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Life Sciences Health Industry Group

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SIGNIFICANT STARK LAW CHANGES ADOPTED IN THE 2009 IPPS FINAL RULE

I. INTRODUCTION

On Aug. 19, 2008, the Centers for Medicare & Medicaid Services ("CMS") published a final rule to implement the Fiscal Year 2009 Hospital Inpatient Prospective Payment System (the "2009 IPPS final rule"). *73 Fed. Reg 48433*. The IPPS final rule includes significant changes to the federal Physician Self-Referral Law, or "Stark Law," regulations. Under the Stark Law, if a physician or a member of a physician's immediate family has a financial relationship with an entity, the physician may not make referrals to that entity for the furnishing of certain "designated health services" ("DHS") under Medicare, unless an exception applies. If a physician makes a prohibited referral for DHS, the entity is prohibited from seeking or keeping payment from Medicare for the DHS. The IPPS final rule adopts as final, numerous changes to the Stark Law regulations that were proposed in the 2009 Hospital Inpatient Prospective Payment System proposed rule ("2009 IPPS proposed rule"), as well as changes that were proposed in the 2008 Medicare Physician Fee Schedule proposed rule ("2008 MPFS proposed rule") and adopted as final in the September 2007 Stark Law, Phase III regulations ("Phase III").

The following changes have a delayed effective date of Oct. 1, 2009, since they have the potential to substantially impact joint venture arrangements between physicians and hospitals, and may require the parties to restructure or dissolve existing financial arrangements in order to bring them into compliance with the Stark Law:

- Prohibition on the use of percentage-based compensation formulae for equipment and office lease arrangements.
- Prohibition on the use unit-of-service ("per click") payments in office space and equipment lease arrangements to the extent the payments reflect referrals between the parties.
- The expanded definition of "entity" to include not only the entity that submits claims to Medicare for DHS, but also the "person or entity that performs the DHS" in an effort to restrict the provision of DHS to hospitals by physician or physician organizations "under arrangements."

Other changes to the Stark Law regulations that become effective Oct. 1, 2008 include:

- Revisions to the "stand in the shoes" provisions.
- Requirement that hospitals disclose to patients on request, physician-ownership.
- Requirement that hospitals disclose financial relationships with physicians.
- Revisions to the exception for payment of obstetrical malpractice insurance subsidies.
- Clarification regarding physician ownership in a retirement plan.
- Creation of a new exception for technical non-compliance with signature requirements.
- Definition of a "period of disallowance."
- Requirement that in an appeal action, the burden of proof for establishing that DHS was not furnished pursuant to a prohibited referral is on the DHS entity.

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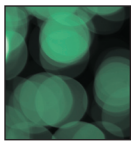


This *Client Alert* describes the key provisions of the 2009 IPPS final rule and provides our commentary on aspects of the proposals that we expect to be of greatest interest to our clients.

II. STARK LAW PROVISIONS IN THE IPPS FINAL RULE

A. "Stand in the Shoes" Provisions

In the 2009 IPPS final rule, CMS revised the physician "stand in the shoes" rule to require its application only to physician-owners of physician organizations (other than those with a mere titular interest) and to permit (without requiring) its application to non-owner physicians, and did not finalize its proposed entity "stand in the shoes" provisions. As a result, many compensation arrangements that are impacted by the current "stand in the shoes" rule can now be analyzed under the more flexible "indirect compensation arrangements" approach that was in effect prior to Phase III.

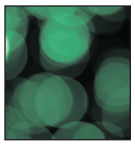
1. Background

The Stark Law's referral prohibition applies if a physician (or immediate family member) has not only a direct, but also an indirect, financial relationship with the DHS entity to which he refers. Prior to Phase III, potential indirect compensation arrangements were analyzed using a two-step approach. The first step was to apply the definition of "indirect compensation arrangement" to determine if such an arrangement exists. If an indirect compensation arrangement exists, the second step was to determine if the exception for indirect compensation arrangements could be satisfied. A key feature of this method of analysis was the focus on the compensation arrangement closest to the referring physician – that is, in applying the definition, one would look at the compensation arrangement closest to the referring physician to determine if the aggregate compensation varies with the volume or value of referrals to, or other business generated for, the DHS entity, and in applying the exception, one would evaluate whether the compensation under that arrangement is consistent with fair market value. This method of analysis was particularly useful in cases where a physician organization that is interposed between the physician and the DHS entity has no physician owners (or physicians who hold the title of owner but do not have any rights to distributions or dividends - referred to by CMS as "titular owners"), such as a faculty practice plan or a clinical practices entity that is part of an academic medical center or a hospital-affiliated integrated delivery system.

In Phase III, CMS adopted the physician "stand in the shoes" concept, whereby a physician who owns, is employed by, or contracts with his or her physician organization is deemed to "stand in the shoes" of the physician organization. The consequence of this approach was that, unlike the prior indirect compensation arrangement approach, a compensation arrangement between the interposed physician organization and the DHS entity would have to meet the requirements of a direct compensation exception in order for the physician to refer to the DHS entity. After publishing Phase III, CMS realized that the Phase III physician "stand in the shoes" rule would cause many academic medical centers and nonprofit integrated health care systems, where support payments among the components of such systems are common, to be unable to comply with the Stark Law. As a result, in November 2007, to allow more time for study, CMS announced a one-year delay in implementation of the physician "stand in the shoes" rule for academic medical centers and nonprofit integrated health care systems.

