

HEALTH LAW FOCUS

STARK LAW PHASE II REGULATIONS - BRIGHT LINES, CLARIFICATIONS AND MORE

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The Centers for Medicare & Medicaid Services ("CMS") published the Stark Phase II regulations on March 26, 2004 as an interim final rule, with a 90-day comment period. The regulations become effective on July 26, 2004, giving providers approximately four months to bring their financial relationships into compliance. The new regulations include several additional exceptions and a broadening of many existing exceptions. Several of the changes take the form of bright line rules. Those rules are helpful in clarifying the permitted scope of many arrangements; however, they also simplify the task of CMS, AUSAs and *qui tam* plaintiffs in arguing that a variety of common arrangements do not comply with the Stark Law. Accordingly, many physician financial relationships may require significant revisions before the new regulations take effect on July 26, 2004.

The final regulations cover nearly 100 pages of fine print in the Federal Register, but CMS has little sympathy for confused providers. The preamble notes that the regulations themselves are relatively straightforward and clear. CMS, in fact, summarizes the regulations and the statute in two sentences: "Most physician ownership in DHS entities is prohibited. Most physician compensation must be fair market value." There are, of course, exceptions to the first statement and a variety of other conditions that go along with the second. This article focuses on a number of key changes made in the Phase II regulations as compared to the 1998 proposed regulations and the 2001 Phase I regulations; however, it is not a comprehensive review of all Stark Law requirements.

A. Prohibition on Referrals (§ 411.353)

1. Temporary Noncompliance (§ 411.353(f))

Although the Phase II regulations do not fundamentally alter the Stark Law's basic scope of prohibited referrals, these regulations nonetheless reflect CMS' expressed intent to provide flexibility to minimize the Stark Law's effect on common business arrangements. One reflection of this flexibility is the protection afforded to arrangements in which there have been certain inadvertent lapses in complying with a Stark Law exception, provided that the arrangement satisfies certain conditions. To qualify for this exception, an arrangement that has "unavoidably and temporarily fallen out of compliance with other exceptions" must have fully satisfied another Stark Law exception for at least 180 consecutive days, and the reasons for the compliance lapse must have been beyond the control of the DHS entity. The parties must act promptly to reform the arrangement so that it complies with Stark, with an outside time limit of 90 days (e.g., 90 days to get a signed contract renewal). If it cannot be reformed within that time, future DHS referrals are prohibited until after the arrangement fits within another exception or it has been terminated. CMS indicated that this new exception is to be used only sparingly. Accordingly, the DHS entity may rely upon this exception no more than once every three years with respect to referrals from the same physician. In addition, the "temporary noncompliance exception" does not cover arrangements that were protected by the exceptions for non-monetary compensation up to \$300 or incidental medical staff benefits.

2. Scope of Prohibition on Referrals (§ 411.353(a)-(e))

While preserving the Stark Law's "core statutory prohibition," the Phase II regulations likewise retain three noteworthy changes effected by the Phase I Final Regulations to the basic scope of prohibited referrals. First, any referrals by nonphysician practitioners (e.g., mid-level providers) that are directed or controlled by a physician will be attributed to that physician. As the preamble notes, the relevant "attribution" inquiry is whether, under all the facts and circumstances surrounding the referral and the relationship between the physician and the nonphysician practitioner, in particular the degree of control or influence exercised by the physician, it is reasonable to draw the inference that the referral should be deemed to be the physician's. Second, Phase II retains the "innocent entity exception" (Section 411.353(e)) that permits a DHS entity to bill for claims that do not comply with the Stark Law if the entity billing those DHS did not have knowledge of (or deliberately disregard) the violation. Under the Phase II formulation, however, the claim must have complied not only with all applicable Federal law but also state law. CMS rejected a request to expand the "innocent entity exception" to referring physicians by pointing out that referring physicians have no liability under the Stark Law unless they knowingly cause the submission of an improper claim or engage in a circumvention scheme. Third, Phase II continues to define "referral" to exclude any DHS personally provided by the referring physician himself or herself (i.e., self-referred services). However, "incident to" services performed by others still constitute referrals, as does the technical component corresponding to a physician's personally performed service. The sole change to the definition of "referral" is to clarify that requests (resulting from a consultation requested by another physician) for clinical diagnostic laboratory tests, pathological examination services and diagnostic radiology services by pathologists, radiologists and radiation oncologists, respectively, are excluded from the definition of referral not only if furnished or supervised by the pathologist, radiologist or radiation oncologist himself/herself, but also if furnished or supervised by another pathologist, radiologist or radiation oncologist in the same group practice.

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B. Definitions (§ 411.351)

There are a number of noteworthy definitional changes in the Phase II regulations, as well as a number of new definitions.

DHS. The Phase II regulations continue to define certain DHS (*i.e.*, clinical laboratory services; physical therapy, occupational therapy, and speech-language pathology services; radiation therapy services; and radiology and certain other imaging services) by reference to specific lists of Current Procedural Terminology (“CPT”) and HCFA Common Procedure Coding System (“HCPCS”) codes. Consistent with Phase I, the published list of codes will be controlling. In a departure from the prior rulemaking, however, CMS notes in the preamble that it will not make service-by-service determinations to exclude a service that otherwise would constitute a DHS on the basis that the service poses a low risk of overutilization or abuse. The practical consequences of this principle are twofold. First, there are no new regulatory exceptions for additional DHS in Phase II. Second, whereas under Phase I CMS published separate lists of CPT/HCPCS codes which, in effect, excluded those enumerated services from being considered DHS, CMS clarifies in the Phase II preamble that a particular service’s ability to qualify for a regulatory exception “does not negate the fact that it is a DHS.” As a result, the above-listed services that are defined by reference to CPT/HCPCS codes will be considered to fit within the definition of that particular service if identified on the list. Further, to the extent that the CPT or HCPCS code for a particular service that is covered by the CPT/HCPCS list (*i.e.*, thus a DHS) includes a professional as well as a technical component, the professional component also will constitute a DHS. The Phase II regulations also continue to provide that when services which constitute DHS, by themselves, are subsumed or “bundled” within another service category and are paid by Medicare as part of a composite payment for a group of services as a separate benefit category (*e.g.*, services that are paid for in the ASC rate), such services are not DHS for purposes of the Stark Law.

Does Not Violate the Anti-Kickback Statute. Numerous exceptions under the Phase II regulations include the requirement that, as a condition of meeting the exception’s terms, the arrangement “does not violate the anti-kickback statute.” The Phase II regulations define this to mean that the arrangement either (a) qualifies for a safe harbor under the Medicare and Medicaid Anti-kickback Statute, (b) has been specifically approved by the HHS Office of Inspector General (“OIG”) in a “favorable advisory opinion” (*i.e.*, the OIG opines that the specific arrangement does not implicate the Anti-kickback Statute, or the party will not be subject to sanctions under the Anti-kickback Statute in connection with the specific arrangement), or (c) does not violate the anti-kickback provisions of that statute (Section 1128(B)(b)).

