Compliance Overview:

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New Stark Rules

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New Stark Rules Tighten Physician Financial Arrangements

CMS published revisions to the Stark Law regulations on August 19, 2008 as part of its Final Inpatient Prospective Payment System (IPPS) rule for 2009.[1] Changes made in the 2009 IPPS rule include implementation of proposals that were made in the calendar year 2008 Physician Fee Schedule rule (72 Fed.Reg. 38122, 38179) and in the fiscal year 2009 IPPS rule (73 Fed.Reg. 23528, 23683). Many of the changes will be effective October 1, 2008, with a few having a delayed effective date of October 1, 2009, to allow providers time to re-craft existing arrangements. The most significant changes are discussed briefly below, and in more detail in the following pages.

> "The changes are another sign that enforcement officials continue to take a stricter stance on non-compliance with the Stark law"

• **Period of Disallowance.** The new regulations establish two "periods of disallowance." These are defined periods during which a physician will be prohibited from referring designated health services and during which a DHS entity will be prohibited from billing Medicare for DHS services. The two period of disallowance rules will be effective for instances of noncompliance that are either (1) unrelated to compensation (e.g., failure to obtain a signature on an agreement); or (2) related to compensation (e.g., underpayment of rent by a physician who leases space from a DHS entity; provision of excess non-monetary compensation). The examples CMS provides of application of the new rule include an instance where a hospital goes $100 over the non-monetary compensation limit and is barred from billing for 9 months of DHS referrals from the physician who received the $100. The examples are striking illustrations of how CMS believes the Stark law and regulations should be applied.

• **Alternative Method for Compliance with Signature Requirements.** The new regulations also provide an alternative method for avoiding the referral and billing prohibitions of Stark when the only non-compliance with an exception is failure to obtain a signature on the written agreement required by a Stark exception. Where the failure is "inadvertent," the new exception requires that the missing signature be obtained within 90 days; if the failure to obtain a signature is "knowing," the new exception requires that a signature be obtained within 30 days.

• **Expansion of the Definition of "Entity."** The definition of a DHS Entity is expanded. Historically, a DHS entity has been defined as the entity that bills or receives payment from Medicare under reassignment for DHS services. That definition is expanded to include both the entity that bills or receives payment for a DHS service, and the entity that provides the DHS service. This change was made to restrict what CMS saw as abusive "under arrangements" agreements between DHS entities and physician owned organizations.

• **Changes to and Implementation of "Stand in the Shoes."** The 2007 amendment to the Stark regulations that requires physicians to "stand in the shoes" of their physician organization for purposes of analyzing

1 73 Federal Register 48434 (August 19, 2008).

compliance with a Stark exception (meaning that the indirect compensation exception is not applicable and a non-compliant relationship with a physician organization is analyzed as a non-compliant relationship with its member physicians) was amended to (1) limit the required application of "stand in the shoes" to physicians with a true ownership or investment interest (physicians whose interest is not ownership or investment or is titular are still allowed, but not required, to "stand in the shoes"), and (2) to provide that "stand in the shoes" is not applicable to arrangements inside of an organization that complies with the academic medical center exception to Stark. The hold that was placed on the effective date for "stand in the shoes" last November will be lifted on October 1, 2008.

• **Changes to CMS interpretation of "set in advance" requirement.** CMS's longstanding interpretation of the "set in advance" language found in many compensation exceptions is modified in the commentary to this rule. CMS allows changes to compensation during the initial year of an arrangement, so long as the new compensation or compensation formula is determined before it is implemented, is sufficiently detailed so that it can be objectively verified, is reflected in an amendment to the written agreement, and is not amended again during the 1 year following implementation of the amendment.

• **Disallowance of Per-Click and Percentage Based Compensation for Space and Equipment Leases.** The exceptions for space and equipment leases, along with the fair market value and indirect compensation exceptions, are amended to prohibit use of per-click and percentage based compensation in space and equipment lease arrangements.

• **Expansion of the Exception for Obstetrics Malpractice Subsidies.** A new alternative is added for providing malpractice subsidies to physicians who provide obstetrics services.

This series of changes to the Stark regulations allow for new compliance exceptions that expand flexibility or address discrete issues with existing exceptions. More importantly, though, the changes are another sign that enforcement officials continue to take a stricter stance on non-compliance with the Stark law. The revisions come in the wake of increasing OIG and DOJ enforcement of the Stark law. The last two years have seen numerous settlements of Stark issues and several CIA's with focused arrangement modules.

