

HEALTH LAW

Update

NEWS FOR THE CLIENTS AND FRIENDS OF BASS, BERRY & SIMS PLC

What Goes Up Must Come Down: Spinning Wheel of Stark Goes 'Round

September 16, 2008

The final rule containing the inpatient prospective payment system update for fiscal year 2009 (the "2009 IPPS Rule") contains several significant changes to the federal physician self-referral regulations (commonly known as "Stark"). In some cases, these changes reverse previous positions taken by the Centers for Medicare & Medicaid Services ("CMS") on which parties have relied to structure arrangements. This Health Law Update summarizes these changes, which will keep many providers and their counsel busy over the next year restructuring or unwinding arrangements.

Prohibition of Per-Click Lease Payments –Effective October 1, 2009

CMS revised the space and equipment lease exceptions, the fair market value exception, and the indirect compensation arrangements exception under Stark to prohibit per-unit-of-service rental charges (commonly known as "per click" charges) for space and equipment to the extent that such charges reflect services provided to patients referred between the parties. This change will effectively prohibit physician-owned leasing companies from entering into per-click leases with hospitals and other designated health services ("DHS") entities. CMS made clear in its commentary accompanying the 2009 IPPS Rule that the prohibition on per-click payments applies regardless of whether the physician is personally the lessor or has an ownership or investment interest in an entity that is the lessor.¹ CMS stated that the new prohibition also applies when the physician is the lessee instead of the lessor, i.e., the rule applies when a DHS entity that refers patients to a physician or physician organization leases equipment or space to the physician or physician organization to which it refers.²

One bright spot for per-click providers is CMS' clarification in the commentary that it is not prohibiting per-click arrangements involving non-physician-owned lessors to the extent that these lessors do not refer patients for DHS. CMS also clarifies that it is not prohibiting per-click payments to physician lessors for services rendered to patients who were not referred to the lessee by the physician lessors.³ So some parties may investigate the feasibility of developing two separate compensation structures, one for patients referred by physician owners (such as a block lease arrangement) and one for patients referred from other sources.

¹ See 73 Fed. Reg. 48434, 48714 (Aug. 19, 2008).

² See 73 Fed. Reg. 48434, 48713-48714 (Aug. 19, 2008).

³ See 73 Fed. Reg. 48434, 48719 (Aug. 19, 2008).

Providers should be mindful, however, that even block leasing arrangements may be restricted by CMS in the future. While the new rules reach only per-click and "on demand" rental agreements, CMS has also indicated that it will continue to study whether to propose additional rules regarding block time leasing arrangements.⁴

Since the rules do not provide for a grandfathering of existing arrangements, any such existing arrangements that do not comply with the new rules must be restructured or unwound prior to rule's effective date of October 1, 2009.⁵

Percentage-based Compensation – Effective October 1, 2009

In addition to prohibiting "per click" charges for the rental of space or equipment (to the extent that such charges reflect services rendered to patients referred between the parties), the 2009 IPPS Rule prohibits the use of compensation arrangements for the rental of space or equipment that are based on a percentage of revenue attributable to the services performed or business generated in the leased office space or in the use of leased equipment. At various points throughout the recent past, CMS has stated that, in originally allowing percentage-based compensation arrangements, CMS intended and contemplated that such arrangements would be used only for personally performed physician services. CMS apparently did not intend for percentage compensation arrangements to expand beyond the realm of personally performed physician services into widespread use for space and equipment leasing. The 2009 IPPS Rule narrows the use of percentage compensation arrangements to conform to CMS' stated intent.

Therefore, CMS will effectively prohibit, as of October 1, 2009, all percentage-based arrangements for the lease of space or equipment, whether the arrangement is a direct or indirect financial arrangement.

CMS did not extend the prohibition against percentage-based fees to other arrangements (such as billing and management services agreements), though it previously stated that it intends to monitor all percentage-based fee arrangements, other than those for personally-performed services, and may choose to limit such arrangements in the future.

Prohibition of "Under Arrangements" Entities with Physician Ownership – Effective October 1, 2009

CMS finalized changes to the definition of "entity" that will effectively prohibit (except in rural areas) physician ownership of entities that provide services to hospitals "under arrangements." Under the revised definition of "entity" effective October 1, 2009, a person or entity is considered to be furnishing DHS if the person or entity either "performs" the DHS or presents a claim or causes a claim to be presented to Medicare for the DHS.⁶ Under the existing definition of "entity" only the person or entity that presents a claim or causes a claim to be presented to Medicare for the DHS is considered the "entity."