The MHA Foundation is hosting the seminar Stark Law Phase II: How the Centers for Medicare and Medicaid Services’ Final Regulations Impact Self-Referrals on April 28, 2004 from 8:30 a.m. to 12:00 p.m., that will explain in detail the new and revised exceptions and help you create an action plan for compliance. Gerald M. Griffith will be one of two featured speakers. Please visit the following website: <http://www.mha.org/education/seminars/Stark%20II%20Brochure/Stark%20II%20Brochure.html> for seminar and registration details.

Entity. The Phase II regulations clarify that an “entity” does not include a physician’s practice when the practice bills Medicare for a purchased diagnostic test, provided that the arrangement complies with the rules governing physician billing for purchased diagnostic tests (under Section 414.50) and the reassignment rules governing purchased diagnostic tests (under Section 3060.4 of the Medicare Carriers Manual).

Fair Market Value. Although the statute, the 1998 proposed regulations and the Phase I Regulations each address the elements that need to be considered in a facts and circumstances analysis of whether compensation constitutes “fair market value” for purposes of the Stark Law, the Phase II regulations afford DHS entities and physicians the opportunity to establish, *with certainty*, that compensation paid to a physician under a services arrangement will be deemed “fair market value.” Specifically, the regulations provide two “safe-harbored” methodologies to ensure that physician services paid at an hourly rate meet the fair market value standard. To qualify for a safe harbor (*i.e.*, for the compensation to be considered fair market value), the hourly payments (a) must be for services personally performed by the physician himself or herself (*i.e.*, consistent with the principle of “personally performed” for purposes of what constitutes a “referral,” merely supervising the provision of the service by another does not suffice), and (b) the compensation must be established using one of the two following methodologies: (1) for those markets in which there are at least three hospitals providing emergency room services, the hourly rate is less than or equal to the average hourly rate for emergency room physician services in that market; or (2) the hourly rate must be determined by averaging the 50th percentile national compensation level for similarly situated physicians (*i.e.*, for physicians with the same specialty or, if the specialty is not identified in the survey, for general practice) in at least four of six nationally recognized surveys identified in the rule, dividing such amount by 2,000 hours. The six surveys identified in the regulations are: Sullivan, Cotter & Associates, Inc.—Physician Compensation and Productivity Survey; Hay Group—Physicians Compensation Survey; Hospital and Healthcare Compensation Services—Physician Salary Survey Report; Medical Group Management Association—Physician Compensation and Productivity Survey; ECS Watson Wyatt—Hospital and Health Care Management Compensation Report; and William M. Mercer—Integrated Health Networks Compensation Survey.

Physician Incentive Plan. In response to comments seeking expansion of the physician incentive plan (“PIP”) provision (*i.e.*, the special incentive compensation provision within the personal services arrangements exception) to include arrangements involving subcontractors of an HMO, CMS modified the PIP provision, as well as the definition of a PIP. The modification clarifies that the PIP provision applies to downstream subcontractor arrangements and includes any compensation arrangement between an entity (or downstream contractor) and a physician/physician group that may have the effect of limiting services to that entity’s enrollees.

Radiology and Certain Other Imaging Services. CMS, in principle, generally is disinclined to exercise discretion to exclude a service from being considered a DHS when such service otherwise falls within one of the eleven categories of DHS. Nonetheless, in a limited departure from that position, CMS expanded the scope of radiology procedures performed in connection with a nonradiological medical procedure that would not be considered a “radiology” service for Stark Law purposes to include certain post-procedure radiology services. In particular, the Phase II

regulations modify the definition of “radiology and other imaging services” to provide that radiology services performed during or immediately after a procedure in order to confirm the placement of an item during the procedure are not DHS. Under Phase I, only such services provided during the nonradiological procedure qualified for the exclusion.

Referring Physician. Under the Phase II regulations, a referring physician and his or her wholly owned professional corporation are deemed to be the same for Stark Law purposes. This change essentially converts what otherwise would be an indirect compensation arrangement between the physician-sole owner of a PC and a DHS entity into a direct compensation arrangement. The preamble offers an example of a hospital contracting with a referring physician's wholly owned PC for the provision of services, noting that under the Phase I regulations, the only exception available to cover that arrangement would be the indirect compensation arrangements exception. Under the revised Phase II rule, however, the agreement would create a direct compensation arrangement between the referring physician and the hospital. By contrast, CMS expressly declined to permit physician members of a group practice to stand in the shoes of their group practices for relying on other exceptions. Thus, when a group practice contracts with a DHS entity, it will continue to be necessary to analyze, first, whether there is an indirect compensation arrangement between the group members and the DHS entity and, if so, whether the indirect compensation arrangement exception will apply.

C. Group Practice (§ 411.352)

The Phase II regulations maintain in effect the nine standards set forth under Phase I for what constitutes a group practice. Consistent with the prior rule, the Phase II standards generally track the statute and, to a significant degree, conform with the Phase I regulations' formulation of the group practice elements, albeit with certain notable changes. One change is the establishment of a “12-month grace period” to address problems faced by a group practice that falls out of compliance with the “substantially all test” when adding new members to the group, another is relaxing the single entity standard to permit groups operating in contiguous states to meet the “single entity” standard. Although CMS discusses the group practice definition at points in the preamble as if it were a separate exception, it is in essence only a definitional provision. The maximum benefit of qualifying as a group practice is derived from fitting within the in-office ancillary, physician services and other exceptions.

Single Legal Entity. Although a group practice still must possess the requisite indicia of the group constituting a single legal entity, the Phase II regulations make several meaningful modifications to the “single entity standard” that provide greater flexibility. First, whereas Phase I focused on whether the group was “formed” primarily for the purpose of becoming a physician group practice, under the Phase II formulation of the primary purpose test, the relevant inquiry is whether the group is “operating” primarily for the purpose of being a physician practice (regardless of the purpose for which it was originally formed). This change does not alter CMS' view that an entity which has a substantial purpose other than operating a physician group practice, for example, a hospital that employs two or more physicians, cannot qualify as a group practice (though a hospital may own a separate entity that qualifies as a group practice). Second, the Phase II regulations clarify that a group practice can be owned by another medical group on the condition that the organizing/owning group itself no longer is an operating physician practice. Thus, while a

group practice owned by another functioning medical group fails to meet the single legal entity standard, a defunct medical group can own or operate a separate entity that meets the definition of a group practice. Third, Phase II offers relief to certain groups operating in multiple jurisdictions through “mirror” entities. Specifically, a group practice operating in two or more contiguous states (though not all states must be contiguous to all other states) that comprises multiple legal entities nonetheless will be considered to be a single legal entity so long as (a) the legal entities are absolutely identical with respect to ownership, governance, and operation, and (b) the group practice organizes into multiple entities in order to comply with the jurisdictional licensing laws of the states in which the group operates.

Grace Period for Substantially All Test with Addition of New Members.

