CMS Finalizes Major Stark Changes-

New Physician-Self Referral Rules in the 2009 IPPS Final Rulemaking will Require Restructuring of Many Common Healthcare Arrangements

On August 19, 2008, the Centers for Medicare and Medicaid Services ("CMS") published final Stark rules in its 2009 Final Hospital Inpatient Prospective Payment Systems Rule ("Final Rule") [1] The Final Rule contains several significant modifications to the Stark regulations, some of which will require physicians, hospitals, or other healthcare providers to unwind or restructure their arrangements. Several of the new Stark regulations are not effective until October 1, 2009,[2] in order to give parties time to unwind or restructure arrangements which are impacted by the changes, but other provisions are effective October 1, 2008.[3] In addition to these new Stark changes, healthcare providers must stay tuned for additional Stark and Medicare payment regulatory changes, which are expected to be published in November 2008 as part of the 2009 Medicare Final Physician Fee Schedule, and in future rulemakings [4]

In the Final Rule, CMS makes various revisions to the Stark regulations Some of these revisions emanate from proposals contained in the 2008 Medicare Proposed Physician Fee Schedule[5] and some of the revisions emanate from proposals contained in the 2009 Inpatient Prospective Payment System Proposed Rule [67] Because many of the proposals are interrelated, CMS opted to finalize them in one rulemaking, making it easier to analyze their integrated application to financial relationships between physicians and entities that provide designated health services ("DHS")

Summary of the Final Rule

This section will summarize the major points contained in the Final Rule Further detail on the significant aspects of the Final Rule will be set forth later in this article. A synopsis of the Stark changes as they appear in the Final Rule is as follows:

- ***"Stand in the Shoes" Provisions:*** Effective October 1, 2008, only physicians who have an ownership or investment interest in their physician organizations (e.g., group practice) will be required to stand in the shoes ("SITS") of those organizations. Employed physicians and physicians with a "titular ownership interest" may (but are not required to) stand in the shoes of their physician organizations The Final Rule also carves out an exception for physicians participating in financial arrangements that satisfy the Stark exception for academic medical centers and grandfathers a limited group of arrangements that previously met the Stark indirect compensation arrangement exception.[8]

- ***"Set in Advance" and Amendments to Agreements:*** CMS now states that it is reversing its prior Stark II Phase III position and permitting multi-year agreements to be amended after the first year without violating Stark's "set in advance" requirement.[9]

- ***Period of Disallowance:*** Effective October 1, 2008, CMS establishes a rule that sets the outer limit of the time period during which referrals are prohibited as a result of a financial relationship that fails to satisfy a Stark exception. Disallowance begins when

the relationship fails to satisfy an exception and ends no later than the date that it satisfies an exception and the parties have returned all overpayments or paid all underpayments.[10]

- ***Alternative Method for Compliance with Signature Requirements:*** Effective October 1, 2008, if a financial relationship complied with an applicable Stark exception, except for meeting the signature requirement, Medicare payments to the entity will be permitted if the signature requirement is satisfied within thirty (30) days (for knowing failures) or ninety (90) days (for inadvertent failures) after the commencement of the relationship.[11]

- ***Percentage-Based Leasing Arrangements***: Effective October 1, 2009, CMS eliminates percentage-based compensation in space and equipment leases, paralleling its new treatment of "per-click" payments in space and equipment leases. Under the Final Rule, compensation for the rental of office space or equipment that is determined using a formula based on a percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed, or business generated in the office space, or the services performed or business generated through the use of equipment is prohibited.[12]

- ***"Per-Click" Leasing Arrangements:*** Effective October 1, 2009, CMS eliminates the use of "per-click" fee payments in space and/or equipment leases when the payments reflect services provided to patients referred between the parties. This "per-click" fee prohibition applies to both direct leasing arrangements and indirect leasing arrangements (e.g., leases between physician-owned leasing companies and hospitals).[13]

- ***Services Provided "Under Arrangements":*** Effective October 1, 2009, both the hospital that bills for services provided "under arrangements" and the entity that performs the services to the hospital will be considered to be furnishing "designated health services" ("DHS") under Stark. This change will effectively eliminate a referring physician's ability to own interests in such service providers. CMS does not define what it means to "perform" the services, but does signify that an organization is not performing a DHS if it only leases or sells space or equipment, furnishes supplies that are not separately billable, or provides management, billing services, or personnel to the entity performing the services.[14]

- ***Exception for Obstetrical Malpractice Insurance Subsidies***: Effective October 1, 2008, CMS adds an alternative exception for subsidies of malpractice insurance premiums provided by hospitals, federally qualified health centers, and rural health clinics.[15]

- ***Ownership or Investment Interest in Retirement Plans***: Effective October 1, 2008, CMS narrows the so-called "retirement plan exception" to ensure that referring physicians cannot use it to evade Stark's self-referral prohibition by investing in a DHS

entity via their employer's retirement plan. Under the Final Rule, only a physician's ownership or investment interest in their employer-sponsored retirement plan is protected.[16]

- ***Burden of Proof:*** Under the Final Rule, CMS revises the regulations to place the burden of proof in appeals of Stark-based payment denials on the entity appealing the denial. This burden is consistent with the burden of proof on Medicare providers and suppliers appealing payment denials based upon other reasons, such as a failure to meet a condition of coverage. Moreover, CMS clarifies that the burden of production at each level of appeal is initially on the DHS entity, but may shift to CMS (or its contractors) depending upon the evidence presented by the DHS entity.[17]