Health care providers should examine their compliance programs to determine if enhancements are needed. Best practice compliance programs have incorporated many or all of the following steps to promote compliance with Stark:

- Implementation of a contract management system
- Reinforcing contract approval process and signature authority
- Establishing and enforcing a no-contract, no-pay policy
- Establishing a non-monetary compensation tracking system
- Ensuring that rents are being collected in accordance with space and equipment leases
- Revising policies to reflect appropriate limitations on gifts and courtesies for physicians
- Expanding bill-hold policies to require that services referred by a physician with a non-compliant financial arrangement must be placed on bill hold
- Conducting a baseline comprehensive review of physician arrangements
- Ensuring that compliance training includes education on Stark rules
- Involving a knowledgeable compliance officer or counsel in strategic planning for physician relationships
- Periodically reviewing a sample of physician arrangements to confirm ongoing compliance

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Period of Disallowance

The revised Stark regulations include the newly defined "period of disallowance"—the period during which a physician will be prohibited from referring services, and a provider will be prohibited from billing Medicare when a Stark violation occurs. This is the most striking development of the new Stark rules. The period of disallowance can begin without the provider having specific knowledge of a Stark violation. In most cases services that are provided during a period of disallowance will not be billable even after the

problem is resolved. And the Stark law not only prohibits billing for services referred pursuant to the non-compliant physician financial relationship—Stark also imposes an affirmative obligation on providers to return to Medicare payments that were made on claims that should not have been billed under the rule.

This new rule establishes two "period of disallowance" rules—one for financial relationships where the non-compliance is unrelated to compensation, and a second for situations where the non-compliance is due either to the payment of compensation in excess of fair market value, or to underpayment of compensation such that the amount paid is insufficient to satisfy the requirements of an applicable exception. Each of these rules sets the beginning of the "period of disallowance" at the time the relationship first fails to satisfy an exception. The rules differ in the conditions that they set for establishing the date on which the provider can be assured that the period of disallowance has ended.

The new rule also includes burden of proof language. When CMS or one of its contractors denies payment on the basis that a service was furnished pursuant to a prohibited referral, the rule shifts the burden to the entity submitting the claim for payment to prove that the services were not furnished pursuant to a prohibited referral. This new rule establishing periods of disallowance will be effective October 1, 2008.

Examples provided with the rule when it was proposed on April 30, 2008, bring the affect of the rule clearly into focus.

> *For example, if a hospital provided nonmonetary compensation totaling $100 in excess of the limits in § 411.357(k) on February 1 and the parties did not discover the noncompliance until October 1 (and, therefore, could not avail themselves of the provisions in § 411.357(k)(3) permitting parties to remain in compliance with the exception if excess nonmonetary compensation (within certain limits) provided inadvertently is discovered and returned with 180 days of its receipt), the period of disallowance would begin on February 1 and end no later than the date that the physician returned the excess nonmonetary compensation or its value ($100 plus interest, as appropriate) to the hospital. Assuming that the physician paid the hospital $100 (plus interest, as appropriate) on October 15, the period of disallowance would run from February 1 through no later than October 15.*

So . . . take a physician to dinner and allow him to select the wine one too many times and a $100 overage in your provision of nonmonetary compensation (the FY 2008 limit for nonmonetary compensation is $338) could result is a loss of your ability to bill for the physician's referrals of designated health services for a significant portion of the year. It is not outside the realm of possibility to imagine a $100 oversight that costs a Medicare provider hundreds of thousand of dollars in Medicare referrals. A simple oversight could cost an organization thousands. Tracking and monitoring of non-monetary compensation is an essential part of an effective physician arrangement compliance program.

CMS also provided an example of application of the rule when noncompliance is cause by payment of an insufficient amount:

> *For example, assume a hospital and physician*

Period of Disallowance:

42 CFR §411.353 Prohibition on certain referrals by physicians and limitations on billing.

(c) Denial of payment for services furnished under a prohibited referral.

(1) Except as provided in paragraph (e) of this section, no Medicare payment may be made for a designated health service that is furnished pursuant to a prohibited referral. The period during which referrals are prohibited is the period of disallowance. For purposes of this section, with respect to the following types of noncompliance, the period of disallowance begins at the time the financial relationship fails to satisfy the requirements of an applicable exception, and ends no later than—

(i) Where the noncompliance is unrelated to compensation, the date that the financial relationship satisfy's all of the requirements of an applicable exception;

(ii) Where the noncompliance is due to payment of excess compensation, the date on which all excess compensation is returned, by the party that received it, to the party that paid it and the financial relationship satisfies all of the requirements of an applicable exception; or

(iii) Where the noncompliance is due to payment of an amount that is insufficient to satisfy the requirements of an applicable exception, the date on which all additional required compensation is paid, by the party that owes it, to the party to which it is owed and the financial relationship satisfies all of the requirements of an applicable exception.

entered into a 2-year office space rental agreement on January 1 (of Year 1) which specified rental charges (consistent with fair market value) of $20 per square foot during Year 1 and automatically adjusted upward each January 1 by any increase in the CPI–U. If, on January 1 of Year 2 of the agreement, the rental charges increased to $21 per square foot based on the amount of increase in the CPI–U, but the physician continued to pay $20 per square foot until the compliance failure was identified on June 30 of Year 2, the period of disallowance would run from January 1 of Year 2 until no later than June 30 of Year 2, provided that the physician paid the hospital on June 30 of Year 2 the shortfall of $1 per square foot for the 6-month shortfall period (plus interest, as appropriate) and, as of July 1 through the term of the agreement, the physician paid $21 per square foot for the office space, and the arrangement otherwise satisfied the requirements of the exception in § 411.357(d).