The Phase I Final Regulations established a 12-month grace period for newly organized groups to comply with the “substantially all” test (which, in pertinent part, requires that at least 75% of patient care services provided by members of the group be provided and billed through the group). Under Phase II, a corresponding grace period is provided in the case of a group practice which adds a new, relocating physician, subject to satisfaction of certain conditions. The rationale for the change is the prospect that a group practice that adds new physicians could risk losing its group practice status if the addition of the new physicians precludes the group from meeting the “substantially all” test. If the addition to an existing group of a new member who has relocated his or her practice would result in that existing group practice falling out of compliance with the “substantially all” test, the group practice is afforded a 12-month period (*i.e.*, following the addition of the new member) to become fully compliant, provided that (a) during such period, the group practice otherwise fully complies with the “substantially all” test if the computation excludes the new member, and (b) the new physician's employment with, or ownership interest in, the group practice is documented in writing by or before the commencement of the relationship. As with start-up groups, this grace period is not available when an existing group practice reorganizes or admits a new member who is not relocating his or her practice. To determine whether the physician has “relocated” for purposes of this provision, the relocating physician must formerly have conducted his or her practice outside the new group practice's “geographic area,” as that term is defined in the “physician recruitment exception,” discussed below.

Two or More Physicians. The Phase I commentary addressing the “two or more physicians test” created uncertainty regarding the identity of the two physicians, in particular whether each of these physicians had to be full-time employees. In the preamble to the Phase II regulations, CMS reiterates that employed physicians, even if part-time, count towards satisfying the “two or more physicians test.” The commentary clarifies, however, that independent contractors, who do not qualify as “members of the group practice,” likewise do not count towards the “two or more physicians test.” Moreover, CMS clearly distinguishes “member of the group practice” from “physician in the group practice.” The former is limited to owners and employees, while the latter also includes independent contractors while under contract with a group to provide patient care services in the group practice's facilities. The difference can be particularly significant in interpreting the scope of the in-office ancillary services exception.

Productivity Bonuses and Profit Shares. Consistent with Phase I, group practices are permitted to pay productivity bonuses and profit shares to their physicians based directly on personal productivity (including services

that are "incident to" those personally performed services). Likewise, the Phase II regulations continue to prohibit groups from paying productivity bonuses or profit shares to their physicians based directly on the volume or value of referrals of DHS performed by others, but those revenues may be indirectly reflected in physician compensation in a group practice setting. Notwithstanding such prohibition, as noted specifically in the preamble, nothing in the statute or the regulations precludes groups from paying productivity bonuses or incentives based on other criteria that do not take into account the volume or value of DHS referrals. Although not reflected in changes to the text of the regulations, the preamble clarifies that (a) groups may pay productivity bonuses and profit shares to any independent contractor who qualifies as a "physician in the group," and (b) for purposes of sub-pooling (*i.e.*, distributing overall profits to a component of the group), any grouping of at least five physicians is still permissible.

Unified Business. CMS notes in the preamble that the unified business test sets forth general parameters that provide indicia of integration, in particular, possessing centralized management that exercises substantial control over the group's activities, rather than merely rubber stamping decisions by the group's various cost centers or locations. Thus, consistent with Phase I, to qualify as a "unified business" under the Phase II regulations, a group must demonstrate: (a) centralized decision-making by a representative board with effective control over the group's assets and liabilities, including budgets and compensation from all sources (not just DHS); and (b) consolidated billing, accounting and financial reporting. Phase II, however, deletes the requirement for centralized, group-wide utilization review.

D. Financial Relationships (§ 411.354)

In addition to the changes in the text of the regulations, CMS made two noteworthy observations about financial relationships generally in the preamble. First, CMS reiterated in the preamble that even financial relationships wholly unrelated to DHS payable by Medicare implicate the Stark Law and require an exception to allow billing and payment for DHS referrals from the physician. Second, despite a general preference for bright line rules in the Phase II regulations, CMS declined to establish a bright line test for determining whether a particular ownership or investment arrangement is a sham. It did, however, reiterate that payments not legitimately related to the ownership or investment interest (*e.g.*, funneling additional remuneration to physicians as ostensible returns on investment) would not be protected by the exceptions. (Examples from the Phase I regulations included an LLC that was losing money but borrowed from a bank to make distributions to physician investors.)

1. Direct Ownership and Investment (§ 411.354(b)(1) & (b)(3)(ii))

The Phase II regulations clarify that stock options and convertible securities (*i.e.*, debt convertible into stock) create an ownership interest if they are purchased or received as dividends or similar distributions (whether or not exercised). If these securities are received as compensation for services, they create an ownership or investment arrangement only after the options are exercised or the securities are converted to equity.

2. Indirect Ownership and Investment (§ 411.354(b)(5))

CMS clarified the definition of indirect ownership and investment arrangements in three important respects. First, it noted that an indirect

ownership or investment interest exists only if there is an unbroken chain between the referring physician and the DHS entity where each link in the chain is an ownership or investment interest (whether upstream, downstream or sideways). If an indirect ownership or investment interest exists, it cannot fit within the indirect compensation arrangement exception. There are also no indirect ownership exceptions, rather the same exceptions apply for indirect and direct ownership or investment interests. Second, in the preamble CMS clarified the scope of the knowledge requirement for establishing existence of an indirect ownership or investment interest. The DHS entity must have knowledge of the chain of ownership or investment interests or be acting with reckless disregard or deliberate ignorance of such a linkage. Although there is no general duty of inquiry about a physician's ownership interest, under certain circumstances a failure to investigate may constitute reckless disregard or deliberate ignorance. Third, giving some encouragement for joint ventures, CMS provided that mere common ownership as investors does not necessarily create an indirect ownership or investment arrangement between the investors. If it does create an indirect ownership interest, *e.g.*, where the joint venture owns a DHS entity, then the parties must fit within one of the existing ownership exceptions.

3. Indirect Compensation Arrangements (§ 411.354(c)(2))

CMS noted confusion among commenters as to the meaning of "varies with or otherwise reflects" in the volume or value standard used to define what constitutes an indirect compensation arrangement. Commenters confused this standard with the similar language in the indirect compensation arrangements exception that requires, among other things, fair market value compensation that does not "take into account" the volume or value of referrals or other business generated by the referring physician. CMS explained the difference in the preamble by pointing out that all per-unit or per-click compensation methodologies would, on some level, vary with or reflect volume or value in the aggregate, which is sufficient to find that an indirect compensation arrangement exists whether or not the compensation methodology fits the safe harbors for unit-based compensation (discussed below). CMS added in the preamble that if the methodology does fit those safe harbors, the arrangement would be deemed not to "take into account" volume or value and would qualify for the indirect compensation arrangements exception because that exception requires fair market value without regard to the volume or value of DHS referrals or other business but it does not look to variations in aggregate compensation. The only substantive change in the text of the rule in the Phase II regulations is to revise the definition of indirect compensation arrangements to specify that an indirect compensation arrangement may exist even if the compensation fits the safe harbor for unit-based compensation.

Each link is counted, even if it fits an exception itself, though such a chain of excepted arrangements is unlikely to create an indirect compensation arrangement in most cases. CMS also observed that even fixed aggregate compensation may take into account the volume or value of referrals, and thus form the basis of an indirect compensation arrangement (*e.g.*, if compensation exceeds fair market value of items or services provided or if it is inflated to reflect the volume or value of referrals).

