payment in this exception must be the lower of (1) the difference between the physician's current income from physician and related services in the recruitment offer (over no more than a 24 month period); or (2) the reasonable costs the hospital or FQHC would otherwise have to expend to recruit a new physician to the geographic area served by the hospital or FQHC. Notably, this new exception does not protect payments made indirectly to a retained physician via another person or entity, including a physician practice. 69. Fed. Reg. at 16097.

Isolated Transactions - Installment Payments Allowed

An isolated transaction, such as a one-time sale of property, is not considered a compensation arrangement for purposes of the self-referral prohibition. 42 CFR 411.357 (f). Phase II modifies the definition of "isolated transaction" to permit installment payments, provided that the total aggregate payment is: (1) set before the first payment is made; and (2) does not take into account, directly or indirectly, referrals or other business generated by the referring physician. 42 CFR 411.351. In addition, in order to address concerns of creating pressure to continue referrals, the installment payment rule requires that payments must be either immediately negotiable or otherwise secured so that the seller is guaranteed payment in the event of the purchaser's default or bankruptcy. 69 Fed. Reg. at 16098.

Payments Made by Physicians for Items or Services

Certain fair market value payments made by a physician to an entity in exchange for items provided or services rendered by the entity are excepted from Stark. 42 CFR 411.357 (i). In 1998, CMS proposed an exception for discounts to physicians based upon the value or volume of referrals, provided that the discount was passed on in full to the patients or their insurers and did not benefit the physician in any manner. 63 Fed. Reg. at 1694. Phase II did not adopt this proposed exception for discounts because CMS believes that legitimate discounts will fall within the range of values that would be considered "fair market value." 69 Fed. Reg. at 16099. However, Phase II does expand the payments made by physicians for items or services exception to cover payments by a referring physician's immediate family member. The preamble provides that Congress did not intend that the fair market value purchase by immediate family members of items or services from health care entities would create a prohibited financial relationship such that the physician could not refer to the entity. 69 Fed. Reg. At 16099.

DHS - Definitions

The Stark II law lists eleven categories of DHS covered by the self-referral prohibition. In response to requests for more clear definitions of DHS, Phase I of the rulemaking defined certain categories of DHS by reference to CPT and HCPCS codes. These categories include: (1) clinical laboratory services; (2) physical therapy services; (3) occupational therapy, and speech pathology services; (4) radiology and certain other imaging services; and (5) radiation therapy services and supplies. The list of codes appeared in an attachment to Phase I and is updated on an annual basis in the physician fee schedule final rule. CMS also maintains the list on its website at www.cms.hhs.gov/. For convenience, Phase II also attaches a list of the codes. 69 Fed. Reg. at 16143-16146. Additionally, Phase I defined the remaining DHS categories in regulatory descriptions, but not by codes. These categories include: (1) durable medical equipment; (2) parenteral and enteral nutrients, equipment, and supplies; (3) prosthetics, orthotics, and prosthetic devices; (4) home health services and supplies; (5) outpatient prescription drugs; and (6) inpatient and outpatient hospital services. In response to Phase I, numerous commenters advocated that certain services be excluded from the definition of DHS or that exceptions be created involving these services. In Phase II, CMS left the DHS categories untouched and declined to make service-by service determinations of risk of abuse. CMS also declined to create any new regulatory exceptions for additional DHS. 69 Fed. Reg. at 16100.

Nuclear Medicine - CMS Declines to Include as DHS

In response to Phase I, an association representing radiologists commented that nuclear medicine should be considered a DHS. The commenters asserted that nuclear medicine is a subspecialty of radiology and that radiologists interpret the vast majority of nuclear medicine studies. Additionally, commenters asserted that the exclusion of nuclear medicine encourages abusive business arrangements involving physician financial relationships with entities that furnish positron emission tomography (PET) scans. In Phase II, CMS declined to incorporate nuclear medicine procedures into the definition of DHS. Notably, however, the preamble provides that CMS is mindful of the issues raised and will continue to consider the possibility of the application of Stark to nuclear medicine procedures in the future. Moreover, CMS reminded that parties should be

mindful that arrangements involving nuclear medicine may violate the anti-kickback statute, depending upon the circumstances. 69 Fed. Reg. at 16104.

Outpatient Prescription Drugs - Will Be Revisited in Future Rulemaking

Phase I defined outpatient prescription drugs as "all prescription drugs covered by Medicare Part B". However, in light of the recent expanded coverage of outpatient prescription drugs pursuant to section 101 of MMA, the Phase II commentary provides that CMS will be revisiting the definition of outpatient prescription drugs in a future rulemaking. 69 Fed. Reg. at 16106.