2. 2009 IPPS Proposed Rule

In the 2009 IPPS proposed rule, CMS put forth two alternatives to address the physician "stand in the shoes" rule. Under the first alternative, termed the "multi-faceted approach," a physician would not "stand in the shoes" of his physician organization if the compensation arrangement between the physician and the physician organization satisfies one of the exceptions for *bona fide* employment arrangements, personal services arrangements, or fair market value compensation. The "multi-faceted approach" also proposed that the physician "stand in the shoes" rule will not apply in connection with indirect arrangements for clinical



training of medical residents at physician practices under the Medicare graduate medical education rules. Under a second, alternative "exceptions approach," CMS proposed to create specific exceptions to the physician "stand in the shoes" provisions to protect non-abusive arrangements not covered by other Stark Law exceptions, such as "mission support" payments between components of an academic medical center or integrated health system.

At the same time, CMS proposed an additional "stand in the shoes" rule that would have been applicable to DHS entities. Specifically, under the proposed entity "stand in the shoes" provisions, a DHS entity would "stand in the shoes" of an entity that it owns or controls; thus, a compensation arrangement between a physician and an entity owned or controlled by a DHS entity to which the physician refers would have to satisfy a direct-compensation-arrangements exception. To make matters even more complex, because these "stand in the shoes" provisions would be applied at both ends of a chain of financial relationships, CMS proposed a set of "conventions" to determine the order in which the physician "stand in the shoes" and entity "stand in the shoes" provisions would be applied.

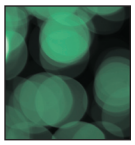
3. 2009 IPPS Final Rule

In the 2009 IPPS final rule, CMS did not adopt either the multi-faceted approach or the exceptions approach to the physician "stand in the shoes" rule. Rather, CMS amended the Phase III physician "stand in the shoes" rule to require its application only to physicians who have an ownership or investment interest in a physician organization (unless such interest is merely titular), and to permit (but not require) non-owner physicians to "stand in the shoes" of their physician organizations. In addition, CMS did not adopt the proposed entity "stand in the shoes" provisions (and did not adopt the complex "conventions" that the proposal would have necessitated).

As a result, beginning Oct. 1, 2008, in order for a physician who is an employee of, or independent contractor to, a physician organization that has a compensation arrangement with a DHS entity to refer to the DHS entity, the compensation arrangement between the physician organization and the DHS entity will no longer need to meet a direct-compensation-arrangements exception. Rather, such referrals could once again be analyzed under the two-step indirect-compensation-arrangements approach described above. In contrast, however, if a physician who is an owner of a physician organization refers to a DHS entity with which the physician organization has a compensation arrangement, that compensation arrangement will need to satisfy one of the exceptions for direct-compensation-arrangements, as is currently the case. As CMS notes, the direct compensation arrangements exceptions generally contain requirements that would not have to be met under the indirect compensation arrangements approach, such as a minimum one-year term and a requirement that compensation be "set in advance."

Since, beginning Oct. 1, 2008, a non-owner physician will be permitted but not required to stand in the shoes of his physician organization, a second, alternative method of compliance will be available to allow referrals from such a physician to a DHS entity with which the physician organization has a financial relationship. That is, even if the indirect-compensation-arrangements approach would not permit referrals, referrals would be permitted if the financial relationship between the physician organization and the DHS entity meets the requirements of a direct-compensation-arrangementsts exception. Thus, a DHS entity will be able to assure itself of compliance solely by considering the terms of the compensation arrangement that it has with a physician organization, rather than through inquiry into the terms of the physician organization's agreements with its employed or contracted physicians.

Under the 2009 IPPS final rule, the physician "stand in the shoes" rule would not apply to physicians with mere titular ownership in a physician organization. Titular ownership is an interest that excludes the ability or right to receive any of the financial benefits of ownership, such as distribution of profits, dividends, proceeds of sale or similar returns on investment. Hence, physicians who are shareholders of "captive" or "friendly" PCs, often used in states



applying the corporate practice of medicine doctrine, might not be treated as owners of the PC.

The 2009 IPPS final rule also does not implement the proposed exception to the physician "stand in the shoes" provisions for training site agreements for medical residents. CMS concluded that such agreements can be properly structured to satisfy the requirements of existing exceptions.

4. Reed Smith Commentary

CMS's revisions to the physician "stand in the shoes" provisions are welcome relief principally for academic medical centers and hospital-affiliated integrated health systems that include physician organizations with no physician ownership (or only titular physician ownership). These physician organizations may include faculty practice plans and clinical practice entities that are subsidized by, or otherwise receive support payments from, hospitals and other DHS entities. The application of the physician "stand in the shoes" provisions to these physician organizations would have been particularly problematic because support payments to such entities would, in many cases, not meet a direct-compensation-arrangements exception.