One can imagine any number of situations where payments are insufficient to comport with fair market value and a period of disallowance results: a physician leasing space or otherwise utilizing hospital space for private practice activities and not paying rent; a physician's utilization of hospital-employed staff for private practice activities without corresponding payment to the hospital for the value of the hospital employee; even late payment of rent, loan payments, or other amounts owed by a physician to an entity implicate this new "period of disallowance" rule. The example CMS provided makes it clear that noncompliance caused by under-reimbursement can even result when a contract comports fair market value and is otherwise consistent with a Stark exception.

The period of disallowance rule leaves open the possibility that the DHS entity may be the party that is responsible for an underpayment that results in a period of disallowance. For example, in the example provided above, insert a home health agency as tenant (in place of the physician-tenant), and a physician as the landlord (in place of the hospital-landlord) in the example above—the home health agency's failure to pay a rent increase to the physician would result in a period of disallowance, banning the physician/landlord from referring to the HHA, and banning the HHA from billing Medicare for the physician's referrals.)

The final example provided in the April 2008 publication of the proposed rule illustrates an instance of noncompliance that is unrelated to compensation:

[W]here a hospital and a physician enter into a personal service arrangement for medical director services and begin performing under the arrangement on January 1, but do not execute a written agreement until January 31, provided that all of the requirements of § 411.357(d) (the exception for personal service arrangements) are satisfied as of January 31, the period of disallowance would begin on January 1 and end no later than January 31.

In considering this final example it is important first to note that the final rule also establishes a new exception (discussed below) for failure to obtain a needed signature on a contract. Assuming that the only thing missing to make a personal service arrangement compliant with the Stark exception is a signature, and that the signature is obtained within time frames provided by the new exception for missing signatures, there would be no period of disallowance. However, the lesson from the example for other technical issues of non-compliance is clear. Failure to comply with all components of the applicable exception will now result in a clearly defined ban on Medicare referrals and payments.

CMS emphasizes in its commentary on this new rule that when noncompliance is related to compensation, partial and "going forward" cures will not be adequate to end the period of disallowance. "[W]here a party has underpaid compensation . . . it is not sufficient for the parties to address the noncompliant compensation on a going forward basis . . . or for some partial period . . . rather all additional compensation must be paid . . . Similarly . . . [it] is not sufficient for the party receiving excess compensation under a financial relationship to repay some of the excess compensation, but rather the party receiving it must repay all of it to the party that paid it." [2]

The commentary also emphasizes repeatedly that the intent of the new period of disallowance rule is to establish an outside date on which parties subject to the Stark rules can be assured that the referral and billing prohibitions will have ended, and that the rule leaves open the possibility that the period of disallowance may

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end sooner then this outside date. The new rule "does not prevent parties from arguing that the period of disallowance ended earlier than that prescribed outside period, on the theory that the financial relationship ended at an earlier time. . . . We further emphasize that the beginning and end dates of a financial relationship do not necessarily coincide with the beginning and end dates of a written agreement." While this discussion may be relevant to technical violations of the Stark law that result in noncompliance not related to compensation, we have some difficulty imagining a situation where the cures required for noncompliance related to compensation have not been implemented and a cogent argument could be made that the period of disallowance has nonetheless ended. Self-disclosure may be the only way to establish the government's agreement to a definitive end date that is sooner then the outside date established by the new regulations.

The commentary also provides an interesting discussion on the question of whether a physician who receives excess compensation from an entity could negotiate a promissory note to the entity at a commercially reasonable rate and thereby end the period of disallowance.