Regulatory Exceptions

Phase I of the rulemaking created several regulatory exceptions using the authority granted under the Act. Phase II also creates additional exceptions under this authority. All of these new exceptions, however, contain important conditions. Specifically, they are conditioned upon the requirement that the arrangement does not violate the anti-kickback statute. Several commenters objected to the conditional nature of the exceptions as they felt it interjects an unnecessary facts and circumstances test into what is supposed to be a bright line area of law. In response to such comments, CMS notes that the authority to create a new exception is strictly limited to arrangements that pose no risk of abuse. As a result, unless a new exception is created with the non-kickback condition, it would not meet the "no risk" standard under the Act. 69 Fed. Reg. at 16108. Moreover, the new regulatory exceptions also contain a billing and claims submission condition, intended to satisify, the "no risk" standard. This condition requires that the financial arrangement is not violative of any Federal or State law or regulation governing billing and claims submission. 69 Fed. Reg. at 16108.

Academic Medical Centers - Easier to Qualify

Recognizing that academic medical centers ("AMCs") often involve multiple affiliated entities that may make qualifying for an exception difficult, Phase I of the rulemaking created an exception for AMCs. As such, services provided in an AMC are exempt from the self-referral ban provided they meet all of the requisite conditions.

These conditions are as follows:

(1) the referring physician:

- is a *bona fide* employee of a component of the AMC on a full-time or substantial part time basis;
- is licensed to practice medicine in the State(s) in which he or she practices medicine;
- has a *bona fide* faculty appointment at the affiliated medical school or at one or more of the educational programs at the accredited academic hospital; and
- provides either substantial clinical teaching services (or a combination of academic services and clinical teaching services) for which the faculty member receives compensation as part of his or her employment relationship with the AMC;

(2) the total compensation paid by all AMC components to the referring physician is set in advance; in the aggregate, does not exceed fair market value for the services provided; and is not determined in a manner that takes into account the volume or value of any referrals or other business generated by the referring physician within the AMC;

(3) the referring physician's compensation arrangement does not violate the anti-kickback statute or any Federal or State law or regulation governing claims submission; and

(4) the AMC meets all of the following conditions:

- all transfers of money between components of the AMC must directly or indirectly support the missions of teaching, indigent care, research, or community service;
- the relationship between the components of the AMC must be set forth in written agreement (s) or other written document(s);
- all money paid to a referring physician for research must be used solely to support *bona fide* research or teaching and must be consistent with the terms and conditions of the grant.

42 CFR 411.355 (e).

The exception also contains a definitional section which defines an AMC as follows: (1) an accredited medical school or an accredited academic hospital; (2) one or more faculty practice plans affiliated with the medical school, the affiliated hospital(s), or the accredited academic hospital; and (3) one or more affiliated hospitals in which a majority of the physicians on staff consists of physicians who are faculty members and a majority of all hospital admissions are made by physicians who are faculty members. Moreover, for purposes of the exception, a faculty member is a physician who is either on the faculty of the affiliated medical school or on the faculty of one or more of the educational programs at the accredited academic hospital. Phase II of the rulemaking modifies this definition to clarify that faculty from any affiliated medical school or accredited academic hospital education program may be aggregated, and residents and non-physicians professionals need not be counted. Modifications were also made to reflect that any faculty member may be counted, including courtesy and volunteer faculty. 42 CFR 411.355 (e) (2).

In an effort to address concerns with the AMC exception expressed by commenters, Phase II makes many revisions and clarifications to the AMC exception in order to make it easier to qualify. Specifically, the definition of

"AMC" has been modified to permit hospitals or health systems to substitute for an accredited medical school provided that they sponsor four (4) or more approved medical education programs and meet the other conditions of the definition. 42 CFR 411.355 (e) (2) (i). However, this alleged expansion may be limited for practical purposes because even if a community hospital had four or more residency programs, it is unlikely that it would be able to satisfy either majority requirement contained in the third component of the definition (i.e., (1) a majority of the physicians on staff consists of physicians who are faculty members and (2) a majority of all hospital admissions be made by physicians who are faculty members.) Community hospitals, however, that cannot meet the AMC exception may still look to other applicable exceptions (employment, personal services, or fair market value) for protection. The preamble notes that the modifications made to the definition will adequately ensure that the hospital or health system has a substantial teaching mission. Finally, to reflect this broader view of an AMC, CMS clarified that the referring physician may be on the faculty of the affiliated medical school or the accredited academic hospital. 69 Fed. Reg. at 16109.