Other deviations from CMS's proposed "stand in the shoes" rules will also be much appreciated by physicians, physician organizations and DHS entities. Specifically, by allowing (but not requiring) a non-owner physician to stand in the shoes of his physician organization, compliance with the requirements of a direct-compensation-arrangements exception will permit referrals from physicians who are both owners and non-owners (without the need to consider the terms of the non-owner physicians' contracts with the physician organization). Also, CMS's decision not to implement the entity "stand in the shoes" provisions (and the related "conventions") avoids the significantly more complex analyses that would have had to be conducted if that proposal was adopted.

B. Percentage-Based Compensation

1. 2008 MPFS Proposed Rule

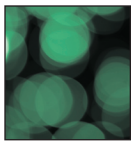
CMS proposed to essentially eliminate the ability to base compensation under a space or equipment lease, or an agreement for management, billing or other services, on a percentage of revenues by restricting use of percentage-based compensation to only those situations where a DHS entity compensates a referring physician based exclusively on revenues generated from the physician's personally performed services. CMS explained that it proposed this more restrictive approach because of what it perceives as potentially abusive arrangements involving percentage-based equipment and office leases, or other payments not related to the physician services provided.

2. 2009 IPPS Final Rule

In this final rule, CMS inserted language prohibiting this compensation arrangement in the applicable exceptions for office and equipment leases, and also in the exceptions for fair market value ("FMV") compensation and indirect compensation arrangements. In each of these exceptions, the 2009 IPPS final rule provides that compensation for the rental of office space or equipment may not be 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 to the services performed or business generated through the use of equipment.

By adding the language not only to the exceptions for lease of office space and equipment but also to indirect compensation and FMV exceptions, CMS is attempting to address situations where physicians lease space or equipment to DHS entities, but they do so by forming a separate investment entity that is not a "physician organization" and, thus, would not be subject to the requirements of the office or equipment lease exceptions. CMS is closing what



would have otherwise been a loophole that physicians could have used to avoid the new prohibition on the use of percentage compensation in lease arrangements.

The new limitation on equipment and space leases becomes effective Oct. 1, 2009, and applies to all existing and future compensation arrangements that rely upon, or seek to rely upon, any of the Stark exceptions listed above. Existing leases of office space and equipment with percentage-based compensation must be amended to provide a flat fee. CMS dismissed concerns that the change in policy is disruptive to existing, long-term arrangements, and reiterated the need to guard against program and patient abuse from overutilization.

CMS views the prohibition on percentage-based compensation as a "targeted approach" that does not extend to other types of non-professional services. In the preamble to the 2009 IPPS final rule, CMS indicated that it will continue to monitor use of percentage-based compensation in other financial arrangements, such as billing and management contracts between physicians and DHS entities.

3. Reed Smith Commentary

Taken together with the proposed restrictions on "per click" arrangements described below, CMS forces office space and equipment leases into a flat-fee model. It is unclear whether CMS's most recent thinking on these issues (after several course reversals) represents the best way to balance real-world contracting models against the legitimate need to prevent abuse. The final rule also presents difficult problems in structuring the compensation formulae in global service agreements that include both services such as billing and management that may be compensated on a percentage-basis, and space or equipment that may not.

C. "Per Click" Lease Arrangements

1. 2008 MPFS Proposed Rule

CMS proposed to modify the existing Stark exceptions for space and equipment leases by adding the following provision to the space and equipment lease exceptions:

Per-unit-of-service rental charges are not allowed to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.

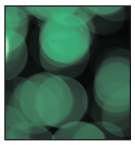
In making this proposal, CMS noted that "such arrangements are inherently susceptible to abuse because the physician lessor has an incentive to profit from referring a higher volume of patients to the lessee. . .." This represented a reversal of CMS's prior regulatory position set forth in the final 2001 Stark II (Phase I) regulations that permits "time-based or unit-of-service-based payments, even when the physician receiving the payment has generated the payment through a DHS referral.[1]"

2. 2009 IPPS Final Rule

In the same manner that CMS prohibited percentage-based compensation formulae, the 2009 IPPS final rule prohibits per unit or per click payments to physician lessors for office space and equipment. CMS revised the exceptions for office and equipment leases, FMV compensation and indirect compensation arrangements, to provide that compensation for the rental of office space or equipment may not be determined using a formula based on:

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

Like the prohibition on percentage-based compensation, the new limitation becomes effective Oct. 1, 2009 and applies to all existing and future compensation arrangements. It also applies to both the indirect compensation arrangement exception and the FMV exception in order to prevent circumvention of the policy through the formation of physician-owned entities that are not "physician organizations."



CMS was careful to note that the prohibition on per-use payments to physician lessors is limited to space and equipment used by DHS entities in services rendered to patients the physician referred. Nothing in the final rule prohibits from leasing equipment or space on a per-use basis for services rendered to patients referred by others. The preamble goes so far as to acknowledge that a physician may have a per-use compensation arrangement for services rendered to patients referred by others, and another compensation arrangement for services rendered to patients referred by the physician.

The prohibition on per-unit leases applies equally to situations where the DHS entity is the lessor or lessee. This mirrored approach reflects CMS's concerns about abusive arrangements in which DHS entities lease space and equipment to physician lessees who pay on a per-click basis.