In the preamble, CMS noted that DHS entities unaware of a prohibited compensation arrangement along the chain are protected by the knowledge requirement for finding an indirect compensation arrangement exists (*i.e.*, requirement of actual knowledge or reckless disregard or deliberate

ignorance by the DHS entity of the physician's compensation arrangement varying with volume or value). CMS, however, declined to provide a blanket exception to allow DHS entities to rely on certifications from physicians that their compensation is consistent with fair market value and satisfies the volume or value standard. A DHS entity has no duty to inquire about variations in a physician's aggregate compensation along the chain unless there are facts and circumstances to suggest that failure to follow up would constitute deliberate ignorance or reckless disregard. CMS also notes in the preamble that common ownership or investment can constitute a link in an unbroken chain for finding an indirect compensation arrangement [DHS entity - {ownership relationship} - joint venture - {ownership relationship} - physician]. If the two remaining criteria for finding an indirect compensation arrangement are present, a joint venture may create an indirect compensation arrangement between the investors. One of those criteria is that the aggregate return on investment (including capital appreciation) varies with or otherwise takes into account volume or value of referrals or other business generated by the referring physician for a DHS entity. If the joint venture does not provide DHS, it is unlikely in CMS' view that this requirement will be met. One example in the preamble of a joint venture that may create an indirect compensation arrangement would be an imaging equipment leasing company co-owned by a hospital (the DHS entity) and a physician. If the hospital leases imaging equipment from the joint venture, the physician's aggregate payout may vary with the volume of imaging business he or she generates for the hospital and the hospital is likely to know this as a co-owner. However, if the hospital pays a fair market value per click fee that does not vary over the term of the agreement the arrangement likely would fit the indirect compensation arrangement exception.

4. Set in Advance, Percentage and Unit-based Compensation (§ 411.354(d)(1) - (3))

The Phase II regulations create a series of safe harbors for compensation arrangements that will be deemed not to violate the volume or value standard. The general volume or value standard relates to referrals or business generated by the referring physician for the DHS entity - other than services personally performed by the referring physician. Several exceptions also require that compensation be set in advance. The Phase II regulations provide significant added flexibility for percentage-based compensation and clarify the scope of permitted per unit of service or "per click" compensation. Specifically, compensation will be considered to be "set in advance" if either the aggregate amount, a per unit amount or a specific formula for calculating compensation are set forth in an agreement entered into before the related items or services are provided. For percentage compensation, the formula must be set out in sufficient detail so that the calculations "can be objectively verified," and the formula cannot be modified during the term of the agreement in any manner that reflects the volume or value of referrals or other business generated by the referring physician.

In the preamble, CMS noted that time-based, per-unit and per-click compensation arrangements are generally allowed "if they are at fair market value without reference to referrals." In the text of the regulations, CMS clarified the unit-based compensation provision in the Phase II regulations by specifying that in order to satisfy the volume or value standard, the unit-based compensation must constitute fair market value "for items and services actually provided." The Phase II regulations also clarify that unit-based compensation that takes into account services personally performed by the referring physician (which would not include

incident to services or their supervision) will not be viewed as taking into account other business generated by the referring physician. Given the definition of referral that carves out such personally performed services, such an arrangement also would not be viewed as taking into account the volume or value of DHS referrals. CMS also noted in the preamble that declining per unit rates for equipment leases would be reviewed on a case-by-case basis and would be acceptable if they are consistent with fair market value and based on costs (*i.e.*, spreading fixed costs over the term of the lease) rather than volume.

5. Mandatory Referrals (§ 411.354(d)(4))

CMS clarified that referrals may be mandated under certain circumstances only for employed physicians, personal services arrangements and managed care contracts. The Phase II regulations purport to limit mandatory referral provisions to referrals that are both (a) related solely to the physician's services covered by the agreement that includes the referral mandate, and (b) reasonably necessary to effectuate the legitimate business purposes of the agreement. For example, the preamble notes that a DHS entity employing a physician on a part-time basis cannot condition the employment on referrals of the physician's private practice business outside the scope of employment. Other requirements continue to apply, including deference to patient choice, insurer requirements and the exercise of professional judgment for the patient's best medical interests.

E. Service Exceptions (Ownership and Compensation, § 411.355)

1. In-office Ancillary Services (§ 411.355(b))

With the Phase II regulations, CMS is taking more steps to eliminate perceived abuses of shared space and equipment outside of bona fide group practices. By tightening the location requirement in particular, CMS noted that it is attempting to assure that DHS qualifying as in-office ancillary services "are truly ancillary to the physician's core medical office practice and are not provided as part of a separate business enterprise." Examples of potentially abusive arrangements that CMS noted in the preamble it is particularly concerned with include "off-site DHS arrangements, such as part-time MRI or CAT scan rentals."

Although CMS describes the revised "same building" standard as providing greater flexibility, in fact it may close the door on many aggressive arrangements. CMS noted that it was concerned that the standard in the Phase I regulations would allow physicians to implement arrangements in which the DHS are insufficiently tied to the referring physician's core medical practice and are essentially separate business enterprises. One example identified in the preamble noted that, under the Phase I regulations, a group practice might lease space at an off-site imaging facility, provide physician services there one day a week and provide only imaging services the rest of the week without any presence or involvement of group practice physicians on site. CMS noted that such arrangements are inconsistent with the intent of the same building requirement and CMS did not intend to permit them. CMS noted that "part-time rentals of DHS equipment are precisely the arrangements that section 1877 of the Act was designed to restrict." CMS also described the Stark Law as being "directed at arrangements that enable physicians to profit from referrals to free-standing DHS that are not ancillary to their medical practices." All providers that have structured joint ventures based on the applicability of the same building requirement in the Phase I regulations should reexamine those arrangements immediately and

complete any necessary restructuring by July 26. Although there may be an argument for up to a 90-day temporary period of noncompliance after July 26 to bring such arrangements into compliance, there can be no assurances that CMS will view aggressive structures as having been in compliance for the past 180 days (a requirement to be entitled to the 90 day grace period of the new temporary noncompliance exception). In fact, in the preamble, CMS stated that any such arrangements that would not qualify under the new "same building" standard should be restructured or unwound before the new rules take effect on July 26, 2004.

The Phase II regulations clarify that a solo practitioner can take advantage of the supervisory provisions in the in-office ancillary exception and directly receive revenue from physicians that he or she supervises in an eligible location, including all three alternatives for the same building standard. CMS also stated clearly in the preamble, however, that a hospital directly employing physicians cannot qualify as a group practice under the Stark Law nor does a faculty practice plan in an academic medical center automatically qualify. Other provisions in the regulations and the preamble make it clear that the employment exception does not protect compensation to employed physicians based on "incident to" services they supervise. What the Phase II regulations fail to address is how CMS would view arrangements where hospital employed physicians (or physicians in a faculty practice plan) are compensated in reliance on the in-office ancillary exception as if they were solo practitioners (*i.e.*, rewarded based on personally performed and directly supervised services).