There were also many comments related to the various aspects of the affiliated faculty practice plan requirement. Many objected to the requirement that the practice plan be a tax-exempt organization under either 501(c)(3) or 501(c)(4) of the IRS Code. Specifically, these objections were related to the fact that many *bona fide* plans are organized as professional corporations or not-for-profit organizations under state law or are not separate legal entities. Others sought clarification that an AMC could have more than one affiliated faculty practice plan. Finally, several commenters asked whether the faculty practice plan could be affiliated with the teaching hospital rather than the medical school. In response to such comments, Phase II eliminates the requirement that the faculty practice plan be organized in any particular manner. Additionally, Phase II modifies the exception to reflect that an AMC may have more than one affiliated faculty practice plan and that faculty practice plans can be affiliated with the teaching hospital, the medical school or the accredited academic hospital. 69 Fed. Reg. at 16109, 42 411.355 (e) (2) (ii).

In response to Phase I, commenters also asked for clarification with respect to what constitutes "substantial academic or substantial clinical teaching services" for purposes of the referring physician's services. Notably, to provide clarity, Phase II adds a safe harbor provision deeming any referring physician who spends at least 20 percent of his or her professional time or, in the alternative, 8 hours per week providing academic services or clinical teaching services (or a combination), as fulfilling the requirement. 69 Fed. Reg. at 16110 and 42 CFR 411.355 (e) (1) (i) (D) . The Phase II preamble notes that this test is a safe harbor only, meaning it is not intended to be an absolute requirement. Accordingly, depending on the circumstances, physicians who do not qualify for the safe harbor may still be deemed to be providing substantial academic services or clinical teaching services. 69 Fed. Reg. at 16110.

Several commenters requested that the requirement that the relationship among the AMC components be set out in writing be modified to reflect that several documents or a course of conduct could satisfy the requirement. In response to such comments, CMS noted that it had not intended to restrict the written agreement to a single document and therefore revised the regulations to permit memorialization in multiple writings. 42 411.355 (e) (1) (iii) (B). The preamble provides that in order to permit the government to verify an AMC's compliance with this exception, it is necessary that the relationship of the components be memorialized in writing or that there be a clearly established course of conduct that is appropriately documented. In addition, CMS states that in the case of a single legal entity AMC, financial reports documenting the transfers of funds between the components will be sufficient. 69 Fed. Reg. at 16110.

Phase II also adds flexibility to the AMC exception by modifying the regulations to cover research money used for teaching, a core AMC function. Specifically, in order to qualify, all money paid to a referring physician for research must be used solely to support *bona fide* research or teaching and must be consistent with the terms and conditions of the grant. 42 CFR 411. 355(e) (1) (iii) (C). Although CMS acknowledged the importance of indigent care and community service, it rejected a proposal to cover such services in the AMC exception because it was overly broad in the context of research grants. CMS did note, however, that payments to referring physicians for indigent care or community service may be structured to fit into another exception. 69 Fed. Reg. at 16110-16111.

Commenters also observed that the requirement that an academic physician's compensation be "set in advance" precluded calculating any component of the compensation using a percentage-based methodology. In addition, commenters noted that the requirement that compensation not take into account "other business generated" by the referring physician within the AMC potentially affected compensation paid by group practices or other physician compensation arrangements. As noted earlier in this article, changes made by CMS to the "set in advance" and "other business generated" definitions address these concerns. In particular, as a result of the definitional changes, AMC physicians can be paid based upon certain limited forms of percentage compensation and can be paid a productivity bonus based on work they personally perform. 69 Fed. Reg. at 16066-16068, 42 CFR 411.354 (d) (1), and 42 CFR 411.354 (d) (3).

Services Furnished Under Certain Payment Rates

In Phase II, CMS deletes the ambulatory surgery center, end stage renal disease, and hospice exception formally at 411.355 (d) because it was considered redundant and had the potential to cause confusion. In eliminating the exception, CMS noted that it was unnecessary as providers can rely upon the DHS definition exclusion for services that are reimbursed by Medicare as part of a composite rate. CMS noted, however, that services separately listed in the definition of DHS that are paid on a composite basis, now or in the future (for example, home health and inpatient and outpatient hospital services) are DHS, notwithstanding the fact that they could be paid on a composite basis. 42 CFR 411.351 and 69 Fed. Reg. at 16111.