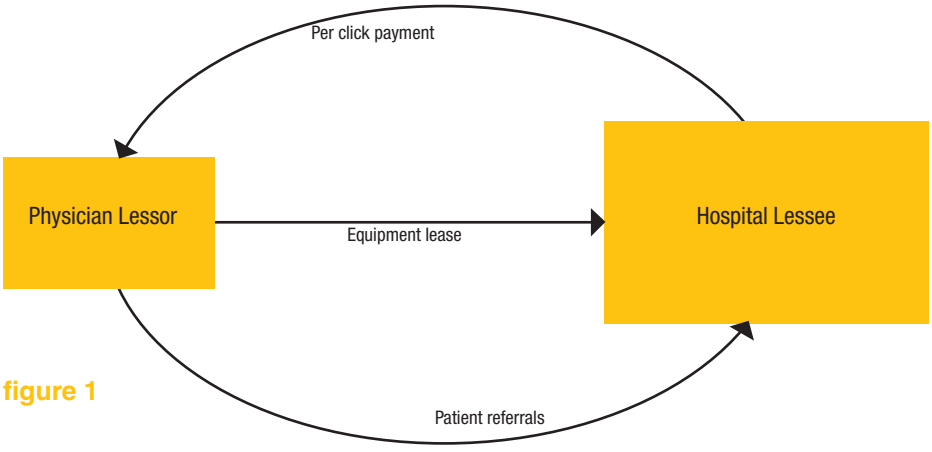
CMS rejected comments from providers and other industry groups asserting that the final rule will stop innovative technologies from being brought to communities. Instead, CMS believes that physician-lessor arrangements can be restructured to block-time basis. CMS also rejected assertions that therapeutic procedures do not pose the risk of overutilization presented by diagnostic radiological procedures. CMS believes there is a risk of abuse regardless of whether the procedure is diagnostic or therapeutic, and cites settlement with cardiac hospital for unnecessary surgeries.

Time-based rental payments, such as block-time leases, can still be structured to meet the requirements of a Stark exception. However, CMS remains concerned with block-time arrangements for very small amounts of time (e.g., once a week for four hours). CMS considers these so-called "on demand" leases to be "per click" arrangements that are now prohibited by the new rule.

The preamble offers further insight into CMS's opinion of per-unit compensation beyond the office and equipment leases impacted by the final rule. The preamble includes a reminder by CMS that an arrangement is not FMV if the lessee is paying a physician substantially more for use of equipment or personnel than it would have to pay a non-physician-owned company for the same or similar equipment or service. CMS also questions whether a lease agreement is commercially reasonable "if the lessee is performing a sufficient 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."

3. Reed Smith Commentary

In a per-use compensation arrangement, the physician receives a lease payment each time the physician makes a referral to the DHS entity (i.e., a hospital) for use of the equipment. See Figure 1. Under the final rule, a physician may not lease equipment (that the physician owns) to a hospital on a per-click basis.



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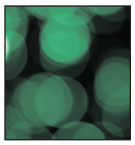


Thus, as suggested in the discussion on percentage-based compensation, CMS is essentially doing a policy "flip-flop" with its proposal changes to the lease exceptions. While recognizing that the Stark Law's legislative history would permit many "per click" arrangements even when the physician-lessor is the referral source, CMS proposes to prohibit such leases by invoking its statutory authority (in the Stark exception for lease arrangements) to impose regulatory requirements to protect against abuse. We believe this raises a potentially significant legal issue, namely, whether CMS can legally utilize this general regulatory authority from the lease exception to impose a restriction that is flatly inconsistent with the Stark II conference report, which clearly states Congress's intent to allow "per click" arrangements as long as the amount of the per-click rates does not fluctuate during the contract period, based on the volume or value of referrals between the parties.

D. Definition of "Entity" / Services Furnished "Under Arrangements"

1. Background

The Medicare statute permits providers, such as hospitals, rural primary care hospitals, skilled nursing facilities, home health agencies, and hospices, to furnish services to beneficiaries "under arrangements" with third party vendors. The vendor has a contractual relationship with the provider under which the provider bills Medicare for the service and reimburses the vendor. In recent years, "under arrangements" joint ventures between hospitals and referring physicians have been used to furnish imaging, ambulatory surgery, cardiac catheterization and other services to hospitals.

CMS expressed concern in both the 2008 MPFS proposed rule and the 2009 IPPS final rule that hospital outpatient services furnished by an "under arrangements" vendor owned by referring physicians creates a risk of overutilization. CMS questioned whether such arrangements were solely a circumvention scheme designed for the purpose of enabling a physician to make money on referrals, particularly where the services furnished by the joint venture were previously directly furnished by the hospital. In addition, CMS expressed concern that the "under arrangements" services might be furnished in a less medically and resource-intensive setting, such as an ambulatory surgery center, but be billed "under arrangements" in order to secure a higher hospital reimbursement rate.

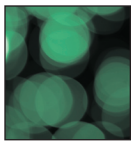
2. 2008 MPFS Proposed Rule

In an effort to curtail the use of "under arrangements" joint ventures, CMS proposed in the 2008 MPFS Proposed Rule to expand the definition of an "entity" to include not only the entity that submits a claim to Medicare for DHS, but also the person or entity that performs the DHS. This provision would effectively preclude physicians from referring patients to an entity that performs DHS billed by a hospital (e.g., a cardiac cath lab) if the physicians are owners or investors in that DHS entity.