- ***Disclosure of Financial Relationships Report ("DFRR")***: The Final Rule announces that CMS is proceeding with its proposal to send the DFRR to 500 hospitals. The DFRR is designed to collect information regarding the ownership and investment interests and compensation arrangements between hospitals and physicians. Hospitals will have sixty (60) days to complete the DFRR and may be subject to civil monetary penalties of up to $10,000 per day that the submission is late, although CMS will first issue a letter to the hospital and the hospital may obtain an extension for good cause.[18]

"Stand in the Shoes" ("SITS")- CMS Simplifies the SITS Doctrine

Under the Stark Phase III SITS doctrine, referring physicians are treated as standing in the shoes of their physician organization for purposes of applying the rules that describe direct and indirect compensation arrangements between the referring physician and a DHS entity.[19] Under Stark Phase III, a physician organization was defined as a physician, physician practice, or a group practice.[20] When performing a Stark analysis, the SITS provisions are applied for purposes of evaluating the relationship between a DHS entity and a referring physician when a physician organization is an intervening link in the chain of relationships and linked to the physician with no other intervening links between them. Under the SITS doctrine, a referring physician is considered to have the same compensation arrangements as the physician organization in whose shoes the physician stands. If a physician stands in the shoes of his or her physician organization, the physician (and DHS entity) will have to satisfy a more stringent direct Stark exception with regard to financial relationships between the physician organization and the DHS entity, to which the physician refers.

Industry stakeholders, such as academic medical centers ("AMCs") and integrated tax-exempt health care delivery systems ("IDSs"), responded to the Phase III SITS provisions with concerns as to how the SITS provisions would apply in such settings, and how "mission support payments" and similar payments ("support payments") would satisfy the requirement contained in many direct Stark exceptions that compensation be fair market value for items or services provided. These stakeholders argued that prior to Stark Phase III SITS, these support payments were analyzed under the indirect compensation arrangement rules, and were permitted.[21] In order to address these concerns, CMS delayed the applicability of SITS for one year only to

certain compensation arrangements involving AMCs and IDSs.[22] Shortly after publication of the one-year delay, other stakeholders urged that the applicability of the SITS provisions to support payments should not be dependent upon whether the system is an AMC or has a particular status under the Internal Revenue Service.[23]

In response, CMS proposed in the 2009 IPPS proposed rule, two alternative ways to address SITS. The first proposal included two options for revising the Phase III SITS provisions, and the second proposal left the Phase III SITS provisions untouched, but proposed creating a new regulatory exception for support payments.[24]

Ultimately, in the Final Rule, CMS provides more flexibility for healthcare providers under the SITS doctrine. Specifically, CMS finalizes certain revisions to the stand in the shoes Phase III provisions to deem only a physician who has an ownership or investment interest in a physician organization to stand in the shoes of that physician organization. Further, physicians with only a "titular ownership interest" are not required to stand in the shoes of their organizations. Physicians with titular ownership interests are those physicians without the ability or the 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 (e.g., captive P.C.).[25] In sum, CMS provides more flexibility under the Final Rule, now only permitting (but not requiring as it did under Stark Phase III), non-owner physicians and titular owners to stand in the shoes of their physician organizations.

Additionally, CMS creates a carve out from the SITS provisions for arrangements that meet the requirements of the AMC Stark exception in Section 411.355(e),[26] but CMS declined to finalize a separate exception for compensation arrangements involving support payments in the context of AMCs and IDS. CMS stated that it was not its intention, "now or in the future, to regulate financial relationships between DHS entities and referring physicians by making exceptions to rules or exceptions within existing exceptions simply in response to complaints or concerns in the industry."[27] CMS also declined to finalize its earlier proposal regarding compensation arrangements between physician organizations and AMC components for the provision of services required to satisfy the AMC's obligations under the Medicare graduate medical education rules, as CMS believes that existing exceptions (e.g., bona fide employment, personal service arrangements, and fair market value) provide adequate protection for arrangements between physician organizations and AMCs for GME-related services.[28]

CMS also continues the grandfathering of certain indirect compensation arrangements and allows those arrangements to continue to avoid SITS until the expiration of their current term (if such term has been in effect since the publication of Stark II Phase III (September 5, 2007)). Arrangements that were grandfathered that are up for renewal prior to October 1, 2008, will need to comply with the current (Phase III) SITS rules, in which all physicians (owners and non-owners) in a physician organization stand in the shoes of the physician organization, but agreements that are up for renewal after October 1, 2008 will need to comply with the new more flexible SITS provisions.[29]

Overall, the final SITS provisions are more flexible and should provide relief for certain industry stakeholders, such as AMCs, IDSs, and physician organizations that are not owned by referring physicians.

Entity SITS not Finalized

Last, CMS did not finalize the entity version of SITS that would have considered a DHS entity to stand in the shoes of an organization in which it had a 100 percent ownership interest. CMS cautions, however, that "arrangements that attempt to evade restrictions on payments for referrals by using interposed organizations are highly suspect under the fraud and abuse laws and will be subject to close scrutiny."[30]

"Set in Advance" and Amendments to Agreements- CMS Changes its Position

In response to comments in the preamble discussion, CMS indicates that it has reconsidered its earlier Stark II Phase III Final Rule position, that a multi-year agreement for rental of office space or a personal service arrangement may not be amended during its term without violating the Stark exceptions' requirements that the compensation under the arrangement be "set in advance" for the term of the agreement.[31] This earlier position was widely criticized as imposing additional transaction costs on the parties to these agreements by requiring them to terminate an existing agreement and enter into a new agreement with modified terms rather than simply amending the agreement.