The most significant limitation on many compensation plans that rely on the in-office ancillary exception is the location requirement. In order to take advantage of this exception, the services must be performed in a centralized building (which still requires full-time lease or ownership, 24/7/365) or in the "same building" (defined in Section 411.351 by postal address and excluding loading docks, parking areas and mobile sites) as other specific non-DHS services. To meet the same building standard, the Phase II regulations require that the ancillary services are furnished in the same building where all of one of the following three sets of requirements are satisfied:

- On-site full-time office: The referring physician or his/her group practice maintains an office in the same building that is normally open to their patients at least 35 hours per week, with the referring physician or another member of the group regularly furnishing physician services at that location at least 30 hours per week. At least some of the physician services must be unrelated to the furnishing of DHS (payable by any payor), even if they may lead to the ordering of DHS. (CMS indicated that it intends this test to reach buildings that are essentially the principal place of practice for a physician or his or her group practice.)
- On-site part-time office: The patient receiving the DHS usually receives physician services at the office from the referring physician or another member of his/her group practice. The office must be owned or rented by the referring physician or his/her group practice and normally open to patients for medical care at least 8 hours per week, with the referring physician (not another member of the group) regularly furnishing physician services at that location at least 6 hours per week. At least some of the physician services must be unrelated to the furnishing of DHS (payable by any payor), even if they may lead to the ordering of DHS. (CMS noted that it intends this test to

reach buildings where the referring physician practices medicine at least one day per week and that are the principal places in which each such physician's patients receive physician services.)

- Referring physician on-site: The referring physician is present and orders the DHS during a patient visit at his/her office on-site, or another member of his/her group practice is present while the DHS are furnished and they are furnished during the group's office hours on-site. The referring physician or his/her group practice must own or rent an office in the building that is normally open to patients for medical care at least 8 hours per week, with the referring physician or another member of the group practice regularly furnishing physician services at that location at least 6 hours per week. At least some of the physician services must be unrelated to the furnishing of DHS (payable by any payor), even if they may lead to the ordering of DHS. (CMS stated that it intends this test to reach buildings where the referring physician or group provides physician services to patients at least one day per week and the DHS are ordered during a patient visit or the referring physicians or group practice members are present when the DHS are furnished.)

CMS noted that the new tests are not intended to preclude occasional weeks where the office is open less, such as for vacations, or where there are patient cancellations or open appointment slots. Rather, the tests look to what is customary, usual or normal for the office. There is also no specific threshold for what qualifies as "some" physician services unrelated to the furnishing of DHS, but CMS indicated that the term should be interpreted in a common sense manner. Moreover, providing interpretations or reads of diagnostic or other tests will not be considered unrelated.

2. Home Health Physicians (§ 411.355(b)(6))

The Phase II regulations continue the special exception to the location requirement for home health physicians and clarify that a patient may have a private home in an assisted living or independent living facility. CMS indicated in the preamble that it will consider such rooms private if the patient occupies the premises as his or her residence (by ownership or lease), and has the right to exclude others from the premises.

3. Prepaid Plans (§ 411.355(c))

CMS has added four additional types of managed care plans within this exception, to allow greater flexibility for certain Medicaid plans in compensating physicians. Other provisions regarding the application of the Stark Law to the Medicaid program have been deferred.

4. ASC, ESRD and Hospice Clinical Laboratory Services (§ 411.355(d))

CMS deleted the separate exception for clinical laboratory services furnished in and included in the composite rate of an ASC or ESRD or by a hospice. In the preamble, CMS explained that the deletion was due to a potential for undue confusion with the regulatory definition of DHS. CMS noted that services separately listed in the statute as DHS that are paid on a composite basis are DHS, notwithstanding the composite payment. The Phase I and Phase II regulations, however, exclude from the definition of DHS all services reimbursed by Medicare as part of a composite rate

except to the extent that those bundled services themselves are specifically enumerated in the statute as a DHS (*i.e.*, home health services, inpatient and outpatient hospital services - all of which remain DHS).

5. Academic Medical Centers (§ 411.355(e))

The Phase II regulations broaden the scope of organizations that may qualify as academic medical centers. For example, supporting organizations such as fundraising foundations that primarily support the teaching mission may qualify as part of an academic medical center. For faculty practice plans, one of the most significant changes is that they no longer need to be tax-exempt in order to qualify as a component of an academic medical center. Components also no longer need to be separately incorporated; however, a practice plan that wants to qualify as a group practice for Stark Law purposes still must be a separate legal entity.

Faculty appointment requirements are also more liberal in the Phase II regulations. A physician can qualify with a faculty appointment either at a medical school or in an educational program at an accredited academic hospital (*i.e.*, a hospital or health system that sponsors at least four approved medical education programs). CMS also permits flexibility in calculating whether a physician performs substantial academic (*e.g.*, classroom and academic research services) or clinical teaching services as an employee of the academic medical center, allowing the parties to use any "reasonable and consistent method." As a safe harbor, the regulations also provide that spending at least 20% of his or her professional time or 8 hours per week providing some combination of these services will be "substantial."

In addition, CMS liberalized the requirements for documentation of funds flow and clarifying the scope of permitted uses of funds in an academic medical center. Specifically, the arrangements may be documented in multiple written agreements instead of a single agreement, and if the academic medical center is a single legal entity, the documentation requirement can be met by reflecting fund transfers among components of the center in routine financial reports. The regulations also clarify that research funds paid to physicians must be used to support either bona fide research or teaching and must be used consistent with the terms and conditions of the grant. The academic medical center's physician compensation arrangements also must comply with the Anti-kickback Statute and all applicable laws regarding billing or claims submission to qualify for this exception.

Finally, CMS relaxed the requirement that faculty physicians form a majority of the medical staff and account for a majority of hospital admissions. Under the Phase II regulations, providers may aggregate faculty from affiliated medical schools and accredited academic hospitals, and residents and nonphysician staff need not be counted. On the other hand, all faculty classifications are counted, including courtesy and volunteer faculty.

6. Implants Furnished by an ASC (§ 411.355(f))

The Phase II regulations clarify that the ASC implant exception applies only if the ASC properly bills Medicare for the implant as an ASC procedure under Section 416.65 of the regulations. If the physician bills for the implant, the physician is a DHS entity and the arrangement must fit another exception for referrals of DHS to be permitted.

7. EPO and Other Dialysis-related Drugs (§ 411.355(g))

CMS has broadened the list of drugs qualifying for the EPO exception (with the current list attached to the regulations). The Phase II regulations, however, clarify that the EPO exception applies to only very limited dialysis-related drugs dispensed for home use (EPO and Aranesp or equivalent drugs identified by CMS). In the preamble, CMS also noted that it intends to monitor use of this exception closely for abuse.

8. Preventive Services (§ 411.355(h))

CMS clarified that preventive screening tests, immunizations and vaccines need not be reimbursed on a fee schedule basis to qualify for the exception. In addition, CMS added more bone densitometry codes to the list of DHS subject to the Stark Law, some of which had already been added following the Phase I regulations. Compensation plans for any physician that reflect referrals for those tests should be revised prior to the effective date of the Phase II regulations.