> *[The new period of disallowance rule] places no restriction on the source of the funds that the physician uses to repay excess compensation (or to make up a shortfall in compensation), and thus, the physician may pay the funds out-of-pocket, or may obtain a loan from a commercial lender, private party or even from the entity itself, in order to repay the excess compensation (or make up the shortfall in compensation). However, where a physician receives excess compensation from an entity and then obtains a loan from the entity to repay the excess . . . the question is raised whether the physician has in fact repaid the excess compensation through a commercially reasonable loan, or whether the loan transaction is a sham.*

The commentary goes on to emphasize that this kind of loan transaction would be highly suspect under both the Stark and Anti-kickback statutes; and that an entity making such a loan would be well advised to both ensure that the terms of the loan are in fact commercially reasonable, that the loan is itself consistent with an exception to Stark, and that the loan is enforced. The implication is that failure either to make such a loan commercially reasonable, or failure to enforce the loan, could result in a continuing period of disallowance implicating not only the period during which the initial excess or under payment of compensation occurred, but also the period during which the entity and physician attempted to cure the noncompliance by establishing the loan.

We believe that the establishment of this new period of disallowance rule is the most striking development in this set of new Stark rules. If there was ever any question that regulators are serious about enforcing Stark's referral and billing prohibitions, that question has been answered.

Alternative Method for Compliance with the Signature Requirements in Certain Exceptions

The new Stark rules include a new temporary noncompliance exception intended to address situations where an arrangement with a physician is in compliance with all requirements of a Stark exception that requires a contract, but one or both of the parties have failed to sign the contract. This new exception provides two rules: one for situations when failure to sign a contract was "inadvertent" and a second for situations where the failure to obtain a signature was not inadvertent (or "knowing.")

An "inadvertent" failure to obtain signatures can be correct (thereby not triggering a "period of disallowance") by obtaining needed signatures within 90 days of the date that the agreement became non-compliant. A non-inadvertent or "knowing" failure can be cured by obtaining required signatures within 30 days of the date that the arrangement became noncompliant. If the requirements of the exception are met, physicians involved can continue to refer DHS, and the entities involved can continue to bill Medicare.

This new exception is striking in part because it is narrow—applying only to situations where a signature has not been placed on a written agreement. It was initially proposed in the calendar year 2008 Physician Fee Schedule rule as an alternate compliance mechanism that could have been used to address any procedure or "form" requirement of an exception (e.g., the requirement that the term of an agreement be for

a year). The proposed exception would have required that noncompliance be inadvertent, that the entity cure the noncompliance within a specified period of time, and would have required self-reporting to CMS. The exception as adopted in this final rule does not require self-reporting to take advantage of the exception.

The exception is striking, too, because it illustrates again that regulators are serious about enforcing the referral and billing prohibitions of Stark—even when the failure to meet a Stark exception is as technical as failing to obtain a signature on a written agreement.

Signature Compliance:

42 CFR §411.353 Prohibition on certain referrals by physicians and limitations on billing.

(g) Special rule for certain arrangements involving temporary noncompliance with signature requirements.

(1) An entity may submit a claim or bill and payment may be made to an entity that submits a claim or bill for a designated health service if—

(i) The compensation arrangement between the entity and the referring physician fully complied with an applicable [general exception, ownership and investment exception or compensation exceptions], except with respect to the signature requirement in [the rental of office space, rental of equipment, personal service arrangements, physician recruitment (including recruitment arrangements with a group), fair market value, indirect compensation, referral services, obstetrical malpractice, retention payments, electronic prescribing items and services, or electronic health records exceptions]; and

(ii) The failure to comply with the signature requirement was-

(A) Inadvertent, and the parties obtain the required signature(s) within 90 consecutive calendar days immediately following the date on which the compensation arrangement becomes noncompliant (without regard to whether any referrals occur or compensation is paid during such 90-day period) and the compensation arrangement otherwise complies with all criteria of the applicable exception; or

(B) Not inadvertent, and the parties obtain the required signature(s) within 30 consecutive calendar days immediately following the date on which the compensation arrangement becomes noncompliant (without regard to whether any referrals occur or compensation is paid during such 30-day period) and the compensation arrangement otherwise complies with all criteria of the applicable exception.

(2) Paragraph (g)(1) of this section may be used by an entity only once every 3 years with respect to the same referring physician.

CMS answered a commentator who questioned the meaning of "inadvertent" by stating "[w]e do not believe that it is necessary to define 'inadvertent;' parties should attach the ordinary meaning to 'inadvertent.'" The commentary on several occasions characterizes those failures that are "not inadvertent" as "knowing" failures, and provides the following example of a "knowing" failure: "a compensation arrangement under which a hospital contracts with a physician to provide medical directorship of a service at the hospital beginning January 1; the physician begins providing services on January 1 and refers patients to the hospital for DHS; the physician does not sign the written agreement until January 15, when it is returned from the physician's attorney following legal review; and at all times up to January 15, both the physician and the hospital are aware that the physician had not signed the agreement."

The commentary cites the situation where a hospital may need to acquire the services of a physician on short notice and may be unable to obtain the physician's signature before physician services commence as one reason for this new alternative compliance mechanism. And this new exception provides cover for such a situation (e.g., for the situation where a hospital must use a physician on short notice to cover for another on-call physician). But we note that the cover provided may be very limited—the new exception on its face applies only to situations where the only missing ingredient to a compliant arrangement is a missing signature.