CMS now states that in light of the new final revisions with respect to percentage-based and "per-click" compensation formulae, an agreement is permitted to be amended as long as the following criteria are met: (1) All of the requirements of an applicable exception are satisfied; (2) The amended rental charges or compensation (or compensation formula) is determined before the amendment is implemented, and the formula is sufficiently detailed that it can be verified objectively; (3) The formula for amended rental charges does not take into account the volume or value of referrals or other business generated by the referring physician; and (4) The amended rental charges or compensation (or compensation formula) remain in place for at least one year for the date of amendment. CMS also clarifies that this rule regarding amendment of arrangements between DHS entities and physicians applies to all compensation exceptions that include a one-year term requirement.[32] This change in position represents CMS' current interpretation of "set in advance" and is not a change in regulation.

Period of Disallowance for Non-Compliant Relationships Defined

Under Stark, the period of time for which a physician cannot refer DHS to an entity and for which the entity cannot bill Medicare because the financial relationship between the referring physician and the entity failed to satisfy all of the requirements of an exception is referred to as the "period of disallowance." In the Final Rule, CMS finalizes its earlier period of disallowance proposals which were intended to place an outside limit on the period of disallowance in certain circumstances. Specifically, 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*: (1) where the noncompliance is unrelated to compensation, the date that the

financial relationship satisfies all of the requirements of an applicable exception; (2) Where the noncompliance is due to payment of excess compensation, the date which *all* excess compensation is returned, and the financial relationship satisfies all of the requirements of an applicable exception; or (3) Where the noncompliance is due to payment of compensation that is insufficient to satisfy the requirements of an applicable exception, the date on which *all* additional required compensation is paid, and the financial relationship satisfies all of the requirements of an applicable exception [33]

In the preamble, CMS notes that this new rule creates only an outside limit and is not intended to prevent parties from arguing that the period of disallowance ended sooner on the theory that the financial relationship ended sooner. CMS does caution, however, that the beginning and end dates of a financial relationship for purposes of the disallowance period do not necessarily correspond with the term of the parties' written agreement.[34] CMS also notes that taking action to fix the outside date of the period of disallowance does not vitiate a DHS entity's overpayment for any claims submitted during the period of disallowance as a result of the prohibited referrals.[35]

CMS provides a practical example of how the period of disallowance rules apply in a situation in which a physician is paid excess compensation under a personal services agreement for months 1-6 and, near the end of month 6, the parties discover the error, with the result that, on July 1, the physician repays the excess compensation for months 1-6 and the arrangement otherwise complies with all of the requirements of an applicable exception. Under the Final Rule, in the example, the period of disallowance will end no later than the date the party repays the excess compensation which is July 1.[36]

In discussing the period of disallowance rules, CMS makes clear its view that simply correcting a financial relationship that falls outside of an applicable Stark exception due to technical noncompliance is not adequate. CMS believes "that the statute does not contemplate that parties have a right to back-date arrangements, return compensation, or otherwise attempt to turn back the clock so as to bring arrangements into compliance retroactively." [37]

Alternative Method for Compliance- CMS Provides Some Flexibility for Technical Defects Due to Missing Signatures

A host of Stark compensation exceptions include a signature requirement. This has created some exposure for certain DHS entities, such as hospitals, because they may have many agreements with physicians that, if not signed, will fall outside of a Stark exception. CMS provides some relief in the Final Rule by adopting a limited amendment that applies to existing compensation exceptions, which permits payments to an entity that fully complied with an applicable Stark exception, except with respect to a *signature requirement*, if: (1) the failure to comply with the signature requirement was inadvertent and the entity rectifies the failure to comply within 90 days after the commencement of the financial relationship (with regard to whether the referrals have occurred or compensation paid), or (2) the failure to comply with the signature requirement was not inadvertent (knowing) and the entity rectifies the failure within 30 days after the commencement of the financial relationship.[38] This accommodation for

temporary noncompliance with a signature requirement, however, may only be used once every three years with respect to a particular referring physician.[39]

Percentage-Based Compensation Formulae- The Demise of Percentage-Based Compensation for Rental of Office Space and Equipment

In an earlier proposal, due to its concerns regarding heightened risk of program and patient abuse, CMS planned on eliminating percentage-based compensation arrangements except in the context of physician personally performed service agreements.[40] In this Final Rule, CMS adopts a more targeted approach and declines to limit percentage arrangements to only personally performed physician services. Rather, CMS targets percentage-based compensation only in the context of space and equipment leases.[41]

Specifically, the Final Rule amends the current Stark exceptions for the rental of office space, the rental of equipment, fair market value compensation arrangements, and indirect compensation arrangements to prohibit the use of compensation formulae for space and equipment leases based upon a percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in the office space lease or to the services performed on or business generated by the use of leased equipment.[42]

Effectively, by implementing these changes, CMS ends most percentage-based arrangements for the lease of space or equipment (direct or indirect) between DHS entities and referring physicians. Current percentage-based leasing arrangements for office space or equipment that run afoul of these new rules will need to be restructured prior to October 1, 2009, the effective date.[43]