3. 2009 IPPS Final Rule

In the 2009 IPPS final rule, CMS adopted the proposal to expand the definition of "entity" to include both the entity that presents a claim to Medicare for the DHS and the "person or entity that performed the DHS." CMS declined to further define the phrase "performed the DHS" and, instead, stated that the phrase should be interpreted as having "its common meaning." CMS stated, however, in the preamble discussion that it does not consider an entity that: a) leases or sells space or equipment used for the performance of the DHS; b) furnishes supplies that are not separately billable but are used in the performance of DHS; or c) provides management, billing services or personnel to an entity that is performing the DHS, to itself be "performing" DHS.

As a result of the expanded definition, it is now possible that through a referral of a single Medicare patient for DHS, a physician would actually be making a referral to two different DHS "entities," each of which may need to be protected under an exception to the Stark Law if the physician has a financial relationship with each entity.



For example, Dr. A is an investor in a Joint Venture with the hospital that owns and operates an imaging center. The Joint Venture has an "under arrangements" relationship with a hospital under which it performs imaging services that are billed by the hospital under its name and billing number. Dr. A refers a Medicare patient to the Joint Venture for an MRI exam that it is subsequently billed by the hospital. Under the current regulations, Dr. A would be making just one referral to an "entity" since the hospital is the only entity billing Medicare for the services. Under the revised regulations, Dr. A. will be making a referral to two entities rather than just one. First, Dr. A will be referring a patient to the hospital for DHS since the hospital submits a claim to Medicare for the services. In addition, Dr. A will be referring a patient to the Joint Venture for DHS since the Joint Venture is the entity "that performed" the DHS. Both of these referral relationships would need to be further analyzed for compliance with an exception to the Stark Law.

Although CMS expanded the definition of "entity," it clarified in the preamble discussion that it does not consider a physician-owned implant or other medical device company to "perform DHS" under this new definition. CMS noted that it may, however, separately issue proposed rulemaking in the future on the issue of physician-owned medical device companies.

4. Reed Smith Commentary

This move to expand the definition of "entity" is one of the most significant changes CMS made to the Stark regulations as it will certainly require many hospital-physician joint ventures that provide "under arrangements" services to hospitals such as cardiac cath labs and imaging centers to be restructured in order to bring the arrangement into compliance with the Stark Law by Oct. 1, 2009.

Previously, the physician would only be making a referral for DHS to one entity - the hospital that billed Medicare for the service. As of Oct. 1, 2009, however, the physician will, as in the imaging center example above, also be making a referral to the entity that "performed the DHS." This second referral will also need to qualify for protection under an exception, but that may not always be possible. In the imaging center example, Dr. A has an ownership interest in the Joint Venture that would need to be protected under an ownership exception. Physicians typically rely on the in-office ancillary services exception to protect referrals to an entity that they have an ownership interest in. In the joint venture scenario above, Dr. A cannot rely on that exception since the Joint Venture is not his or her group practice but merely an imaging center. Therefore, the Joint Venture would need to be unwound or restructured.

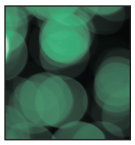
E. Financial Relationships Between Hospitals and Physicians

1. Disclosure of Physician-Ownership to Patients

a. 2009 IPPS Proposed Rule

In the 2008 IPPS final rule, CMS adopted requirements that each physician-owned hospital: i) provide written notice to patients that the hospital is physician-owned; ii) make available on request a list of the hospital's physician owners or investors; and iii) that does not have a physician present in the hospital 24 hours per day, 7 days per week, provide written notice to patients of this fact and indicate how the hospital will meet the medical needs of any patient who develops an emergency medical condition when no physician is present. In the 2009 IPPS proposed rule, CMS proposed several clarifications and additional provisions to the physician-owned hospital disclosure requirements, including:

- Expanding the reporting requirements to also apply when an immediate family member of a physician holds an ownership or investment interest in the hospital.
- Creating an exception to the disclosure requirement if none of the physician-owners refers patients to the hospital and the hospital attests to this fact in writing.



- Clarifying that the list of physician owners and investors must be furnished at the time that the patient or someone on the patient's behalf requests it.
- Adding a requirement that all physicians who are members of the hospital's medical staff must agree, as a condition of continued medical staff membership or admitting privileges, to disclose in writing to all patients who they refer to the hospital, any ownership or investment interest in the hospital held by themselves or by an immediate family member.
- Permitting CMS to terminate the Medicare provider agreement of any hospital that fails to comply with the physician ownership disclosure requirements or the 24/7 physician presence disclosure requirements.

b. 2009 IPPS Final Rule

CMS adopted in the 2009 IPPS final rule all of the disclosure requirements for physician-owned hospitals as described above.

c. Reed Smith Commentary

The change with the most practical significance for hospitals with physician ownership is the new requirement to condition medical staff membership and clinical privileges on physician disclosure to patients. Hospitals with physician ownership need to consider how they will implement the new requirement, such as through agreements with the physician owners or provisions in the hospitals' medical staff bylaws, rules or regulations, and the implications of these alternative approaches on such things as medical staff due process rights. Furthermore, the addition of this requirement could imply some obligation on the part of the hospital to enforce physician disclosure to patients.