Implants in an ASC

In Phase I, CMS created an exception for implants furnished in an ASC. 66 Fed. Reg. at 934 and 42 CFR 411.355 (f). The exception was created because many implantable items are DHS, but are not bundled into the ASC composite rate. Although Phase II of the rulemaking does not change this exception, CMS clarified two issues. First, CMS clarifies that this exception only applies when the implant is billed by the ASC and not when a physician or other entity bills for the implant. CMS notes that when a physician bills for the implant, another exception must be satisfied. Second, CMS notes that the exception applies only to "implanted prosthetics, implanted prosthetic devices and implanted DME." Therefore, it does not apply to the implantation of radioactive brachytherapy seeds. 69 Fed. Reg. at 16111.

Non-Monetary Compensation up to $300 and Medical Staff Incidental Benefits

The non-monetary compensation exception permits entities to provide physicians with non-monetary items or services (not cash or cash equivalents) that do not exceed an aggregate of $300 per year. 42 CFR 411.357 (k). Although, CMS declined to adopt a higher threshold in Phase II, it did modify the exception to include annual inflationary adjustments. 42 CFR 411.357 (k) (2).

In a similar exception, hospitals are permitted to provide incidental benefits of low value (less than $25 per occurrence) to their medical staffs. In order to qualify for this exception, the compensation cannot be in the form of cash or cash equivalents and the items or service must be used on the hospital's campus. In addition, the compensation must be offered (but not necessarily accepted) to all members of the staff practicing in the same specialty without regard to the volume or value of referrals or other business generated between the parties. The compensation offered by the hospital can only be provided during periods when members of the staff are making rounds or are engaged in a service that benefits the hospital or patients. 42 CFR 411.357 (n). Like the non-monetary compensation exception, Phase II modifies this exception to allow for annual inflation. 42 CFR 411.357 (m) (5). Additionally, Phase II deletes the requirement contained in Phase I that the compensation provided by the hospital be commensurate with the benefits offered by other hospitals in the local region. 69 Fed. Reg. at 16113. Phase II also extends the exception beyond hospitals to cover other health care facilities (including FQHCs) that have *bona fide* medical staffs. 42 CFR 411.357 (m) (8).

Several commenters sought clarification with respect to the "on-campus" requirement of the medical staff incidental benefit exception. In particular, commenters viewed the rule as overly restrictive with respect to electronic communications, internet access, and pagers or two-way radios. Moreover, commenters stated that many hospitals are developing integrated information systems and may provide dedicated computers to allow remote access to the hospital's system. In response to such comments, Phase II modifies the exception to make clear that compensation such as two-way radios, pagers, and internet access will meet the "on-campus" requirement. 42 CFR 411. 357 (m) (3). Phase II also modifies the regulations to include the simple listing or identification of medical staff on a hospital's website as incidental benefits that are excepted from the self-referral ban. 42 CFR 411. 357 (m) (2).

Community-Wide Health Information Systems

In Phase II, CMS creates an exception for community-wide health information systems. This exception allows an entity to furnish to a physician items or services of information technology that allow the physician access to and sharing of electronic medical records, complementary drug information systems, general health information, medical alerts, and related information for patients serviced by community providers and practitioners. Entities and physicians relying upon this exception must meet the following four requirements: (1) the items or services are available as necessary to enable the physician to participate in a community-wide health information system and are principally used by the physician for that purpose; (2) the items or services must not be provided in any manner that takes into account the volume or value of referrals or other business generated; (3) the community-wide health information system must be available to all providers, practitioners, and residents of the community; and (4) the arrangement must not violate the anti-kickback statute or any Federal or State law or regulation governing billing or claims submission. 42 CFR 411. 357 (u). With respect to the first requirement, the preamble provides that if a physician already owns a computer it may only be necessary to provide software or training specific to the health information system. Similarly, it would not be considered necessary to provide internet access to a

physician who already has internet service. 69 Fed. Reg. at 16113.

CMS Invites Advisory Requests

In the Phase II preamble commentary, an association representing hospitals inquired about the treatment of several types of benefits commonly provided to physicians that may not fit within an exception. Specifically, such benefits would not fit within the non-monetary exception because they are worth more than $300; the medical staff incidental benefits exception, because they are worth more than $25 per occurrence; or the fair market value exception because they do not involve a written contract. The association gave the following examples: (1) business meetings with physicians that include a meal (for example to discuss hospital operations); (2) a dinner in which hospital physicians are invited to meet and recruit potential new staff members; (3) free use of a dedicated computer terminal located in the physician's office; and (4) free CME or other training at the hospital. 69 Fed. Reg. at 16114. In response, CMS attempted to address these scenarios claiming that in certain circumstances some may fit within an exception (with respect to examples (1), (2), and (4)) and that others did not appear to involve remuneration to the physician (with respect to example (3)). Notably, however, CMS recognized that the regulations do not address every possible relationship and, in some cases, relationships may trigger the Act, with no apparent available exception. CMS went on to note that it expects that questions of the kind posed by the hospital association will arise with frequency and that parties may submit advisory opinion requests about specific arrangements. 69 Fed. Reg. at 16114.