Further, of particular significance, although CMS did not extend this new percentage-based prohibition outside of the space and equipment lease context (e.g., management services), CMS warns that it intends to "continue to monitor compensation formulae in arrangements between DHS entities and referring physicians and, if appropriate, may further restrict percentage-based formulae in a future rulemaking."[44]

"Per-Click" Leasing Arrangements Prohibited- Block Time Leases Survive for Now

Although unit-of-service ("per-click") payments were generally permitted under the Stark law, due to concerns that this type of compensation methodology was inherently susceptible to abuse, CMS introduced a proposal in the 2008 Proposed Physician Fee Schedule which prohibited the use of per-click payments involving space and/or equipment leases in those situations where a physician (or entity owned by a physician) leases space and/or equipment to another entity and the physician subsequently refers patients to that other entity for services. For example, this would prohibit a cardiologist from leasing a CT scanner to a hospital on a per-click basis if that cardiologist refers patients to the hospital for CT services.[45] While the original proposal only restricted "per-click" payments when the physician was a lessor, CMS also sought comment on whether it should prohibit per-click payments in situations in which the physician is the lessee and a DHS entity is the lessor.[46]

Under the Final Rule, CMS prohibits the use of "per-click" payment methodologies for leasing arrangements under the space and equipment lease exceptions, fair market value exception, and the exception for indirect compensation arrangements to the extent that these charges reflect services provided to patients referred between the parties.[47] Notably, the "per-click" prohibition applies whether the lessor is the referring physician or an entity in which the referring physician has an ownership interest. The Final Rule is also broader than the original proposal and applies if the lessor is a DHS entity that refers patients to a physician or physician organization lessee.[48]

CMS notes that it is not prohibiting per-click compensation arrangements involving non-physician-owned lessors to the extent that such lessors are not referring patients for DHS, nor are they prohibiting per-click payments to physician lessors for services rendered to patients who were not referred to the lessee by the physician lessors. However, CMS reminds stakeholders that all such arrangements must still satisfy all of the requirements of the lease exceptions, including the requirements that they be fair market value and commercially reasonable.[49]

Notably, in addition to the per-click restrictions, CMS also states that "on demand" rental agreements are effectively per-click or per-use arrangements, and that it considers these types of agreements to be covered by the final provision. Accordingly, "on demand" rental payments are also now prohibited for leases of space and equipment to the extent that these charges reflect services provided to patients referred between the parties.[50] However, CMS declined to prohibit all time-based leasing arrangements (e.g., block time leases), as CMS believes that may meet the requirements of the space and equipment lease exceptions. CMS cautions, however, that the same concerns that arise with respect to per-click payments can exist with certain time-based leasing such as leasing the space or equipment in small blocks of time (e.g., once a week for 4 hours), and parties entering into block leases should carefully structure them taking into account the anti-kickback statute.[51]

The final per-click prohibitions are effective for lease payments made on or after October 1, 2009. CMS delayed the effective date of these changes to provide parties sufficient time to restructure existing arrangements or to unwind such arrangements.[52]

Services Provided "Under Arrangements"- Time to Unwind

Under current Stark law, only entities to which CMS makes payment for the DHS are considered to be furnishing DHS.[53] Prior to the changes contained in the Final Rule, Stark generally permitted physicians to invest in entities which provided services "under arrangements" to hospitals because the physician did not have an ownership interest in the hospital (i.e., entity furnishing DHS). The Final Rule significantly expands the definition of "entity" to include entities that perform services that are in turn billed as DHS by another entity.[54] As a practical matter, this change means that referring physicians likely will not be able to have an ownership or investment interest in "under arrangements"[55] service providers

Specifically, under the Final Rule, effective October 1, 2009, an "entity" for purposes of Stark will include the person or organization that has: (1) billed for the DHS; or (2) performed

the DHS.[56] Under these new rules, where one entity performs a service that is billed by another entity, both entities are considered DHS entities with respect to that service.[57] Pursuant to the Final Rule, any financial relationship between the service provider and the physicians who refer to it for services that the hospital bills "under arrangements" will need to comply with a Stark exception. The arrangement will be analyzed as a direct financial relationship if the referring physician stands in the shoes of the service provider or as an indirect financial relationship if the physician does not, or is not required to, stand in the shoes of the service provider. Direct compensation exceptions should be available to protect referrals for the service provider's non-owner physicians, but very few exceptions are available for referring physicians who own an interest in the service provider.[58]

CMS does not define what it means to "perform" a service, but does indicate that an organization is not performing DHS if it only leases or sells space or equipment, furnishes supplies that are not separately billable, or provides management, billing services or personnel to the entity performing the service.[59] CMS does state that the common meaning of the term "perform" applies and it considers a physician or physician organization to have performed DHS if the physician or physician organization does the medical work for the service and could bill for the service, but the physician or organization has contracted with a hospital and the hospital bills for the service instead."[60] CMS warns, however, that a physician service provider cannot escape the reach of the statute by doing substantially all of the medical work for a service, and arranging for the billing entity or some other entity to complete the service.[61]

Further, certain entities such as physician-owned medical device companies, are safe for now. In response to commenters that were concerned that implant or medical device companies should not be considered an entity under Stark, CMS states that "we are not adopting the position that physician-owned implant or other medical device companies necessarily 'perform the DHS', and are therefore an 'entity' on that basis."[62]