2. Hospital Reporting of Financial Relationships with Physicians

a. Background

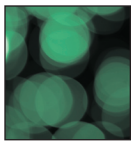
The Stark Law requires DHS entities to provide the Secretary of the Department of Health and Human Services with information concerning the entity's ownership, investment and compensation arrangements in such form and at such times at the Secretary specifies. Currently, Stark Law regulations require entities to make such information available only upon request. In response to The Deficit Reduction Act of 2005, which requires the Secretary to address issues relating to physician-owned specialty hospitals, CMS sent a voluntary survey to 130 specialty hospitals and 220 competitor hospitals seeking certain information about their physician relationships. In addition, CMS included in its Report to Congress a statement that it was going to require all hospitals to provide this information on a periodic basis. Thereafter, CMS prepared a collection instrument, called the "Disclosure of Financial Relationships Report" or "DFRR," which was supposed to be sent to 500 hospitals to determine their compliance with the Stark Law and to assist in developing future regulations.

b. 2009 IPPS Proposed Rule

Rather than sending out the DFRR, CMS decided through the 2009 IPPS proposed rule to seek public comment on the DFRR collection instrument that requires, among other things, completion of worksheets listing all of the hospital's direct and indirect physician ownership or investment relationships; a listing of its rental, personal services and recruitment arrangements; and certain information relating to other types of compensation arrangements.

c. 2009 IPPS Final Rule

In response to public comments, CMS increased the estimated amount of time and cost involved for a hospital to complete the DFRR. Despite the increase in estimated costs, CMS stated that it intends to proceed with sending out the DFRR to 500 general acute care and specialty hospitals. CMS noted that it may, however, decrease the number of hospitals depending on comments it receives in response to its Paperwork Reduction Act package being separately published in the *Federal Register*. In addition, CMS indicated that this will be



a one-time collection effort rather than a regular reporting or updating requirement, as was originally contemplated in the proposed rule.

d. Reed Smith Commentary

Because CMS clearly indicates that it will use the collected information to determine whether the hospitals submitting the data are in compliance with the Stark Law and the Stark regulations are now being significantly changed, hospitals receiving the DFRR may need to re-evaluate and, in some cases, restructure their relationships prior to submitting the DFRR. This could be time consuming and costly, particularly because older agreements may have been analyzed under regulations and guidance available at the time, rather than under more current Stark Law regulations and guidance.

F. Obstetrical Malpractice Insurance Subsidies

1. 2008 MPFS Proposed Rule

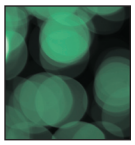
In the 2008 MPFS proposed rule, CMS expressed concern that the exception for obstetrical malpractice insurance subsidies is "unnecessarily restrictive; that is, …[the] exception does not allow for certain obstetrical malpractice insurance subsidies that may be provided without a risk of program or patient abuse." CMS proposed listing the conditions that it believes are necessary to "safeguard against program or patient abuse" in the Stark regulations. The agency suggested:

- A requirement for a written agreement between the parties
- Physician certification (or, in subsequent years, actual data indicating) that a specified percent of the physician's obstetrical patients treated under the coverage of the subsidized malpractice insurance will either reside in a HPSA or medically underserved area, or be part of a medically underserved population
- Location of the entity making the malpractice insurance premium subsidy payment
- Location of the medical practice of the physician receiving the malpractice insurance subsidy payment
- A requirement that the payment not be conditioned on the physician making referrals to, or otherwise generating business for, the entity
- No restriction on the physician establishing staff privileges at, referring any service to, or otherwise generating any business for any other entity
- A requirement that the amount of the payment may not vary based on the volume or value of any previous or expected referrals to or business otherwise generated for the entity by the physician
- A requirement that the physician must treat obstetrical patients who receive medical benefits or assistance under any federal health care program in a nondiscriminatory manner
- A requirement that the insurance is a *bona fide* malpractice insurance policy or program, and the premium, if any, is calculated based on a *bona fide* assessment of the liability risk covered under the insurance

2. 2009 IPPS Final Rule

The 2009 IPPS final rule retains the provisions of the current exception and provides an additional set of requirements under which hospitals, federally qualified health centers ("FCQCs"), and rural health clinics may provide obstetrical malpractice insurance subsidies.

The new alternative requirements permit only hospitals, FCQCs, and rural health clinics 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:



- Located in a primary care Health Professional Shortage Area ("HPSA"), rural area, or an area with a demonstrated need (as determined by the HHS Secretary); or
- Comprised of patients at least 75 percent of whom reside in a Medically Underserved Area ("MUA") or are part of a Medically Underserved Population ("MUP").

3. Reed Smith Commentary

CMS's broadening of the Stark exception for hospital-subsidized obstetrical malpractice insurance provides greater flexibility for hospitals, FCQCs and rural health clinics to facilitate continued patient access to obstetrical care, as well as to address any shortage of obstetrical providers in their service areas. Although some commenters questioned CMS's use of a primary care HPSA (as opposed to creating some form of obstetrical shortage area) as a basis for qualifying under the exception, the broadening of an exception is certainly refreshing.