The personal service exception requires among other things that an arrangement be (1) set out in a written agreement, (2) that the arrangement be for a term of at least one year, and (3) that compensation must be "set in advance" and consistent with fair market value. While there is language in the commentary suggesting that the reason for a missing signature might be continuing review by the physician's attorney, it would appear from the regulatory language on its face that this exception will require that there be a written agreement in place that meets all of the requirements (but the signature requirement) of the personal services exception. A hospital may be able to use this exception to avoid the on-call dilemma, but we believe that they will still need to have an agreement in principle with the physician that is evidenced in a contract that meets all elements of the personal services exception but the signature requirement. A form contract that is utilized to cover this fill-in situation, and a payment schedule or formula

that is the basis for payment calculations seem to be two critical pieces of a compliance strategy for short notice personal service arrangements with physicians. This new exception for missing signatures can be utilized only once every three years as to any one physician.

DHS Entity as Both the Entity that Submits the Claim and the Entity that Performs the DHS Service; Services Provided "Under Arrangements"

The new Stark rules expand the definition of "Entity" to include both the entity that submits claims and receives payments for DHS services from Medicare (this has been the rule historically), and the entity that actually performs the DHS services (this "entity that performs the DHS services" is the addition to the rule.) This change to the definition of Entity was based on a belief that hospitals were establishing joint ventures with physicians where the physician/hospital joint venture (JV) provided a DHS services "under arrangements" with the hospital, and the hospital purchased the service from the JV and billed the service as a hospital service.

For example, a physician/hospital joint venture might be established to provide cardiac cath services, with physicians contributing their time to conduct the cath services and the hospital contributing management services and facilities to the JV. The hospital would then buy the cath services from the JV "under arrangement" and bill them to Medicare as hospital services. Because Stark's historic definition of "Entity" captured only the entity that billed Medicare or received payment under reassignment from Medicare for DHS services, the physician/hospital JV in the "under arrangements" scenario was not an Entity for Stark purposes. The physician's financial relationship with the hospital was analyzed as an indirect compensation relationship and could be crafted to comply with that exception. Physicians were not subject to the referral prohibition, and the hospital was not subject to the billing prohibition. This new definition of "Entity" will mean that both the hospital and the joint venture in the example above will be "Entities" for purposes of Stark, and physician owners of the JV will need to meet an ownership exception.

Several commentators suggested that this change to the definition of Entity might be less than effective because of potential ambiguity in the meaning of the phrase "performed services." CMS responded by declining to provide a specific definition of the term "perform," stating instead that "[p]hysicians and other suppliers and providers generally know when they have performed a service and when they are entitled to bill for it. . . . We do not consider an entity that leases or sells space or equipment used for the performance of the service, or furnishes supplies that are not separately billable but used in the performance of the medical service, or that provides management, billing services, or personnel to the entity performing the service, to perform DHS."[3]

CMS comments provide a clear picture of the impact of the new definition of "Entity" on physician/hospital joint ventures providing services "under arrangements."

> *Where a group practice or other physician organization provides the service and bills for it, the service is not DHS and the physician self-referral statute will not apply. Where a group practice or other physician organization provides the service and, pursuant to a contractual arrangement, a hospital bills for it as an outpatient or inpatient*

3 73 Federal Register 48726

New Applicable Regulations:

42 CFR §411.351 Definitions.

Entity means--

(1) A physician's sole practice or a practice of multiple physicians or any other person, sole proprietorship, public or private agency or trust, corporation, partnership, limited liability company, foundation, nonprofit corporation, or unincorporated association that furnishes DHS. An entity does not include the referring physician himself or herself, but does include his or her medical practice. A person or entity is considered to be furnishing DHS if it--

(i) Is the person or entity that has performed services that are billed as DHS; or

(ii) Is the person or entity that has presented a claim to Medicare for the DHS, including the person or entity to which the right to payment for the DHS has been reassigned in accordance with §424.80(b)(1) (employer) or (b)(2) (payment under a contractual arrangement) of this chapter (other than a health care delivery system that is a health plan (as defined at §1001.952(l)of this title), and other than any managed care organization (MCO), provider-sponsored organization (PSO), or independent practice association (IPA) with which a health plan contracts for services provided to plan enrollees).

service, the service is DHS [because it is now an inpatient or outpatient hospital service] and therefore the group practice or other physician organization would be a DHS entity [because it is now an entity providing DHS] with respect to the service. If the referral to the group practice or other physician organization is made by a physician owner/investor, an ownership exception would be needed to protect the referral. If the referral is made by a non-owner/investor physician who has a compensation relationship with the group practice or other physician organization (that is a physician employee or contractor), a compensation exception would be needed to protect the referral.[4]

CMS declined in the commentary to grandfather existing "under arrangements" relationships. "We are not grandfathering existing arrangements because we believe it is inconsistent with the statute to treat an entity that performs DHS as something other than a DHS entity." However, it did delay the effective date of definition change until October 1, 2009, to allow providers to re-craft existing relationships. CMS also requested comments on whether a new ownership exception for physician ownership/investment interests in physician service providers should be created and, if so, what conditions the exception should contain.