Currently, a physician-owned entity providing services "under arrangements" to a hospital creates a compensation arrangement between the referring physicians and the hospital. Under the new rules effective October 1, 2009, the physician-owned entity will be a DHS entity and the arrangement must meet an ownership exception to the Stark prohibition.⁷ Because ownership exceptions are generally more restrictive

⁴ See 73 Fed. Reg. 48434, 48719-48720 (Aug. 19, 2008).

⁵ See 73 Fed. Reg. 48434, 48713-48714 (Aug. 19, 2008).

⁶ See 73 Fed. Reg. 48434, 48721 (Aug. 19, 2008).

⁷ This is the case regardless of whether the services would be DHS if not billed by the hospital. CMS made this comment in response to questions regarding cardiac catheterization services, which are not DHS unless billed by a hospital as inpatient or outpatient hospital services. CMS wrote that it would consider an entity providing cardiac catheterization services to a hospital "under arrangements" to be a DHS entity under the new rule. CMS clarified,

than compensation exceptions, except for entities located in rural areas as defined by Stark, it will be difficult for many entities to meet an ownership exception.⁸

CMS delayed the effective date of this change to October 1, 2009. The new rules do not grandfather existing relationships, so existing "under arrangements" structures with physician ownership must be restructured or unwound by October 1, 2009.⁹

The new rules do not provide a specific definition of "perform," an ambiguity that creates uncertainty regarding the scope of the new rule. In the preamble discussion, CMS indicates that it does not consider an entity that leases or sells space or equipment used for the performance of a service, or furnishes supplies that are not separately billable but are used in the performance of a medical service, or provides management, billing services or personnel to an entity to be "performing" a service. It is not clear, however, whether an entity that provides some combination of the foregoing items and services, or even turnkey management services that fall short of full-blown "under arrangements" outsourcing, would be "performing" DHS. We hope that CMS will provide additional guidance in this area.

"Stand-In the Shoes" – Effective October 1, 2008

The 2009 IPPS Rule implements certain changes designed to simplify the physician "stand in the shoes" rules originally promulgated as part of the Phase III rulemaking published on September 5, 2007.¹⁰ The Phase III "stand in the shoes" rules, which took effect January 1, 2008, require physicians to stand in the shoes of "physician organizations" ("POs") with which they have a financial relationship.¹¹ As defined in the Phase III rulemaking, a PO is generally considered as any organization primarily engaged in providing physician services.¹² Financial relationships between the PO and DHS entities are analyzed as if such relationships are directly between a physician and the DHS entity. These relationships must therefore meet a direct compensation exception under the Stark law rather than be analyzed under the "indirect compensation arrangements" definition and exception.

The 2009 IPPS Rule changes the stand in the shoes doctrine (the "SITS Doctrine") in three ways: (i) it modifies the types of financial relationships between physicians and POs that are subject to the rule; (ii) it alters the application of the physician "stand in the shoes" rules to academic medical centers (AMCs); and (iii) it declines to implement to the so-called "entity stand in the shoes" doctrine that had previously appeared in the 2008 Medicare Physician Fee Schedule ("2008 MPFS") and, with some refinements, in the proposed version of the 2009 IPPS Rule. Each of these changes to the SITS Doctrine is addressed separately below.

Types of Physician Relationships That Trigger Application of SITS

The 2009 IPPS Rule requires only physicians with an ownership or investment interest in a PO, as opposed to a compensation relationship with the PO, to stand in the shoes of the PO.¹³ Mere "titular" owners, such as

however, that lithotripsy would not be considered DHS even if billed by a hospital as outpatient or inpatient hospital services. See 73 Fed. Reg. 48434, 48729-48730 (Aug. 19, 2008).

⁸ See 73 Fed. Reg. 48434, 48721 (Aug. 19, 2008).

⁹ See 73 Fed. Reg. 48434, 48721 (Aug. 19, 2008).

¹⁰ See 72 Fed. Reg. 51012, 51026 (Sept. 5, 2007).

¹¹ See 72 Fed. Reg. 51012, 51026 (Sept. 5, 2007).

¹² See 72 Fed. Reg. 51012, 51026 – 28 (Sept. 5, 2007).