Risk Sharing Arrangements - Downstream Entities Covered

In Phase I of the rulemaking, CMS created a risk-sharing arrangement exception. The exception applies to compensation (including, but not limited to, withholds, bonuses, and risk pools) between a managed care organization or an independent practice association and a physician (either directly or indirectly through a subcontractor) for services provided to enrollees of a health plan. 42 CFR 411.357 (n). This exception was created in response to concerns that the self-referral prohibition would require wholesale restructuring of commercial managed care arrangements with physicians.

In response to Phase I, commenters requested a definition of the term "managed care organization" as used in the exception or clarification that the exception is meant to cover all downstream risk-sharing compensation paid to physicians by any type of health plan, insurance company, or HMO. Another commenter sought clarification that the downstream entity could itself be an entity that furnishes DHS, such as a hospital. In response to such comments, Phase II clarifies that the exception is intended to encompass all downstream risk-sharing compensation paid to physicians by an entity of any type of health plan, insurance company, HMO or IPA provided the arrangement relates to enrollees and meets the conditions set forth in the exception. Additionally, CMS confirmed that *all* downstream entities are included, such as a hospital that is also a DHS entity. CMS noted that it purposefully declined to define the term "managed care organization" in order to create a broad exception with maximum flexibility. 69 Fed. Reg. at 16114.

Compliance Training

In Phase I, CMS recognized the benefit of hospitals offering compliance training programs for their staff physicians or for physician's in the community. As a result, CMS created an exception for hospitals that provided compliance training to physicians in the hospital's local community or service area, provided the training is held in that area. 42 CFR 411.357 (o). Phase II modifies the exception to clarify that all entities (not just hospitals) can provide compliance training to physicians. Phase II also adds the physician's office staff as those people allowed to receive the compliance training from the entity. The Phase II preamble, however, notes that compliance training does not include continuing medical education (CME) because compliance training is primarily intended to promote legal compliance. However, in some cases, hospitals that provide CME may be able to utilize the non-monetary compensation up to $300 exception. 69 Fed. Reg. at 16115.

Anti-Kickback Safe Harbors: Referral Services and Obstetrical Malpractice Subsidies Incorporated

In the Phase I preamble, CMS indicated that it was considering creating an exception for arrangements that fit squarely within an anti-kickback "safe harbor." Many providers urged CMS to create this exception because they were frustrated by having to apply two separate sets of standards to their arrangements. Notably, in Phase II, CMS declined to adopt a wholesale importation of the anti-kickback safe harbors into the Stark exceptions. CMS explained that it would be problematic given the varying aspects of the two laws. Despite these differences, CMS reviewed the existing list of safe harbored arrangements that did not have a Stark counterpart and concluded that the safe harbors for referrals services (1001.952(f)) and obstetrical malpractice insurance subsidies (1001.952 (o)) should be incorporated by reference into Stark. CMS also noted that as the anti-kickback safe harbor regulations are amended or supplemented, it will consider whether any additional safe harbors should be incorporated in the future. 69 Fed. Reg. at 16115, 42 CFR 411.357 (q), and 42 CFR 411.357 (r).

Professional Courtesy

In recognition of the long-standing tradition and widespread practice of extending professional courtesy to

physicians and their families, Phase II creates an exception allowing entities to extend "professional courtesy" to a physician, members of the physician's immediate family, or members of the physician's office staff pursuant to several conditions. 42 CFR 411.357(s). Phase II defines professional courtesy as the provision of free or discounted health care items or services. 42 CFR 411.351. To qualify for the professional courtesy exception, the arrangement must meet the following conditions: (1) the professional courtesy is offered to all physicians on the entity's *bona fide* medical staff or in the entity's local community without regard to the volume or value of referrals generated between the parties; (2) the health care items and services provided are of a type routinely provided by the entity; (3) the entity's professional courtesy policy is set out in writing and approved in advance by the governing body of the health care provider; (4) the professional courtesy is not offered to any physician (or immediate family member) who is a Federal health care program beneficiary, unless there has been a good faith showing of financial need.; (5) if the professional courtesy involves any whole or partial waiver of any coinsurance obligation, the insurer is informed in writing of that reduction so that the insurer is aware of the arrangement; and (6) the arrangement does not violate the anti-kickback statue or billing or claims submission laws or regulations. 42 CFR 411. 357 (s).