Changes to and Implementation of the "Stand in the Shoes" Provisions

The addition in 2007 of "stand in the shoes" provisions to the Stark regulations changed the definition of a compensation arrangement and an indirect compensation arrangement by providing that a physician stands in the shoes of his or her physician organization[5] for purposes of analyzing whether indirect compensation relationships meet a Stark compensation exception. The commentary to the Phase III final rule in 2007 provided the following example of how the "stand in the shoes" provisions would affect a Stark analysis: "Thus [for example], if a DHS entity leases office space to a group practice, the lease will be deemed to be a direct compensation arrangement with each physician in the group practice, [and will need to fit the rental of office space exception] if the DHS entity wants to submit claims for DHS referrals from those physicians."[6] The basic effect of the "stand in the shoes" provision is to eliminate the use of the indirect compensation exception when arrangements are with a physician organization.

After receiving several complaints in 2007 about the unintended effects of "stand in the shoes," CMS issues a final rule on November 15, 2007, delaying the effective date of "stand in the shoes" until December 4, 2008 for two categories of compensation arrangements: (1) compensation between a faculty practice plan and another component of an academic medical center (AMC) (as described in §411.355(e)(2)), and (2) compensation arrangements between an DHS entity and a physician practice that were both part of or affiliated with the same integrated 501(c)(3) health system.

The revised final rule changes that will be effective on October 1, 2008 will:

- Limit required application of the "stand in the shoes" provisions to physicians who have an ownership or investment interest in their physician organization (a physician's whose interest is only compensation or is "merely titular" will not be required to "stand in the shoes");
- Clarify that physicians whose ownership or investment interest is merely titular (that is, physicians without the ability or right to receive the financial benefits of ownership or investment, including but not limited to, the distribution of profits, dividends, proceeds of sale, or similar returns on investment) are not required to "stand in the shoes;"
- Permit (but not require) physicians who do not have an ownership or investment interest, or whose ownership or investment interest is merely titular, to "stand in the shoes" for purpose of Stark analysis (this component of the rule was added, in part, so that arrangements that had been restructured since September 5, 2007, to meet the requirements of the original "stand in the shoes" would not need to be restructured again as a result of the changes occurring in this rulemaking);

4 73 Federal Register 48730

5 "Physician organization" in whose shoes a physician would stand is defined by the "stand in the shoes" provisions as including (1) another physician who employs the referring physician, (2) the referring physician's wholly-owned professional corporation, (3) a physician practice that employs or contracts with the referring physician, or in which the referring physician has an ownership interest, and (4) a group practice in which the referring physician is a member or independent contractor.

6 72 Federal Register 51028

- Clarify that the "stand in the shoes" provisions do not apply to arrangements that satisfy the requirements of the academic medical center exception at 42 CFR §411.355(e); and
- Clarify that (1) a physician and the professional corporation of which the physician is a sole owner are always treated the same for purposes of applying "stand in the shoes", and (2) a physician who stands in the shoes of his or her wholly owned PC also stands in the shoes of his or her physician organization.

In the commentary associated with the "stand in the shoes" changes, CMS declined to amend the academic medical center exception at 42 CFR §411.355(e) to allow faculty practice plans to share profits with their physicians in the same way that group practices are allowed to do so if they meet the group practice exception's requirements at 42 CFR §411.352. CMS responded that a faculty practice plan is free to meet the requirements of the group practice exception and, thereby be treated in the same way as a group practice,

Stand in the Shoes:

42 CFR §411.354 Financial relationship, compensation, and ownership or investment interest.

* * *

(c) Compensation Arrangement.

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(1) Direct Compensation Arrangement.

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(ii) Except as provided in paragraph (c)(3)(ii)(C) of this section, a physician is deemed to stand in the shoes of his or her physician organization and have a direct compensation arrangement with an entity furnishing DHS if--

(A) The only intervening entity between the physician and the entity furnishing DHS is his or her physician organization; and

(B) The physician has an ownership or investment interest in the physician organization.

(iii) A physician (other than a physician described in paragraph (c)(1)(ii)(B) of this section) is permitted to "stand in the shoes" of his or her physician organization and have a direct compensation arrangement with an entity furnishing DHS if the only intervening entity between the physician and the entity furnishing DHS is his or her physician organization.