9. Intra-family Rural Referrals (§ 411.355(j))

One common complaint from physicians is that the Stark Law unfairly penalizes two-physician families. CMS provided limited relief for physicians in the Phase II regulations with a new exception for certain referrals to family members in rural areas. The new exception protects referrals by a physician to a member of his or her immediate family or a DHS entity with which the family member has a financial relationship if all of the following requirements are met: (a) the patient resides in a rural area; (b) there is no other provider available within 25 miles of the patient's residence to furnish the DHS in a timely manner considering the patient's condition (except that for DHS furnished in the patient's home, the test relates to availability to furnish the DHS in the patient's home without regard to where the provider is located); and (c) the financial relationship does not violate the Anti-kickback Statute or any laws applicable to billing or claims submission. To satisfy requirement (b), the referring physician or the family member must make reasonable inquiries as to the availability of other providers to furnish the DHS (though they are not required to inquire about availability of providers located more than 25 miles from the patient's residence). Actual knowledge of available alternatives fitting the standard of (b) above would preclude reliance on this exception. In other circumstances, the preamble notes that a reasonable inquiry may "include, for example, consulting telephone directories, professional associations, other providers, or Internet resources." Dissatisfaction with quality of care, however, will not justify ignoring an otherwise available DHS entity. (CMS also reiterated that if a physician refers to a family member who subsequently orders DHS for the patient, the order of DHS may fit within the in-office ancillary services exception so long as DHS were not the reason for the original referral.)

F. Ownership and Investment Exceptions (§ 411.356)

1. Publicly-traded Securities (§ 411.356(a))

CMS revised the publicly-traded securities exception to measure public availability of the securities at the time the DHS referral is made, not at the time the securities are acquired by the referring physician or family member.

2. Hospitals (§ 411.356(c))

The Stark Law includes three entity ownership exceptions: rural DHS entities; hospitals in Puerto Rico and whole hospitals (outside Puerto Rico). CMS has not altered any of these exceptions in the Phase II regulations other than by incorporating a recent Congressional moratorium related to physician referrals to specialty hospitals they own outside of Puerto Rico. (In the preamble, however, CMS did note that the whole hospital exception requires a bona fide authorization to perform services at the facility, and granting privileges to a physician who is not expected to perform services at the facility would not qualify.)

In Section 507 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 ("MMA"), Congress enacted an 18 month moratorium (starting December 8, 2003 and ending June 8, 2005) on physicians referring to those specialty hospitals unless they fit within a grandparenting exception. During the first 15 months after enactment of MMA, MedPAC and HHS are to conduct studies of the costs, patient selection, referral patterns, payor mix, quality of care, charity care differentials and financial impact of specialty hospitals and file a report with Congress, including recommendations for legislative or administrative changes. MMA defined a "specialty hospital" as any hospital that is primarily or exclusively engaged in one of the following categories: cardiac care, orthopedic care or surgical procedures. Although the Secretary of HHS has the authority to add other categories the initial guidance from CMS does not expand the statutory list.

The moratorium does not apply to hospitals that the Secretary of HHS determines to be in operation before or under development on November 18, 2003 if (a) the number of physician investors does not increase (presumably including resales by physicians and indirect ownership), (b) the hospital does not provide any different specialty services covered by the moratorium, (c) there is no increase in the number of beds other than on the main campus and then not more than the greater of 50% or five beds, and (d) the hospital meets other requirements specified by the Secretary. MMA also provides that, in determining whether a hospital was "under development" on November 18, 2003, the Secretary shall consider the status of architectural plans, financing, satisfaction of zoning requirements, receipt of required state agency approvals, and any other evidence the Secretary deems relevant. In guidance issued on the moratorium on March 19, 2004 (CMS Pub. 100-20, Transmittal 62, Change Request 3036), CMS indicated that it recognizes that in some cases it may not be feasible for a specialty hospital to have completed all four of the steps identified as factors in MMA and CMS will make the determinations on a case-by-case basis. CMS also stated that any specialty hospital with a Medicare provider agreement in effect as of November 18, 2003 will be considered to have been in operation on that date. Other hospitals seeking a determination of whether they met the "under development" criteria may request an advisory opinion from CMS; however, fiscal intermediaries are not authorized to provide guidance on the application of the moratorium. CMS expects to be able to process opinion requests within 60 days of receiving complete information, and anyone receiving an adverse opinion may appeal to the CMS Administrator.

Both MMA and the CMS guidance leave open a variety of questions, such as the meaning of "primarily or exclusively" engaged in multiple specialties on the list, and whether CMS will take the position that an advance determination from CMS is required to qualify for the

grandparenting exception (though that option certainly poses the least risk).

G. Compensation Exceptions (§ 411.357)

1. Space and Equipment Leases (§ 411.357(a) & (b))

In the 1998 proposed regulations, CMS proposed several interpretive changes to the space and equipment lease exceptions. First, CMS proposed interpreting the requirement that the lease term be for one year as permitting leases to be terminated for cause within the one-year period, provided the parties did not enter into another lease until after the expiration of the original term. The proposed rule also provided that CMS would interpret the one-year term requirement as requiring that any renewal of a lease be for at least one year, thereby precluding holdover month-to-month leases. Second, CMS proposed interpreting the exclusive use provisions to prohibit subleases, unless the sublease itself satisfied the conditions of the exception. Third, CMS proposed interpreting the exceptions as applying to operating leases, but not capital leases. Finally, CMS proposed 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.

In the Phase II regulations, CMS has adopted the language of the proposed regulations with the following changes:

- Leases may be terminated with or without cause as long as no further agreement is entered into within the first year of the original lease term and any new lease fits on its own terms in an exception.
- Month-to-month holdover leases are allowed for up to six months immediately following an agreement of at least 1 year provided the holdover rental is on the same terms and conditions as the original lease.
- All leases or rental agreements, whether operating or capital, are eligible for the lease exceptions if they meet the applicable criteria.
- The "exclusive use" provision was revised to allow many subleases. The exclusive use test will be met as long as the lessee (or sublessee) does not share the rented space or equipment with the lessor (or any person or entity related to the lessor, including, but not limited to, group practices, group practice physicians, or other providers owned or operated by the lessor) during the time it is rented or used by the lessee (or sublessee). A subleasing arrangement may create a separate indirect compensation arrangement between the lessor and the sublessee that would need to be evaluated under the indirect compensation rules.
- "Per click" rental payments are permitted for DHS referred by the referring physician as long as the payments are fair market value and do not take into account the volume or value of referrals or other business generated by the referring physician.

2. Bona Fide Employment Relationships (§ 411.357(c))

The 1998 proposed regulations included additional requirements to the statutory exception set forth at Section 1877(e)(2) of the statute that would exclude the payment of any productivity bonus based on a physician's own referrals of DHS, even where personally performed. The proposed regulations also included a restriction on compensation related to other

business generated between the parties that is not present in the statute. In the commentary to the Phase II regulations, CMS notes that the proposed limitations are no longer relevant (and were not included in the Phase II regulations) given CMS' determination in the Phase I regulations that personally performed DHS are not referrals for purposes of the Stark Law.