In the Phase II preamble, CMS cautions that the regulations should not be construed as requiring or encouraging courtesy arrangements. CMS also reminds parties that some professional courtesy arrangements may run afoul of the anti-kickback or civil monetary penalties law. Additionally, CMS notes that although professional courtesy discounts may be covered under the employee exception, this exception does not preclude hospitals or other entities from extending their professional courtesy policies to employees, including non-physician employees, pursuant to this new exception. 69 Fed. Reg. at 16116.

Hospitals and other entities that choose to take advantage of the professional courtesy exception should be prepared to demonstrate compliance with the documentation requirements of the exception. Specifically, the policy must be set out in writing and properly approved. Moreover, if the entity's policy involves the reduction of co-insurance, it is obligated to notify its insurers of the policy. From a compliance perspective, entities should fully document any notification of reduction of co-insurance to insurers. In addition, entities may want to incorporate these documentation requirements into their existing compliance programs. Entities that do not have an existing compliance program would be well advised to implement a compliance program incorporating the Stark documentation requirements.

Charitable Donations

A commenter to the 1998 proposed rule raised concern that charitable contributions by physicians to DHS entities created a financial relationship with no applicable exception. Phase II addresses this concern by creating an exception for *bona fide* charitable donations made by a physician (or immediate family member). 42 CFR 411.357 (j). To qualify for this exception, donations must be made to a tax-exempt organization under the IRS Code (or to a supporting organization, such as a hospital foundation). The exception also requires that the donation is not solicited or made in any manner that reflects the volume or value of referrals or other business generated between the parties. CMS notes that broad based solicitation, such as sales of tickets for charity balls, will qualify for the exception. However, parties that engage in more selective or targeted fund-raising activities are cautioned to ensure that those activities are not conducted in manner that reflects the referral relationship. 69 Fed. Reg. at 16116.

Preventive Screening Tests

In Phase I of the rulemaking, CMS created an exception for certain preventive screening tests, immunizations and vaccines which required that these tests be reimbursed by Medicare under a fee schedule. 42 CFR 411.355 (h). However, the Phase II preamble provides that it was discovered that some of the vaccines covered under the exception are reimbursed under different methodologies. Accordingly, Phase II modifies this exception by deleting the fee schedule requirement. 69 Fed. Reg. at 16116.

EPO and Other Dialysis-Related Outpatient Drugs Furnished In or By an ESRD

Phase I of the rulemaking created an exception for EPO and certain other dialysis-related outpatient prescription drugs furnished in or by an ESRD facility. 42 CFR 411.355 (g). The drugs that qualify for this exception were initially identified by CPT and HCPCS codes in an attachment to the Phase I regulations. 66 Fed. Reg. at 965. Additionally, updates to the list appear on the CMS website at www.cms.hhs.gov/ and in annual updates in the Federal Register. In Phase II, CMS adds several drugs to the list of drugs covered under the exception because the original list was not broad enough to cover all drugs that should be excepted. 69 Fed. Reg. at 16117. The drugs added are: albumin; levocarnitine; darbepoetin alfa (Aranesp) (for purposes of the exception, the term EPO includes both epoetin alfa and darbepoetin alfa); calcitonin-salmon; streptokinase; urokinase; and retaplase. CMS stated that the addition of these drugs do not pose a risk of abuse because of the high correlation between the use of these drugs and dialysis. 69 Fed. Reg. at 16118. In addition, CMS emphasizes that, except when the qualifying facility furnishes EPO to a patient who dialyzes at home, this exception applies only to drugs that are not self-administered. 69 Fed. Reg. at 16118.

New Exception Created for Intra-Family Referrals in Rural Areas

The Phase II final interim rule creates a new limited exception for certain referrals from a referring physician to DHS entity with which his or her immediate family member has a financial relationship, if the patient being referred resides in a rural area and there is no DHS entity available in a timely manner in light of the patient's condition to furnish the DHS to the patient in his or her home (for DHS furnished to patients in their homes such as home health services or certain DME) or within 25 miles of the patient's home (for DHS furnished outside of the patient's home). 42 CFR 411.355 (j).