* * *

(2) Indirect Compensation Arrangement.

* * *

(iv)(A) For purposes of paragraph (c)(2)(i) of this section, except as provided paragraph (c)(3)(ii)(C) of this section, a physician is deemed to "stand in the shoes" of his or her physician organization if the physician has an ownership or investment interest in the physician organization.

(B) For purposes of paragraph (c)(2)(i) of this section, a physician (other than a physician described in paragraph (c)(2)(iv)(A) of this section) is permitted to "stand in the shoes" of his or her physician organization.

*(3) * * **

(ii) The provisions of paragraphs (c)(1)(ii) and (c)(2)(iv)(A) of this section--

(A) Need not apply during the original term or current renewal term of an arrangement that satisfied the requirements of §411.357(p) as of September 5, 2007 (see 42 CFR Parts 400-413, revised as of October 1, 2007);

(B) Do not apply to an arrangement that satisfies the requirements of §411.355(e); and

(C) Do not apply to a physician whose ownership or investment interest is titular only. A titular ownership or investment interest is an ownership or investment interest that excludes the ability or right to receive the financial benefits of ownership or investment, including, but not limited to, the distribution of profits, dividends, proceeds of sale, or similar returns on investment.

(iii) An arrangement structured to comply with an exception in §411.357 (other than §411.357(p)), but which would otherwise qualify as an indirect compensation arrangement under this paragraph as of [date of this final rule in the Federal Register], need not be restructured to satisfy the requirements of §411.357(p) until the expiration of the original term or current renewal term of the arrangement.

if it wished to share profits in a way that would preclude it from meeting the AMC exception requirements.[7]

CMS had proposed to exclude from coverage under the "stand in the shoes" provisions arrangements between a component of an AMC and a physician organization (including non-AMC community physician organizations) for the provision only of teaching services required by the Medicare GME rules. This proposal was based on a concern that "set in advance" requirements for direct compensation exceptions that would apply under "stand in the shoes" would be in conflict with the GME requirement that the AMC hospital must pay for all or substantially all of the costs of training residents. More specifically, that cost of training residents may only be calculable after completion of the hospital's cost report, requiring a post cost report reconciliation payment between the AMC and the physician organization and precluding the AMC from setting the physician organization's compensation in advance.[8]

In discussing its decision not to exclude GME arrangements from the "stand in the shoes" rule, CMS concludes that "a properly structured formula for the compensation to the community physician organization could meet an applicable "set in advance" requirement if it is determined at the commencement of the compensation arrangement, does not take into account the volume or value of referrals or other business generated between the parties and satisfies the other requirements in 42 CFR §411.354(d)(1) (the "set in advance" requirements) [even if the formula might include a reconciliation and payment after the hospital's cost report is finalized.] CMS elected not to finalize proposed "stand in the shoes" rules for DHS entities, and for this reason also elected not to finalize rules that would have controlled coordination of physician "stand in the shoes" and DHS "stand in the shoes" rules. The new "stand in the shoes" rules will be effective October 1, 2008.

Changes to CMS's Interpretation of the "Set in Advance" Requirement

In its commentary on the "stand in the shoes" provisions, CMS discusses its historic interpretation of the "set in advance" requirement as meaning that, where a compensation exception requires a written agreement for a term of at least one year, an entity may not change its compensation formula during the first year of a written agreement. CMS notes that commentators have expressed valid concerns about the impact of this interpretation of "set in advance" when combined with the "stand in the shoes" provisions that will impose a significant burden on providers. In response, CMS announces in this commentary a significant loosening of its interpretation of the "set in advance" requirements.

> *We are sympathetic to the concerns of the commenter with respect to arrangements between DHS entities and physician groups that may require modification during the term of the arrangement. Moreover, in light of the revisions we are finalizing with respect to the use of percentage-based and per-click compensation formulae for determining rental charges for office space and equipment leases . . . we believe that an interpretation that permits amendments to an agreement between a DHS entity and a physician (or physician organization) during the term of the agreement is consistent with our mandate to safeguard against program or patient abuses and is consistent with our rules regarding compensation that is "set in advance," provided that (1) all of the requirements of an applicable exception are satisfied; (2) the amended rental charges or other compensation (or formula for the amended rental charges or other compensation) is determined before the amendment is implemented and the formula is sufficiently detailed so that it can be verified objectively; (3) the formula for the amended rental charges does not take into account the volume of value of referrals or other business generated by the referring physician; and (4) the amended rental charges or compensation (or the formula for the new rental charges or compensation) remain in place for at least 1 year from the date of the amendment. We are taking the opportunity here to clarify that the rule regarding the amendment of arrangements between DHS entities and physicians (or physician organizations) applies to all of the exceptions for compensation arrangements in 42 CFR, Subpart J that include a 1-year term requirement for satisfying the exception.*[9]

7 73 Federal Register 48695
8 73 Federal Register 48699
9 73 Federal Register 48697

Per Click and Percentage Based Lease Arrangements

The new Stark rules do away with the ability to use per click and percentage based compensation formulas for space and equipment leases. While we do not believe that these changes will be the most significant for the majority of DHS entities, the commentary discussing CMS's reasons for adopting these changes is certainly the most entertaining of the commentary included in this rule making.