¹³ CMS has also grandfathered into the new regulations those arrangements that were not direct compensation arrangements and that would not have been indirect compensation arrangements under the provisions in Section 411.354(c) prior to Phase III, but were restructured to comply with physician "stand in the shoes" rules set forth in Phase III. Such arrangements would need to be restructured as appropriate once the original term expires. 73 Fed. Reg. 48695.

physician owners in a captive or "friendly" PC, would not stand in the shoes of the PO.¹⁴ CMS explains in the preamble that ownership is titular where the physician is not able or entitled to receive any of the financial benefits of ownership or investment, including not only distribution of profits, but also proceeds of sale or similar returns on investment.¹⁵ CMS has also indicated that where a physician is entitled only to receive a return of the capital invested in a PO, without any appreciation in value, a physician may be deemed to have titular ownership.¹⁶

By contrast, physicians who have no ownership or investment interest in their PO, but rather only a compensation relationship with it, may *elect* to, but are not required to, stand in the shoes of their PO for purposes of meeting a Stark law exception.¹⁷ Some physician-owned entities may make this election for the sake of administrative simplicity if they already have physician owners and therefore must meet a direct compensation exception for their financial relationships with DHS entities.

It is possible that CMS may further refine the SITS Doctrine in the future. While CMS has chosen at the present time not to require non-owner and titular owner physicians to stand in the shoes of their PO, CMS remains concerned that there are instances where non-owner physicians' employees and contractors have compensation arrangements that are not based on fair market value and would benefit from payments made by a DHS entity to their PO.¹⁸

Effect of New SITS Doctrine on AMCs

The new SITS Doctrine, with its mandatory application only to ownership interests, means that AMC faculty practice plans, which do not have "owners," would be able to continue to use the "indirect compensation" exception to protect payment arrangements.

The Demise of "Entity Stand in the Shoes"

In the 2009 IPPS Rule, CMS declined to finalize the so-called entity "stand in the shoes" rules that were initially proposed in the 2008 MPFS.¹⁹ The proposed version of the 2009 IPPS Rule modified the original proposal such that a DHS entity would stand in the shoes of only an organization in which it had a 100% ownership interest. The proposed version of the 2009 IPPS Rule also included a series of "conventions" to apply in a situation where a financial relationship might trigger both the SITS Doctrine and the "entity stand in the shoes" rules.²⁰ None of these aspects of "entity stand in the shoes" was ultimately adopted in the 2009 IPPS Rule.

"Set in Advance" Guidance – No Regulatory Text Change

In the Phase III Stark rulemaking, CMS expressed the position that an amendment to the compensation provisions of an agreement (and to terms "material" to those compensation provisions) occurring at any time during the term of the agreement, even a multi-year term, would violate the intent of the "set in advance" requirements.²¹ CMS required instead that such an agreement be terminated and a new agreement be executed (so long as at least one year of the term of the original agreement had passed prior to the new

¹⁴ 73 Fed. Reg. 48433, 48693 (August 19, 2008).

¹⁵ 73 Fed. Reg. 48693 and 48752.

¹⁶ 73 Fed. Reg. 48693 and 48752.

¹⁷ 73 Fed. Reg. 48693-4.

¹⁸ 73 Fed. Reg. 48694.

¹⁹ 72 Fed. Reg. 38122, 38179 (July 12, 2007).

²⁰ 73 Fed. Reg. 48433, 48699-700 (August 19, 2008).

²¹ 72 Fed. Reg. 51012, 51044-45 (Sept. 5, 2007).

agreement being executed).²²

In the 2009 IPPS Rule, CMS reconsidered its position on amendments.²³ CMS has now re-interpreted "set in advance" to permit the amendment of a contract during its term, so long as (1) all requirements of an applicable exception are met, (2) the amended compensation is determined before the amendment is implemented and the formula is sufficiently detailed so that it can be objectively verified, (3) the amended charges do not take into account the volume or value of referrals or other business generated by the referring physician, and (4) the amended compensation remains in place for at least one year from the date of amendment.²⁴

It seems clear, then, that amendments to compensation are permitted after the first year of a multi-year term if all other requirements are met. What is less clear, and would benefit from written clarification by CMS, is whether amendments to compensation during the first year of an agreement's terms are permitted.