This new intra-family referral exception focuses on the location where the services are furnished, not where the DHS entity is located. That is, if a physician knows that a home health agency located 50 miles away is willing to provide home health services to a patient, the patient may not be referred to a family-owned home health agency pursuant to this new exception. Under the new exception, the physician or immediate family member does have a duty to make reasonable inquiries as to the availability of other person or entities to furnish DHS. However, neither the referring physician nor the family member has any obligation to inquire as to the availability of person or entities located farther than 25 miles from the patient's residence. The Phase II preamble commentary notes that reasonably inquiry might include, for example, consulting telephone directories, professional associations, internet resources, or other providers. 42 CFR 411.355 (j), 69 Fed. Reg. at 16084. Finally, the exception, as with all of the new regulatory exceptions created in Phase I and Phase II, requires that the financial relationship not violate the Anti-kickback prohibition or any other Federal or State law or regulation governing billing and claims submission. 42 CFR 411.355 (j).

Temporary Noncompliance

Once again demonstrating flexibility, in Phase II, CMS creates an exception to accommodate situations in which parties to a financial arrangement fall out of compliance with aspects of an exception through events outside of their control. 42 CFR 411.353 (f). This exception was prompted in response to several commenters who requested some type of "grace period" for parties unable to comply with an exception for temporary periods of time. 69 Fed. Reg. at 16057. In order to qualify for this exception, parties must meet the following conditions: (1) the financial relationship between the entity and the referring physician fully complied with an applicable exception (under 411.355, 411.356, or 411.357) for at least 180 days prior to the date the relationship became noncompliant; (2) The relationship fell out of compliance for reasons beyond the control of the entity, and the entity promptly takes steps to rectify the noncompliance; (3) the relationship does not violate the anti-kickback statue, and the claim or bill otherwise complies with all applicable rules and regulations; (4) the exception applies only to DHS furnished during the period of time it takes the entity to rectify noncompliance , which must not exceed 90 consecutive calendar days; and (5) the exception may only be used once every three years with respect to the same referring physician. Additionally, this exception does not apply for relationships under the non-monetary compensation up to $300 exception or the medical staff incidental benefit exception. 42 CFR 411.353 (f).

In the Phase II preamble, CMS states that it believes that this exception should address a number of situations that present special temporary compliance problems, such as conversion of publicly traded companies to private ownership, loss of rural or HPSA designations, or delays in obtaining fully-signed renewal agreements.

Parties taking advantage of this exception should take caution to properly document the reasons for noncompliance and the steps taken to rectify the situation. In order to avoid penalties for violations of Stark, CMS notes that by the end of the 90 day period, parties must either comply with an exception or have terminated their otherwise prohibited relationship. 69 Fed. Reg. at 16057. Additionally, CMS emphasizes that this exception is not intended to allow DHS entities to file otherwise prohibited claims or bills when they purposefully take or omit to take action that results in their noncompliance. In this regard, as with the other Stark documentation requirements, parties should strongly consider incorporating these requirements into their compliance programs.

Reporting Requirements

The Stark law contains a reporting provision requiring all entities to submit certain information to the Secretary. In the 1998 Proposed Rule, CMS stated that it was developing a procedure and form for implementing these reporting requirements and that the public would be notified when this information was available. Until this information was made available, however, no reporting would be required. Phase I of the rulemaking did not address the reporting requirements but rather left them for consideration in Phase II.

Phase II addresses the reporting requirements and makes several modifications. As a result of such modifications, the final rule requires that, if requested by CMS or the Office of the Inspector General (OIG), all entities (except those furnishing 20 or fewer Part A or Part B services in a calendar year or those furnishing services outside of the United States) submit certain information. The information that can be requested by CMS or OIG includes: (1) the name and unique identification number (UPIN) of each physician who has a "reportable financial relationship" with the entity; (2) the name and UPIN of each physician who has an immediate family member who has a "reportable financial relationship" with the entity;

and (3) the covered services furnished by the entity. 42 CFR 411.361.

For purposes of the reporting requirements, a "reportable financial relationship" means any ownership or investment interest (as defined in 411.354(b)) or any compensation arrangement (as defined in 411.354(c)), except for ownership or investment interests that satisfy the exceptions set forth in 411.356 (a) or (b) regarding publicly traded securities and mutual funds. 42 CFR 411.361 (d). Although interests in publicly traded securities and mutual funds are excluded from the reporting requirements, this exclusion is strictly limited to shareholder information. As a result, contractual arrangements concerning these interests are still reportable. 69 Fed. Reg. at 17933.[1]

The reporting requirements provide that, upon request, entities must submit the required information within the time period specified by the request. Note that entities will be given at least 30 days from the date of request to provide the information. Moreover, any person who is required, but fails to submit information concerning his or her financial relationships, is subject to a civil monetary penalty of up to $10,000 for each day after the deadline until the information is submitted. Several commenters expressed concern with the 30 day response period. In response, CMS indicated that 30 days should be sufficient and, in most cases, the records requested will already be retained in the course of conducting business. CMS further noted that the rule leaves open the possibility that a greater period of time may be granted if reasonably necessary. 69 Fed. Reg. at 17934.