In the preamble commentary, many stakeholders expressed concern that the proposals would disrupt access to care, particularly in underserved or rural areas.[63] In response, CMS notes that it is not prohibiting services to be furnished "under arrangements." For example, with respect to service providers that furnish services to rural patients, CMS states that the new rules will not alter the availability of the exception for an ownership interest in a rural provider, but as a DHS entity, a physician owner/investor in such a service provider would need to meet an ownership exception (such as the rural provider exception) in order to protect his or her referrals to the service provider.[64]

With respect to ownership or investment interests that will not qualify for the rural provider exception, CMS believes access will not be significantly disrupted for several reasons. First, CMS states that the final rules do not prohibit physician group practices or other physician organizations from contracting with a hospital for the provision of services "under arrangements." CMS points out that any physician that has a compensation arrangement (not an ownership or investment interest) with the physician group practice or other physician organization may refer patients for services that are provided by the hospital "under arrangements" provided that one of the compensation exceptions is met. Moreover, CMS notes that to the extent that an owner/investor in the physician service provider has referred the patient

for a service but then personally performs the service, there is no referral and Stark is not implicated. CMS does caution, however, that despite the personal performance of the professional component, the technical component to any service or a facility fee that is billed by any provider "under arrangements" is considered a referral. CMS also believes that in many cases physician groups could provide the services and bill for them directly (without the need to contract with a hospital to provide them "under arrangements"), and that to the extent that the services would be DHS when performed and billed by the physician group directly, referrals to the physician entity could be protected by the in-office ancillary services exception.[65]

It is expected that there are a substantial number of existing "under arrangements" transactions involving physician-owned entities that will have to be unwound or restructured before the October 1, 2009 effective date. One issue that appears to be left uncertain is whether an entity that performs some, but not substantially all, of the medical work for the service (e.g., turnkey management service provider) will be considered to be performing DHS.

New Alternative Exception for Obstetrical Malpractice Insurance Subsidies

The current Stark regulations include an exception for obstetrical malpractice insurance premium subsidies that meet the anti-kickback safe harbor for such subsidies.[66] In order to address concerns that the current exception was unnecessarily restrictive and limited access to obstetrical care in underserved areas, CMS finalizes an alternative exception for malpractice insurance premium subsidies, which protects subsides paid by a hospital, federally qualified healthcare center ("FQHC"), or rural health clinic ("RHC").[67] CMS did not extend the new alternative exception to other entities because it was not persuaded that there would be no risk of program or patient abuse.[68]

The new alternative exception allows hospitals, FQHCs, and RHCs to provide an obstetrical malpractice insurance subsidy to a physician who regularly engages in obstetrical practice as a routine part of a medical practice that is: (1) located in a primary care HPSA[69], rural area, or area with a demonstrated need, as determined by the Secretary in an advisory opinion; or (2) is comprised of patients at least 75% or whom reside in a medically underserved area ("MUA") or are part of a medically underserved population ("MUP"). The criteria of this new exception focus on the patient population served by the physician receiving the subsidy, rather than focusing on the location of the entity providing the subsidy.[70]

In addition, the new alternative exception requires the following: (1) the arrangement is set out in writing, signed by the physician, and the hospital, FQHC, or RHC, and specifies the payments to be made and the terms under which the payments are to be provided; (2) the arrangement is not conditioned on the physician's referral of patients to the entity providing the payment; (3) the hospital, FQHC, or RHC does not determine (directly or indirectly) the amount of payment based upon the volume of value of any actual or anticipated referrals or other business generated between the parties; (4) the physician is allowed to establish staff privileges any hospital, FQHCs, or RHCs and to refer business to such entities (except as referrals may be restricted under an employment contract); (5) The payment is made to the person or organization (other than the physician) that is providing malpractice insurance (including a self-funded organization); (6) the physician treats obstetrical patients who receive medical benefits

or assistance under any Federal health care program in a nondiscriminatory manner; (7) the insurance is a bona fide malpractice insurance policy or program and the premium, if any, is calculated based on a bona fide assessment of the liability risk covered under the insurance; (8) for each coverage period (not to exceed one year), at least 75% of the physician's obstetrical patients treated under the coverage of the malpractice insurance during the prior year (not to exceed one year) (a) resided in a rural area, HPSA, MUA, or an area with a demonstrated need for the physician's obstetrical services as determined by the Secretary in an advisory opinion or (b) were part of a medically underserved population[71]; and (9) the arrangement does not violate the anti-kickback statute, or any Federal or State law or regulation governing billing or claims submission.[72]

With respect to physicians with a part-time obstetrical practice, the new alternative exception also allows payment of the obstetrical portion of malpractice insurance that is related exclusively to services provided in a rural area, primary care HPSA, or an area with demonstrated need for the physician's obstetrical services, or in any area if at least 75% of the physician's obstetrical patients treated in the coverage period resided in a rural area or MUA or were part of a MUP.[73]

DHS entities and physicians who rely upon this new alternative exception will not be protected under the anti-kickback safe harbor.[74]

Ownership or Investment Interest in Retirement Plans- Loophole Closed

Under current Stark regulations, ownership and investment interests do not include an interest in a retirement plan.[75] In response to concerns that some physicians were using retirement plans to purchase or invest in other entities (other than the one that is sponsoring the retirement plan), CMS finalizes its earlier proposal to make clear that the exclusion from the definition of "ownership or investment interest" of an interest in a retirement plan pertains only to an interest in an entity arising from a retirement plan offered by that entity to the physician (or his or her immediate family member) through the physician's (or immediate family member's) employment with that entity.[76]