Alternative Method of Compliance Provision with Signature Requirements – Effective October 1, 2008

In the proposed 2008 MPFS, CMS stated that it had received multiple comments in response to an earlier rulemaking seeking relief from "innocent and trivial" violations of the Stark law that may result in huge penalties.²⁵ The proposed 2008 MPFS rule covered a broad array of situations where an arrangement fails to satisfy the procedural or "form" requirements of an exception.²⁶ The final FY 2009 IPPS rule finalizes that proposal only for one such situation, i.e., only where there is a failure to meet the signature requirement of certain exceptions. The final rule allows parties to remedy non-compliance due to missing signatures within certain grace periods.²⁷ If the failure was due to an inadvertent error, the grace period is 90 days. If the failure was not inadvertent, then the grace period is reduced to 30 days.²⁸

Period of Disallowance – Effective October 1, 2008

CMS has also finalized rules that would address the "period of disallowance" for which a physician may not refer patients for DHS services to an entity (and for which the entity may not bill Medicare) due to failure of the financial relationship between those parties to satisfy all of the requirements of a Stark exception. The provision, effective October 1, 2008, states that the period of disallowance ends no later than: (1) when the arrangement comes into compliance, if the non-compliance does not relate to compensation; (2) the date when the excess remuneration is returned, if the non-compliance relates to excess compensation; or (3) the date on which additional money is paid, if the non-compliance relates to insufficient payment.

CMS has further specified that the rule creates an "outside date" and that parties are free to take the position that the period of disallowance ended earlier (if, for example, they can establish that the financial relationship ended earlier).²⁹ However, CMS indicated that the beginning and ending dates of the financial relationship do not necessarily coincide with the terms of the parties' written agreement. According to CMS' preamble commentary accompanying the 2009 IPPS Rule, correcting a financial relationship that falls outside a Stark exception due to technical noncompliance by back dating or otherwise attempting to turn back the clock is not

²² 72 Fed. Reg. 51012, 51044-45 (Sept. 5, 2007).

²³ 73 Fed. Reg. 48433, 48697 (August 19, 2008).

²⁴ 73 Fed. Reg. 48433, 48697 (August 19, 2008).

²⁵ 72 Fed. Reg. 38122, 38185 (July 12, 2007).

²⁶ 72 Fed. Reg. 38122, 38185 (July 12, 2007).

²⁷ 73 Fed. Reg. 48433, 48705 (August 19, 2008).

²⁸ 73 Fed. Reg. 48433, 48705 (August 19, 2008).

²⁹ See 73 Fed. Reg. 48433, 48700 (Aug. 19, 2008).

adequate.³⁰ Additionally, as strict compliance is expected of providers, CMS states that the financial impact of correcting nonconformance is irrelevant.³¹

Obstetrical Malpractice Insurance Subsidies – Effective October 1, 2008

The 2009 IPPS Rule expands the exception for obstetrical malpractice insurance subsidies effective October 1, 2008. The expanded exception, in addition to allowing the subsidies contained in the original exception, allows hospitals, federally qualified health centers, and rural health clinics to provide obstetrical malpractice insurance subsidies to certain eligible physicians. Eligible physicians are those who routinely engage in obstetrics as part of a medical practice that is located in either (1) a primary care Health Professional Shortage Area ("HPSA"), a rural area, or an area with demonstrated need as determined in an advisory opinion, or (2) an area comprised of patients at least 75% of whom live in a medically underserved area or are part of a medically underserved population.

Interests in Retirement Plans – Effective October 1, 2008

Historically, the Stark regulations have carved out from the definition of "ownership or investment interests" those interests that a physician holds in a retirement plan. The 2009 IPPS Rule modifies this carve-out to clarify that it only applies to interests in an entity arising from a retirement plan offered by that entity to the physician (or immediate family member) through that physician's (or immediate family member's) employment with the entity.

Burden of Proof – Effective October 1, 2008

In the 2009 IPPS Rule, CMS adopted a burden of proof standard. Effective October 1, 2008, when an entity/provider appeals a claim for payment that was denied on the basis that it was furnished pursuant to a prohibited referral, the entity/provider will have the burden of proof at each level of the appeal to establish that the service was not furnished pursuant to a prohibited referral. Also, the burden of production on each issue at each level of appeal is initially on the DHS entity, but may shift to CMS or its contractors depending on the evidence the DHS entity presents.

Conclusion

The 2009 IPPS Rule represents yet another significant round of Stark changes grafted onto an annual payment update that will keep providers and their counsel busy for the next year. If you have any questions on this *Health Law Update*, please contact any of the attorneys in our Healthcare Industry Practice Group listed on the following page.

³⁰ See 73 Fed. Reg. 48433, 48703 (Aug. 19, 2008).

³¹ See 73 Fed. Reg. 48433, 48703 (Aug. 19, 2008).

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