3. Personal Service Arrangements (§ 411.357(d))

The Phase II regulations adopt the provisions included in the 1998 proposed regulations with some modifications. First, CMS clarified that it is permissible to terminate a personal service arrangement without cause before the end of the one-year term for any reason as long as the parties do not enter into a substantially similar arrangement within the first year of the original term. Second, the PIP exception has been modified to clarify that payments from downstream subcontractors are included in the exception. Additionally, the incorporation by reference requirement (which, as proposed, would have required multiple agreements to incorporate one another by reference) has been revised to require either the incorporation by reference of other agreements or cross-referencing to one or more master lists of contracts that are maintained and updated centrally so long as the master lists cover all of the contracts between a provider and a referring physician or immediate family member.

4. Physician Recruitment (§ 411.357(e))

The Stark Law excepts remuneration provided by a hospital to a physician to induce the physician to relocate to the geographic area served by the hospital in order to become a member of the hospital's medical staff. The 1998 proposed regulations included a requirement that the recruited physician reside outside the hospital's geographic area and actually relocate into the area. The Phase II regulations expand the exception to include payments by federally qualified health centers ("FQHCs") and they substantially revise the exception in the following respects:

- The relocation requirement now focuses on the recruited physician's medical practice, rather than his or her residence. A physician will be deemed to have relocated to the hospital's geographic area if: (i) the physician relocates the site of his or her practice at least 25 miles; or (ii) at least 75% of the physician's professional services revenues (including services to hospital inpatients) are derived from services provided to new patients (or a reasonable expectation of that change in patient base with respect to the first year of an arrangement).
- Residents and physicians who have been in medical practice less than one year will not be subject to the relocation requirement, except that they must establish their medical practice in the geographic area served by the hospital.
- The Phase II regulations permit hospitals to provide recruitment support through an existing medical group in connection with the recruitment of a new physician provided that: (i) the payments made to the group are passed directly to the recruited physician less the actual costs incurred by the group in recruiting the physician; (ii) in the case of an income guarantee, the costs allocated by the group to the physician may not exceed the actual additional incremental costs to the group attributable to the recruited physician; and (iii) the group may not impose additional practice restrictions on the recruited physician (such as a noncompete) other than conditions related to quality of care.

- CMS clarifies its position that recruitment payments not be used to lock in physician referrals to the hospital, except insofar as there may be a separate, excepted employment or contractual arrangement under which required referrals are permitted in accordance with Section 411.354(d)(4). The Phase II regulations also make clear that recruits must be allowed to establish staff privileges at other hospitals and, except as noted in the prior sentence, to refer to other entities (even competitors) - however, reasonable credentialing restrictions on physicians becoming competitors of a hospital are permitted.

5. Isolated Transactions (§ 411.357(f))

The Phase II regulations include two principal changes to this exception. First, CMS modified the definition of "isolated transaction" to permit installment payments, provided the total aggregate payment is: (i) set before the first payment is made; and (ii) does not take into account, directly or indirectly, referrals or other business generated by the referring physician. Additionally, the outstanding balance must be guaranteed by a third party, secured by a negotiable promissory note, or subject to a similar mechanism to assure payment even if the purchaser defaults. Second, post-closing adjustments that are commercially reasonable and not dependent on referrals or other business generated by the referring physician will be permitted if made within 6 months of the date of a purchase or sale transaction.

6. Remuneration Unrelated to the Provision of DHS (§ 411.357(g))

Remuneration provided by a hospital to a physician that does not relate to the furnishing of DHS does not constitute a prohibited compensation arrangement under the Stark Law. In the preamble to the Phase II regulations, CMS states that it will interpret this exception narrowly, and that it will be available only if remuneration is wholly unrelated to the provision of DHS and does not take into account the volume or value of a physician's referrals. Generally, for purposes of this exception, CMS will treat any item, service, or cost that could be allocated in whole or in part to Medicare or Medicaid under applicable cost reporting principles to be related directly or indirectly to the provision of DHS. In addition, other remuneration will be considered related to DHS for purposes of this exception if it is furnished, directly or indirectly, explicitly or implicitly, in a selective, targeted, preferential, or conditional manner to medical staff or other physicians in a position to make or influence referrals.

7. Certain Group Practice Arrangements with Hospitals (§ 411.357(h))

The Phase II regulations do not include any material modifications to this exception, which applies only to certain arrangements continuously in effect since December 19, 1989.

8. Payments Made by a Physician for Items and Services (§ 411.357(i))

This exception protects payments that a physician makes to a laboratory in exchange for clinical laboratory services or to an entity as compensation for other items or services, if the items or services are furnished at a price that is consistent with fair market value. The 1998 proposed regulations would have interpreted "other items or services" to mean any kind of items or services that a physician might purchase, but not including clinical

laboratory services, or any items or services specifically listed under other compensation exceptions (*i.e.*, the exceptions would be mutually exclusive). In addition, the 1998 proposed regulations included a new exception for discounts to physicians based on the volume of referrals, provided the discount is passed on in full to the patients or their insurers and does not benefit the physicians in any way. The Phase II regulations adopt the proposed rule without the proposed exception for discounts because CMS believes that legitimate discounts will fall within the range of values that is "fair market value" and be eligible for protection under the fair market value exception. Moreover, CMS has extended the protection under the exception to cover payments by a referring physician's immediate family member based on CMS' interpretation of Congressional intent.

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

The Phase I regulations included an exception for non-monetary compensation up to \$300 and an exception for incidental benefits provided by a hospital to its medical staff. In response to comments that the \$300 and \$25 thresholds in such exceptions should be indexed for inflation, the Phase II regulations include revisions pursuant to which the \$300 limit in Section 411.357(k) and the \$25 limit in Section 411.357(m) will be adjusted annually for inflation to the nearest whole dollar effective January 1 of each year using the increase in the Consumer Price Index-Urban All Items (CPI-U) for the 12-month period that ends the previous September 30.

10. Fair Market Value (§ 411.357(l))

In response to comments advocating the expansion of this exception to include the transfer, lease or license of real property, intangible property, property rights or a covenant not to compete, CMS has clarified that this exception is applicable only to written arrangements for the provision of items and services by a physician. Moreover, CMS clarified in the preamble that this exception would not protect space leases or physician recruitment arrangements.

11. Risk-Sharing Arrangements (§ 411.357(n))

This exception applies to compensation (including, but not limited to, withholds, bonuses, and risk pools) between a managed care organization or an independent physician's association and a physician (either directly or indirectly through a subcontractor) for services provided to enrollees of a health plan. The commentary to the Phase II regulations includes a clarification that this exception is meant to cover all risk-sharing compensation paid to physicians by an entity downstream of any type of health plan, insurance company, HMO, or Independent Practice Association (IPA), provided the arrangement relates to enrollees and meets the conditions set forth in the exception.

12. Compliance Training (§ 411.357(o))

The Phase II regulations expand the exception for compliance training offered by a hospital to physicians practicing in the hospital's community or service area to include compliance training (a) offered by any DHS entity, or (b) offered to a physician's immediate family members or office staff. CMS also clarified that the provision of CME to a physician does not constitute compliance training for the purposes of this exception.