G. Ownership or Investment Interest in Retirement Plans

1. 2008 MPFS Proposed Rule

Section 411.354(b)(3)(i) excludes an "interest in a retirement plan" from the definition of ownership and investment interests. CMS reported that it received information indicating that some physicians are using retirement plans to purchase DHS entities to which the physicians refer patients. In the 2008 MPFS proposed rule, CMS proposed to "clarify" that the exclusion of retirement plans from the definition of "ownership or investment interest" pertains only to an interest arising from a retirement plan offered by that entity to the physician (or the physician's immediate family members) through the physician's (or the physician's immediate family members') employment with that entity.

2. 2009 IPPS Final Rule

CMS adopted the earlier proposal to clarify that when a retirement plan offered by the entity that employs the physician (or the physician's immediate family members) purchases or invests in another DHS entity, the physician's interest (or that of the physician's immediate family members) in that other DHS entity through a retirement plan does not qualify for protection under the exception for ownership or investment interests in a retirement plan. In other words, the exception does not extend to any DHS entity in which the employer's retirement plan invests.

3. Reed Smith Commentary

This clarification will require physicians and the DHS entities that employ them to more carefully gauge the investments made by retirement plans offered to physicians or their immediate family members.

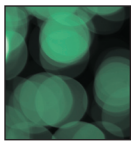
H. Technical Non-Compliance with Signature Requirements

1. 2008 MPFS Proposed Rule

In the 2008 MPFS proposed rule, CMS discussed previously received comments regarding "technical" violations of the Stark Law and the fact that innocent or trivial violations could result in draconian penalties. CMS stated that it does not have discretion to waive violations of the Stark Law, but it proposed eight potential changes to the regulations that would provide an alternative method for satisfying a Stark exception in instances where there has been an unintentional violation of a procedural or "form" requirement of the exception.

2. 2009 IPPS Final Rule

CMS decided not to adopt the numerous proposed changes that would have provided an alternative method for satisfying technical or "form" requirements of an exception. Instead, CMS only adopted an exception relating to missing signatures. This new exception provides that a financial relationship that otherwise would be out of compliance with an exception that



has a signature requirement will remain in compliance with that exception (assuming all other requirements are satisfied), provided that certain conditions are met:

- If there has been an inadvertent failure to obtain a signature for an agreement that otherwise complies with an exception, the parties have 90 days from beginning of financial relationship to have the agreement signed.
- If there has been a failure to obtain a signature for an agreement that is not inadvertent, the parties have 30 days from beginning of financial relationship to have the agreement signed.
- This signature exception can be used only once every three years per physician.

3. Reed Smith Commentary

The adoption of the missing signature exception provides DHS entities and physicians with a small, yet long-sought, compliance safety net. Although the timeframe during which the exception can be employed is, at most, 90 days, this exception represents CMS's recognition that some issues relating to technical compliance should not automatically result in a finding of noncompliance. Furthermore, the lack of any discussion in the final rule regarding self-disclosure indicates that CMS has not attached the requirement of self-disclosure of the technical noncompliance to CMS as a condition to using the new exception (despite the fact that the eight criteria to avoid technical noncompliance proposed in the 2008 MPFS proposed rule were contingent upon self-disclosure).

I. Period of Disallowance

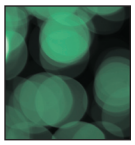
1. 2009 IPPS Proposed Rule

In the IPPS proposed rule, CMS proposed to establish an outside limit on the time period (referred to as the "period of disallowance") during which a physician would be prohibited from referring patients to a DHS entity and for which the DHS entity, would be prohibited from billing Medicare if a financial relationship between the referring physician and the DHS entity failed to satisfy a Stark Law exception.

2. 2009 IPPS Final Rule

With only technical modification to some of the language in the proposed rule, CMS finalized the proposal with respect to only the following three circumstances:

- If the reason for noncompliance is not related to compensation, the period of disallowance would begin on the date the arrangement first was out of compliance, and end no later than the date the arrangement was brought into compliance.
- If the reason for noncompliance is related to the payment or receipt of excess compensation, the period of disallowance would begin on the date the arrangement first was out of compliance and end no later than the date all excess compensation (including interest, as appropriate) was returned by the party receiving it to the party that provided it, and all other requirements of the applicable exception are met. For example, if on February 1 a hospital provided nonmonetary compensation to a physician in excess of the annual regulatory limit by $100, and noncompliance was not discovered until Oct. 1, the period of disallowance would begin Feb. 1 and end no later than the date on which the physician returned the all of the excess nonmonetary compensation (or its value). (CMS noted in the proposed rule that if the noncompliance was discovered and the excess returned within 180 days of its receipt, existing regulations permit the parties to maintain compliance.)
- If the reason for noncompliance is related to the payment or receipt of insufficient compensation, the period of disallowance would begin on the date the arrangement first was out of compliance and end no later than the date the entire shortfall was paid to the party to which it is owed, and all other requirements of the applicable exception are met. In the proposed rule, CMS provided an example of a hospital and physician that entered into a two-year office space rental agreement that provides for a CPI rent adjustment after



the first year, but the physician continued to pay the same rate during the second year, until noncompliance was discovered in the middle of the second year. CMS stated that the period of disallowance would run from the first day of the second year of the lease until no later than the date on which noncompliance was discovered, as long as the physician paid the hospital the entire rent shortfall on that date; paid the CPI adjusted rate for the remainder of the term; and the arrangement otherwise satisfied the requirements of the space lease arrangements exception.