Phase II also modifies the reporting requirements to specify that the information required is only that information that the entity knows or should know in the course of prudently conducting business, including but not limited to, records that the entity is already required to retain to comply with IRS and SEC rules and other rules under the Medicare and Medicaid programs. 42 CFR 411.361 (c) (4). CMS also noted that it does not intend to develop any specific reporting forms but is merely requiring that records be retained for the length of time specified by the applicable regulatory requirements. 69 Fed. Reg. at 17934.

Several organizations requested that the reporting requirements be limited to only those financial relationships that do not meet a Stark exception. CMS rejected this proposal noting that there continues to be a concern that an entity could decide one or more of its financial relationships fall within an exception, fail to report data concerning those relationships, and thereby prevent the government from reviewing arrangements to see if they qualify. CMS noted, however, that this concern was not as great in the situation of ownership interests in publicly traded securities and mutual funds since the burden of collecting, retaining, and reporting shareholder information was extremely burdensome and also there was little risk of abuse in this situation. 69 Fed. Reg. at 17934.

General Documentation

Although the majority of the modifications in the Phase II regulations reflect a more flexible approach and a good faith effort by CMS to implement the Stark law in a more practical manner, health care providers must still be prepared to document their compliance with Stark. In light of Stark's reporting requirements and general documentation requirements, which are incorporated throughout the various exceptions, providers should incorporate the various requirements into their compliance programs. Documentation supporting compliance is particularly important in today's health care environment, which has had an increase in False Claims Act litigation and investigations stemming from Qui Tam whistleblowers utilizing technical violations of Stark as a predicate for Federal False Claims Act violations.

In particular, physicians and providers should be advised to document their compliance with Stark. A few examples include:

- Group practices should document compliance with the "substantially all" test, a new members employment with, or ownership in a group practice, and the total time each member spends on patient care services;
- Group practices should document the method used to calculate profit shares or productivity bonuses and the resulting amounts of compensation;
- AMCs should document the relationship between the components of the AMC, and compliance with "substantial academic" or "substantial teaching" services for purposes of the referring physician's services;
- Entities relying upon the space and equipment rental agreements, personal services arrangements, physician recruitment, fair market value compensation, and indirect compensation exceptions, must maintain a signed written agreement of the arrangement;
- Entities and physicians relying upon the fair market value safe harbors for payment for a physician's personal services should document compliance with the safe harbor;
- Entities that take advantage of the professional courtesy exception, should have the policy set out in writing and be prepared to provide documentation that its insurers were notified with respect to any reductions in coinsurance offered as part of the policy;
- Parties entering into personal service arrangements must be documenting all separate arrangements between the parties either by incorporation by reference or by maintaining a master list of contracts; and
- Parties that fall out of temporary compliance with an exception

should document the reasons for the temporary non-compliance and the actions taken to rectify the situation.

Conclusion

This article is intended to provide the substantive provisions of Stark II Phase II. However, it does not cover every aspect of the regulations. Attorneys advising their health care clients regarding potential relationships that may implicate the self-referral ban should carefully scrutinize the statute and implementing regulations. Attorneys counseling health care providers must also remain mindful of the Federal anti-kickback statute and State laws regarding self-referrals. Although, many of the Stark exceptions appear similar to the anti-kickback safe harbors, they are not identical and require separate examination. Attorneys should also stay alert for Phase III of the regulations which will address comments received on the March 26, 2004 Phase II Interim Final Rule.

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Endnotes

1 It should be noted that FR Doc. 04-6668 of March 26, 2004 (69 Fed. Reg. 16054) was published with a technical error. CMS inadvertently omitted two sections from the preamble document, Section IX Reporting Requirements and Section X Sanctions. These two sections were published on April 6, 2004 in a Corrections of Errors notice (69 Fed. Reg. 17933).

THE HEALTH LAWYER

THE ABA HEALTH LAW SECTION
750 N. Lake Shore Drive
Chicago, IL 60611

SPECIAL EDITION
APRIL 2004

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