Accordingly, under the Final Rule, a referring physician, for example, that is employed by a practice, and through his employment which such practice, has an interest in the practice's retirement plan, and the practice's retirement plan then invests in a home health agency, will need to rely upon an ownership exception for his investment in the home health agency, just as if he or she had invested directly in the home health agency. As a practical matter, unless the rural provider exception applies, there likely is no applicable ownership exception for which the referring physician can rely. CMS views this regulatory clarification as closing a loophole that otherwise would have allowed physicians and group practices to skirt the general prohibition under Stark.[77]

Burden of Proof- Not on CMS

The Final Rule clarifies, by modifying regulatory text, that when a DHS entity appeals a claim for payment that was denied on the basis that it was furnished pursuant to a prohibited

referral under Stark, the DHS entity has the burden of proof[78] at each level of the appeals process to establish that the service was not provided pursuant to such a prohibited Stark referral.[79] CMS states that this approach is consistent with the current Medicare claims appeals process.[80]

Further, CMS clarifies that the burden of production, at each level of appeal, is on the claimant initially, but the burden may shift to CMS or its contractors during the course of the proceeding depending upon the sufficiency of the evidence presented by the claimant.[81]

Although CMS insists that it is appropriate to require a provider or supplier to demonstrate that its financial relationship with a referring physician does, in fact, satisfy an exception and that the claim at issue should be paid, it is notable that Medicare's Recovery Audit Contractors ("RACs") who are paid on a contingency fee basis and who will be auditing providers nationwide in the near future[82], have in their arsenal a new Stark payment denial code Specifically, CMS issued a transmittal to contractors, which instructs such contractors to use new claim adjustment reason code No. 213 when denying claims based on noncompliance with Stark Interestingly, in the transmittal, CMS attempts to educate such contractors regarding Stark and then states, in part, "please note that the statute enumerates various exceptions, . . . You can read these exceptions in Section 1877 of the Social Security Act Sec. 1877 . . ."[83] Given the complexity of the Stark prohibition and related regulations, arming CMS contractors, including RACs, with a Stark denial code may have unforeseen results for healthcare providers

Disclosure of Financial Relationships Report ("DFRR")- It's Coming

In order to assist in enforcement of Stark, CMS created an information collection instrument, referred to as the Disclosure of Financial Relationships Report ("DFRR"). The DFRR is designed to collect information concerning the ownership and investment interests and compensation arrangements between physicians and hospitals.[84] In the Final Rule, CMS announces that it is proceeding with its proposal to send the DFRR to 500[85] hospitals, both general acute care hospitals and specialty hospitals. Notably, CMS states that to the extent that it does not find a physician self-referral violation based upon the results of the DFRR, this should not be taken as an affirmative statement that the financial relationships are in compliance, and the government will not be estopped from determining that there is such a violation.[86]

In the Final Rule, CMS announced that the DFRR would only be used as a one-time information collection effort, and at this time, CMS is not instituting a regular ongoing reporting or disclosure process for hospitals. Depending upon the information received, however, CMS may propose future rulemaking to use the DFRR or some other instrument as a periodic or regular collection instrument.[87]

Under the DFRR collection effort, hospitals will have 60 days to complete the DFRR, and although a hospital may be subject to civil monetary penalties of up to $10,000 per day for each day beyond the deadline for disclosure of such information, CMS states that it would not impose a civil monetary penalty in any amount before issuing a letter to a hospital. A hospital may also, upon a demonstration of good cause, obtain an extension for submitting the DFRR.[88]

In response to commenters' concerns regarding confidentiality of the information collected under the DFRR, CMS states that it has "...established numerous safeguards to physically house the data ... In addition, we will release such information, where appropriate, to federal law enforcement agencies such as the HHS's Office of the Inspector General (OIG) and the Department of Justice (DOJ)" CMS does state, however, that it will not release the information collected as a matter of course to such agencies, but will do so only where a specific referral is warranted.[89]

Notably, the preamble language is silent on whether CMS will share the information collected under the DFRR with its own contractors to meet their stated purpose "[t]o assist in enforcement of the physician self-referral statute".[90]

What's Next?

Without a doubt, many of the changes to Stark contained in the Final Rule will require modification, restructuring, or unwinding of numerous existing common healthcare arrangements. Healthcare providers will have some additional time to comply with many of the significant aspects of the Final Rule,[91] but providers should begin identifying arrangements that will need to be changed in some manner to ensure that the arrangement comes into compliance before the effective date

Healthcare providers, in particular physicians and group practices, must also stay tuned for future Stark and Stark-related changes, as CMS is expected to continue to focus on areas it believes are vulnerable to patient and program abuse Specifically, there are many additional Stark and Medicare payment rules which are expected to be published in some form later this year as part of the 2009 Medicare Final Physician Fee Schedule and in future rulemakings.[92] For example, as part of the 2009 Medicare Proposed Physician Fee Schedule ("2009 MPPS"), CMS is proposing to require all physicians to enroll as an IDTF for each practice location furnishing diagnostic testing services (except diagnostic mammography). If adopted, this rule will eliminate the ability of physician practices to share diagnostic imaging equipment and facilities, even if the equipment or facility is located in the "same building" as the term is defined under the Stark law in connection with the location requirements of the in-office ancillary services exception.[93]