CMS begins its discussion of percentage based compensation formulas by recounting the history of rule making on this subject—essentially providing its historical reasoning when it decided not to limit such formulas in the Phase I and Phase II rules. The discussion focuses on CMS's realization that placing broad based limitations on the ability to use percentage based formulae would unnecessarily restrict the ability to structure compensation arrangements for physician services that posed no risk of program abuse. The changes adopted in this set of rule making are repeatedly characterized as targeted limitations on percentage based and per click compensation formula—the changes apply only to space and equipment leases and not to employment or personal services. Changes are made to the Rental of Office Space, Rental of Equipment, Fair Market Value, and Indirect Compensation Arrangement to implement the new prohibition on per-click and percentage based models.

Several commenters express concern that restrictions on the use of percentage based formula in these areas would prohibit a lessor from charging a lessee for the pro-rata share of real estate taxes and other costs associated with operating the common areas of a property. CMS responded with its belief "that there is a difference between determining rental charges using a percentage-based formula and assessing a tenant (lessee) for the expenses incurred that are related to the space leased by the tenant (lessee). . . . We do not consider a percentage of expenses imposed or levied by a third part, such as property taxes or utilities, to be prohibited percentage compensation. . . . Moreover, we do not interpret the revisions to §411.357(a) (or to §411.357(b), §411.357(l) and §411.357(p)) as prohibiting a lessor from charging a lessee a pro rata share of expenses that are attributable to that portion of the medical office building or other space (or the equipment) that is leased by the lessee." [10]

CMS notes in its commentary that, if the lease of space or equipment is between a DHS entity and a physician organization, the "stand in the shoes" provision may apply to require analysis of the lease as being directly with any physicians who have an ownership or investment interest in the physician organization. The commentary also emphasizes that CMS is intentionally not limiting percentage based compensation formulas in certain types of arrangements, including practice management arrangement and contracts for out-source

10 73 Federal Register 48711

Per Click and Percentage Based Lease Arrangements:

42 CFR §411.353(a)&(b) Definitions.

[In this rule making the following language is added to the Rental of Office Space and Rental of Equipment exceptions:]

(5) The rental charges over the term of the agreement are not determined--

(i) In a manner that takes into account the volume or value of any referrals or other business generated between the parties; or

(ii) Using a formula based on—

(A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in the office space; or

(B) Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred between the parties.

42 CFR §411.353(l)&(p)

[Similarly, the following language is added to the Fair Market Value and Indirect Compensation Arrangement Exceptions:]

Compensation for the rental of office space or equipment may not be determined using a formula based on--

(A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in the office space or to the services performed or business generated through the use of the equipment; or

(B) Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred between the parties.

billing arrangements, but warns that it will continue to consider whether limitations in these areas may also be appropriate.

In discussing the changes limiting per-click compensation, CMS provides some insight into it thinking on what may limit a DHS entity from claiming that an arrangement is at fair market value or is commercially reasonable.

> *For example, we do not consider an agreement to be at fair market value if the lessee is paying a physician substantially more for a lithotripter or other equipment and a technologist than it would have to pay a non-physician-owned company for the same or similar equipment and service.* [When you are establishing the fair market value of a transaction with a physician-owned organization, it might be a good idea to obtain bids for the service from a non-physician owned entity to support your FMV determination.] *As a further example, we would also have a serious question as to whether an agreement is commercially reasonable if the lessee is performing a sufficiently high volume of procedures, such that it would be economically feasible to purchase the equipment rather than continuing to lease it from a physician or physician entity that refers patients to the lessee for DHS.* [So periodically update your pro-forma and include an analysis of when it might make sense for you to bring the service in house.]

Expanded Provision for Providing Malpractice Subsideies to Obstetricians

The final significant addition to the Stark regulations is an expansion of the exception for malpractice subsidies for obstetricians. The exception has historically allowed an entity to provide malpractice subsidies to obstetricians if the subsidies are consistent with the Antikickback Safe Harbor for such subsidies. The new provisions allow a hospital, federally qualified health care center or rural health clinic to provide subsidies that will pass muster with a new Stark exception under alternate conditions.

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