Importantly, with respect to these and all other instances of noncompliance not covered by the three circumstances described above, the period of disallowance will depend on the facts and circumstances.

3. Reed Smith Commentary

While CMS's final rule provides some degree of certainty as to the period of disallowance under some circumstances, it leaves this question unaddressed for a great many circumstances, such as where an arrangement was noncompliant for reasons other than those specified in the three scenarios identified. The best that CMS can say about such circumstances is that the period of disallowance will be made on a case-by-case basis considering applicable facts and circumstances. Though the final rule provides more clarity regarding the period of disallowance, it does not provide guidance for many possible situations.

J. Burden of Proof

1. 2008 MPFS Proposed Rule

In the 2008 MPFS proposed rule, CMS proposed adding a new provision that would "clarify" the burden of proof when a provider appeals a claim that was denied payment because the DHS allegedly arose from a prohibited referral. The regulations were previously silent on this subject. The proposed language stated that "the burden is on the entity submitting the claim for payment to establish that the service was not furnished pursuant to a prohibited referral (and not on CMS or its contractors to establish that the service was furnished pursuant to a prohibited referral)."

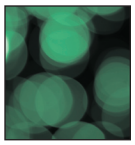
2. 2009 IPPS Final Rule

In the IPPS final rule, CMS finalized its proposed clarification. As finalized, the burden of persuasion is on the provider submitting the claim for payment to establish that the service was not furnished pursuant to a prohibited referral (and not on CMS or its contractors to establish that the service was furnished pursuant to a prohibited referral). The burden of production, however, is initially on the provider/claimant, but may shift to CMS during the course of the proceeding. CMS also notes that this clarification is generally consistent with the agency's policy for claims denials.

3. Reed Smith Commentary

As a result of this clarification, proper document retention and recordkeeping policies have assumed even greater importance since, when challenged by CMS, providers will have to prove they were operating in compliance with the Stark Law and its exceptions, rather than CMS having to prove that the provider is guilty of violating the law. In other words, once CMS alleges through a claims denial that a Stark violation has occurred, the burden will shift to the provider to prove otherwise.

Furthermore, CMS declined to prescribe the type or quantity of evidence a provider/claimant must produce in order to shift the burden of production from the provider to CMS. This lack of guidance on the part of CMS indicates that it is likely that providers have the initial responsibility to prove compliance with all components of the relevant Stark exception, including any required compliance with the federal anti-kickback statute. CMS does not normally determine compliance with the anti-kickback statute and, under the final rule, is not subject to any particular standards or procedures for explaining and justifying its findings in



response to a provider's appeal of a Stark-related claims denial. Despite CMS's contention that the burden of production associated with potential anti-kickback violations may shift to CMS, the final rule provides no comfort to providers in the form of how a shift in the burden of production can be triggered.

The following Stark exceptions require compliance with the anti-kickback statutes:

- In-office ancillary services
- Academic medical centers
- Implants furnished by an ASC
- Provision of EPO in a dialysis facility
- Contacts following cataract surgery
- Intra-family referrals
- Personal services arrangements (general reference)
- Physician recruitment
- Charitable donations by a physician
- FMV compensation exception
- Medical staff incidental benefits
- Indirect compensation
- Professional courtesy
- Retention payments in undeserved areas

III. CONCLUSION

Hospitals and other health care providers that have "under arrangements" deals, facility leasing arrangements, joint ventures, or any other arrangements with entities owned by referring physicians that involve the provision of DHS or the leasing of space or equipment, should carefully review those arrangements for compliance with the revised Stark Law regulations. It is possible that such financial relationships with service or leasing companies owned by referring physicians may need to be dissolved or restructured within the next year in order to assure compliance with the new definition of entity and prohibitions on percentage compensation and per click lease payments that take effect as of Oct. 1, 2009.

Footnotes

[1] 66 Fed. Reg. at 876.

Our prior *Client Alerts* describe each of these developments. For a discussion of the Stark Law provisions in the proposed 2009 IPPS regulations, see our May 2008 *Client Alert* 08-088 entitled "Proposed Stark Law Changes in CMS's 2009 IPPS Proposed Rule." For a discussion of the Stark Law provisions in the 2008 proposed MPFS regulations, see our July 24, 2007 *Client Memo* entitled, "Update on Important Stark Law Developments", which is available on our website at http://www.reedsmith.com/_db/_documents/hc0706.pdf. For a discussion of the Stark Law, Phase III final regulations, see our Oct. 4, 2007 *Client Memo* entitled "Stark II (Phase III) Final Rule."

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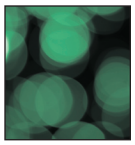

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