Further, physicians providing and billing for diagnostic testing services must also stay apprised of changes related to the purchased diagnostic testing rule (or anti-markup rule).[94] CMS is revisiting changes it had enacted to the anti-markup rule, which are currently slated to go into effect on January 1, 2009.[95] With respect to the anti-markup final rule, CMS is now proposing two alternative approaches for application of this rule. One proposal would apply the anti-markup rule in all cases in which the professional or technical component of a diagnostic testing service is either: (1) purchased from an outside supplier, or (2) performed or supervised by a physician who does not share a practice with the billing physician or group. For purposes of this rule, a physician will "share a practice" if he or she is employed or contracts with only one physician or group practice The second alternative approach would maintain the current final rule which looks to the location (billing physician's office) of the test, but the proposal

would expand the definition of such location to include testing services performed within the same building in which the billing physician regularly furnishes patient care (as opposed to the earlier approach of same office suite).[96]

Last, CMS has also promised future proposals, which may narrow the in-office ancillary services exception,[97] an exception that is crucial to many physicians and group practices providing ancillary services (e g., physical therapy, imaging services, lab) through their offices.[98]

Healthcare attorneys need to analyze the application of these final Stark rules to existing and future financial relationships between referring physicians and entities that provide designated health services, and stay apprised of future developments in order to assist clients in making business decisions in this continually changing healthcare arena.

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[1] 73 Fed Reg. 48688 (2008)

[2] Final Stark rules addressing percentage-based compensation formulae, unit-of-service ("per-click") leasing arrangements, and services provided "under arrangements" are effective October 1, 2009

[3] Final Stark rules addressing "stand in the shoes" (SITS), period of disallowance, alternative method for compliance with certain exceptions, obstetrical malpractice insurance subsidies, ownership or investment in retirement plans, and burden of proof are effective October 1, 2008

[4] For example, regulatory changes in connection with Medicare's anti-markup prohibition, and requirements for Independent Diagnostic Testing Facilities (IDTFs) are expected to be published in the 2009 Medicare Final Physician Fee Schedule. Further, CMS has promised future proposals which may narrow Stark's in-office ancillary services exception.

[5] 72 Fed. Reg. 38122, 38179 (2007).

[6] 73 Fed Reg. 23538, 23683 (2008)

[7] CMS provides a chart which indentifies the revisions to the Stark regulations and indicates the rule in which the revisions were proposed at 73 Fed. Reg. 48689 (2008).

[8] 73 Fed Reg. 48690-48700 (2008).

[9] 73 Fed Reg 48696-48697 (2008)

[10] 73 Fed. Reg 48700-48705 (2008).

[11] 73 Fed Reg. 48705-48709 (2008)

[12] 73 Fed. Reg 48709-48713 (2008).

[13] 73 Fed Reg. 48713-48721 (2008)

[14] 73 Fed Reg. 48721-48733 (2008).

[15] 73 Fed. Reg. 48733-48737 (2008)

[16] 73 Fed. Reg. 48737-48738 (2008).

[17] 73 Fed Reg. 48738-48740 (2008)

[18] 73 Fed. Reg 48740-48745 (2008).

[19] 72 Fed Reg. 51026-51030 (2007).

[20] 42 CFR Section 411 351 (2007).

[21] 73 Fed. Reg 48691 (2008)

[22] 72 Fed. Reg 64164 (2007)

[23] 73 Fed Reg. 48691 (2008).

[24] 73 Fed Reg. 48691-48692 (2008)

[25] 73 Fed. Reg 48693, 48752, 42 CFR Section 411 354 (c) (2008)

[26] 73 Fed Reg 48693, 48752, 42 CFR Section 411 354 (c) (2008)

[27] 73 Fed Reg. 48693 (2008).

[28] 73 Fed. Reg. 48698 (2008)

[29] 73 Fed Reg 48752, 42 CFR Section 411 354 (c) (3) (2008)

[30] 73 Fed. Reg. 48699-48700 (2008).

[31] 73 Fed. Reg. 48697 (2008).

[32] 73 Fed Reg 48697 (2008).

[33] 73 Fed. Reg. 48751, 42 CFR Section 411 353 (c) (2008)

[34] 73 Fed Reg 48701-48702 (2008)

[35] 73 Fed. Reg. 48702 (2008)

[36] 73 Fed Reg 48701 (2008).

[37] 73 Fed Reg 48703 (2008).

[38] 73 Fed. Reg. 48751, 42 CFR Section 411.353 (g) (2008)

[39] 73 Fed Reg 48751, 42 CFR Section 411.353 (g) (2) (2008)

[40] 72 Fed. Reg. 38184 (2007)

[41] 73 Fed. Reg. 48709-48713, 48752-48753, 42 CFR Sections 411 357(a) 5(ii) (A), 411 357 (b) 4 (ii) (A), 411.357 (l) (3) (i), 411.357 (p) (1) (A) (2008)

[42] *Id*

[43] Percentage-based compensation formulae prohibitions applicable to office space and equipment leases have a delayed effective date of October 1, 2009. 73 Fed. Reg. 48690 (2008)

[44] 73 Fed. Reg. 48710 (2008)

[45] 72 Fed Reg 38182-38183 (2007)

[46] *Id*

[47] 73 Fed. Reg. 48752-48753, 42 CFR Sections 411 357(a) 5(ii) (B), 411 357 (b) 4 (ii) (B), 411.357 (l) (3) (ii), 411 357 (p) (1) (B) (2008)

[48] 73 Fed Reg 48714 (2008).

[49] 73 Fed. Reg. 48719 (2008)

[50] 73 Fed. Reg. 48719 (2008).