H. New Compensation Exceptions (§ 411.357)

1. Retention Payments in Underserved Areas (§ 411.357(t))

The Phase II regulations include a new exception for remuneration provided by a hospital or FQHC directly to a physician on the hospital's or FQHC's medical staff to retain the physician's medical practice in the geographic area served by the hospital or FQHC if all of the following conditions are met: (a) the requirements of the physician recruitment exception for solo practices are satisfied (*i.e.*, written agreement, not conditioned on referrals, amount of assistance not determined based on actual or anticipated volume or value of referrals or other business, allowed to establish staff privileges and refer elsewhere unless within the mandatory referral provisions of the regulations); (b) the geographic area served by the hospital or FQHC is a HPSA (regardless of the physician's specialty) or is an area with demonstrated need for the physician as determined by the Secretary in an advisory opinion; (c) the physician has a bona fide firm, written recruitment offer from a hospital or FQHC that is not related to the hospital or FQHC making the payment, and the offer specifies the remuneration being offered and would require the physician to relocate his or her practice at least 25 miles *and* outside of the geographic area served by the hospital or FQHC making the retention payment; (d) The retention payment is limited to the lower of - (1) the amount obtained by subtracting (A) the physician's current income from physician and related services from (B) the income the physician would receive from comparable physician and related services in the recruitment offer, provided that the respective incomes are determined using a reasonable and consistent methodology and are calculated uniformly 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 replacement physician; (f) any retention payment is subject to the same obligations and restrictions, if any, on repayment or forgiveness of indebtedness as the recruitment offer; (g) the hospital or FQHC does not enter into a retention arrangement with a particular referring physician more than once every 5 years and the amount and terms of the retention payment are not altered during the term of the arrangement in any manner that takes into account the volume or value of referrals or other business generated by the physician; (h) the arrangement otherwise complies with all of the conditions of this section; and (i) the arrangement does not violate the Anti-kickback Statute or any Federal or state law or regulation governing billing or claims submission.

2. Community-Wide Health Information Systems (§ 411.357(u))

The Phase II regulations include a new regulatory exception for the provision of information technology items and services (including hardware and software) by a DHS entity to a physician to participate in a community-wide health information system designed to enhance the overall health of the community, so long as the following conditions are met: (a) the health information system must be community-wide (*i.e.*, available to all providers, practitioners, and residents of the community who desire to participate); (b) the system must allow providers to access and share electronic health care records (the system also may permit access to, and sharing of, complementary drug information systems, general health information, medical alerts, and related information for patients served by the community's providers); (c) the DHS entity may only provide information technology items and services that are necessary to enable the physician to participate in the health information system (*i.e.*, the

information technology items or services furnished under the exception must principally be used by the physician as part of the community-wide health information system); (d) the items and services may not be provided in any manner that takes into account the volume or value of referrals or other business; and (e) the arrangement must not violate the Anti-kickback Statute and all claims submission and billing must comply with applicable Federal and state laws and regulations.

3. Referral Services and Obstetrical Malpractice Insurance Subsidies (§ 411.357(q) & (r))

The Phase II regulations create two new exceptions that incorporate the provisions of the Anti-kickback Statute safe harbors for physician referral services (Section 1001.952(f)) and obstetrical malpractice insurance subsidies for certain OB practices in HPSAs (Section 1001.952(o)).

4. Professional Courtesy (§ 411.357(s))

The Phase II regulations include a new compensation exception for professional courtesy (*i.e.*, the provision of free or discounted services to physicians and their family members). For purposes of this exception, the term "professional courtesy" is defined as the provision of free or discounted health care items or services to a physician or his or her immediate family members or office staff. To qualify for the new exception, the arrangement must meet the following conditions: (a) the professional courtesy is offered to all physicians on the entity's bona fide medical staff or in the entity's local community without regard to the volume or value of referrals or other business generated; (b) the health care items and services provided are of a type routinely provided by the DHS entity; (c) the DHS entity's professional courtesy policy is set out in writing and approved in advance by the entity's governing body; (d) 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; (e) if the professional courtesy involves any whole or partial waiver of any coinsurance obligation, the insurer is informed in writing of the reduction; and (f) the arrangement does not violate the Anti-kickback Statute or any Federal or state law or regulation governing billing or claims submission.

5. Charitable Donations by a Physician (§ 411.357(j))

The Phase II regulations include a new compensation exception for bona fide charitable donations made by a physician (or immediate family member) to a DHS entity. To qualify for the exception: (a) the donation must be made to an organization exempt from taxation under the Internal Revenue Code (or to a supporting organization); (b) the donation may not be solicited or made in any manner that takes into account the volume or value of referrals or other business generated by the physician (broad-based solicitations not targeted at physicians are acceptable, such as the sale of charity ball tickets and general fundraisers); and (c) the arrangement must not violate the Anti-kickback Statute or any Federal or state law or regulation governing billing or claims submission.

I. Reporting Requirements (§ 411.361)

The Phase II regulations require all entities furnishing services for which payment may be made under Medicare (except those entities that furnish 20 or fewer Part A and Part B services during a calendar year) to retain reportable information and furnish it to CMS or to OIG upon request, in the form, manner, and at the times that CMS or OIG specify. The information requested by CMS or OIG can include: (a) name and unique physician identification number (UPIN) of each physician who has a reportable financial relationship with the entity; (b) name and UPIN of each physician who has an immediate family member who has a reportable financial relationship with the entity; (c) the covered services furnished by the entity; and (d) with respect to each physician identified in (a) and (b), the nature of the financial relationship (including the extent and/or value of the ownership or investment interest or compensation arrangement) as evidenced in records that the entity knows or should know about in the course of prudently conducting business, including, but not limited to, records that it is already required to retain to comply with the rules of the IRS and the Securities and Exchange Commission and other rules of the Medicare and Medicaid programs.

DHS entities will be given at least 30 days to comply with a request for disclosure. For purposes of the Phase II regulations, a reportable financial relationship is any ownership or investment interest, as defined in Section 411.354(b), or any compensation arrangement, as defined in Section 411.354(c) (except for ownership or investment interests that satisfy the exceptions regarding publicly-traded securities and mutual funds). Any person who is required, but fails, to submit information concerning his or her financial relationships is subject to a civil money penalty of up to \$10,000 for each day past the deadline until the information is submitted.

J. Michigan Self-referral Law (Mich. Comp. Laws § 333.16221(e)(iv)(B))

Michigan's version of the Stark Law essentially adopts the federal statute and regulations as they existed on June 3, 2002, applying the provisions to all DHS referrals regardless of the payor. Accordingly, the specialty hospital moratorium in MMA and the revisions in the Phase II regulations are not automatically applicable under the Michigan statute. In the event of any subsequent revision in the statute or regulations, the Michigan Department of Community Health ("MDCH") is required to officially take notice of the revision; however, Section 16221(e)(iv) does not specify when MDCH is required to take notice or whether it is automatic. After MDCH takes notice of the revision, it has 30 days to determine whether the revision (a) pertains to DHS referrals by physicians, and (b) continues to protect the public from inappropriate referrals by physicians. If MDCH determines that the revision satisfies both criteria, MDCH may adopt a rule incorporating the revision by reference, but it may not vary the terms of the revision. If MDCH declines to adopt a new rule, Michigan providers would be forced to comply with two different versions of the Stark Law, one for Federal purposes and one for state purposes.

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