[51] 73 Fed Reg 48719-48720 (2008)

[52] 73 Fed Reg 48721 (2008)

[53] 42 CFR Section 411 351

[54] 72 Fed. Reg. 48751, 42 CFR Section 411 351 (2008)

[55] Medicare allows certain providers to furnish services "under arrangements". For example, a hospital can bill for a service line that is furnished by another entity pursuant to a contract under the hospital's oversight

[56] 73 Fed Reg 48751, 42 CFR Section 411.351 (2008)

[57] 73 Fed. Reg 48721 (2008).

[58] In most cases, the only exception that is potentially applicable for owners is the exception for rural providers at 42 CFR Section 411 356 (c) 1 The rural provider exception is very narrow and applies only in the case that an entity furnishes not less than 75% of the DHS it furnishes to residents of a rural area.

[59] 73 Fed. Reg. 48726 (2008).

[60] 73 Fed. Reg. 48726 (2008).

[61] 73 Fed Reg 48726 (2008)

[62] 73 Fed. Reg. 48727 (2008). CMS notes that future proposals may address this issue

[63] 73 Fed Reg 48727-48728 (2008)

[64] 73 Fed Reg 48728-48729 (2008).

[65] 73 Fed. Reg. 48729 (2008). CMS also notes that to the extent that the physician service providers are furnishing lithotripsy, it presently does not consider lithotripsy to be DHS.

[66] 42 CFR Section 411 357 (r). The anti-kickback safe harbor is set forth in 42 CFR Section 1001.952 (o).

[67] 73 Fed. Reg 48753 42 CFR Section 411 357 (r) (2) (2008)

[68] 73 Fed Reg. 48734 (2008)

[69] HPSA refers to Health Professional Shortage Area

[70] 73 Fed. Reg 48734, 48753, 42 CFR Section 411 357 (r) (2) (i)

[71] For the initial coverage period (not to exceed one year), the requirements of this section (411 357 (r) (2) (ix) (A) will be satisfied if the physician certifies that he or she has a reasonable expectation that at least 75% of the physician's obstetrical patients treated under coverage of the malpractice insurance will: (a) reside in a rural area, HPSA, MUA, or an area with a demonstrated need for the physician's obstetrical services as determined by the Secretary in an advisory opinion; or (b) be part of a medically underserved population

[72] 73 Fed. Reg 48753-48754, 42 CFR Section 411.357 (r) (2) (2008)

[73] 73 Fed Reg. 48754, 42 CFR 411 357 (r) (3) (ii) (2008).

[74] 73 Fed. Reg. 48734 (2008)

[75] 42 CFR Section 411.354 (b) (3) (i).

[76] 73 Fed. Reg. 48737, 48752, 42 CFR Section 411.354 (b) (3) (i) (2008)

[77] 73 Fed Reg. 48738 (2008)

[78] This is also referred to as the burden of persuasion.

[79] 73 Fed Reg. 48751, 42 CFR Section 411 353 (c) (2) (i) (2008)

[80] 73 Fed Reg 48738 (2008)

[81] 73 Fed. Reg 48751, 42 CFR Section 411 353 (c) (2) (ii) (2008).

[82] RACs will be nationwide by 2010

[83] See, MLN Matters Number MM6131, Related CR Release Date: August 15, 2008, Related CR Transmittal #R1578CP "Implementation of a New Claim Adjustment Reason Code (CARC) No. 213. 'Non-compliance with the physician self-referral prohibition legislation or payer policy'".

[84] 73 Fed Reg 48740 (2008)

[85] This number may be reduced, but not increased, based upon further review and comments CMS may receive in response to the revised Paperwork Act Reduction package that will be published separately in the Federal Register 73 Fed. Reg. 48741 (2008).

[86] 73 Fed. Reg. 48741 (2008)

[87] 73 Fed Reg 48741 (2008).

[88] 73 Fed. Reg. 48741 (2008)

[89] 73 Fed Reg 48745 (2008).

[90] 73 Fed. Reg. 48740 (2008)

[91] *Supra* at 2

[92] On July 7, 2008 CMS published the Medicare Proposed Physician Fee Schedule for 2009, which included, among others, a controversial proposal to require independent diagnostic testing facility ("IDTF") enrollment of physician office based imaging providers, proposals addressing gainsharing exceptions under Stark, and significant revisions to the anti-markup rules See, 73 Fed. Reg 38502 (2008).

[93] See, IDTF proposal at 73 Fed Reg 38533-38534, 38603-38604 (2008).

[94] 42 CFR Section 414 50

[95] The 2008 Medicare Final Physician Fee Schedule (72 Fed. Reg 66222 (2007), amended the anti-markup provisions for certain diagnostic tests Subsequent to the publication of the 2008 Medicare Final Physician Fee Schedule, CMS received informal comments from various stakeholders that stated that the application of the rule was unclear In response, CMS delayed until January 1, 2009 the applicability of the revised anti-markup provision in Section 414 50 except for anatomic pathology diagnostic testing services furnished in space that: (1) is utilized by a physician practice as a "centralized building" for purposes of complying with the physician self-referral rules; and (2) does not qualify as a "same building" under Section 411 355 (b) (2) (i), 73 Fed Reg 404 (2008).

[96] 73 Fed Reg 38544-38548, 38606 (2008)

[97] 42 CFR Section 411 355 (b).

[98] 73 Fed. Reg. 23683 (2008)