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Life Sciences Health Industry Alert

If you have questions or would like additional information on the material covered in this Alert, please contact one of the authors:

Daniel A. Cody
Partner, San Francisco
+1 415 659 5909
dcody@reedsmith.com

Paul Pitts
Associate, San Francisco
+1 415 659 5971
ppitts@reedsmith.com

…or the Chair of the Life Sciences Health Industry Group,

Michael K. Brown
Partner, Los Angeles
+1 213 457 8018
mkbrown@reedsmith.com

…or the Reed Smith lawyer with whom you regularly work.

Stark Law Changes Effective October 1, 2009

Introduction

On October 1, 2009, additional changes to the Stark Law regulations adopted by the Centers for Medicare & Medicaid Services ("CMS") in the 2009 Hospital Inpatient Prospective Payment System final rule (the "Final Rule") will go into effect and cause many "under arrangements" relationships between hospitals and physician-owned, third-party service providers to fall out of compliance. In addition, new rules governing the compensation terms of lease agreements involving physicians will become effective the same date. As existing arrangements will not be grandfathered, the Final Rule's new restrictions will force many arrangements between physicians and hospitals, particularly hospital/physician joint ventures, to be restructured, or noncompliant arrangements to be abandoned.

This memorandum is intended to remind our clients of these important changes to the Stark Law effective October 1, 2009, and to encourage parties to revise potentially noncompliant arrangements.* The Stark Law is a strict liability statute. Financial relationships implicating the law but not meeting a relevant exception are noncompliant, regardless of whether one or both of the parties to the arrangement was unaware of or did not intend the defect, or whether the arrangement has benign or even beneficial attributes.

Summary

Although most of the changes to the Stark regulations adopted in the Final Rule went into effect October 1, 2008, the following changes were delayed until October 1, 2009:

- The definition of an "entity" is expanded to include not only the entity that bills and receives payment for the designated health service ("DHS"), but also the person or entity that performs the DHS.
- Percentage of revenue rental charges are prohibited in office space or equipment leases between DHS and referring physicians, or entities in which referring physicians have an ownership or investment interest.
- "Per-click" rental charges are prohibited in office space and equipment lease arrangements to the extent the payments reflect referrals between the parties.

"Under Arrangements"

Unless an exception applies, the Stark Law prohibits a physician from making referrals for certain DHS payable by Medicare or Medicaid to an *entity* with which the physician (or an immediate family member) has a direct or indirect financial relationship (either ownership/investment or compensation). The Stark Law also prohibits the *entity* from filing claims with Medicare or Medicaid for DHS rendered as a result of a prohibited referral. One of the most significant changes in the Final Rule is the change in the definition of *"entity"* that will result in new limits on "under arrangements" ventures beginning October 1, 2009.

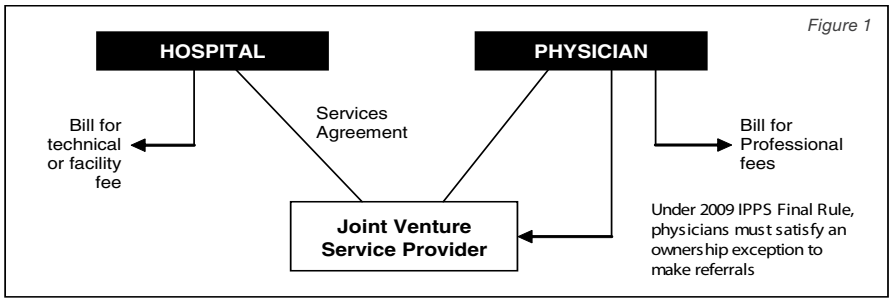
Under the Medicare payment rules, providers such as hospitals, rural primary care hospitals, skilled nursing facilities, home health agencies, and hospices can provide services to their patients directly or "under arrangements" with a third party, and bill Medicare or Medicaid for those services. Examples of physician-owned third parties that provide "under arrangements" services to hospitals include entities such as clinical laboratories, sleep laboratories, cardiac catheterization laboratories, orthopedic and prosthetic supply companies, physical, occupational and speech therapy providers, radiation therapy service facilities, and radiology and other imaging services ventures.

Currently, the Stark Law defines an *"entity"* as the entity that bills *and* receives payment for DHS. This definition generally excludes providers that furnish DHS "under arrangements" to another entity

that bills for the services. This definition of *"entity"* allowed many "under arrangements" ventures to be structured to comply with a Stark Law exception (*e.g.*, indirect compensation exception). With the Final Rule, however, CMS has determined to revise the Stark Law regulations to limit "under arrangements" ventures, citing concern that such arrangements enable physicians to profit on referrals and create a risk of overutilization. To address this concern, the Final Rule includes a modification to the definition of *"entity"* that will have a significant impact on "under arrangements" between DHS providers and physician-owned entities.

Under the Final Rule, CMS expanded 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." As a result of the expanded definition, it is now possible that through a referral of a single Medicare or Medicaid 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. Physician investors would have to satisfy an ownership exception under the Stark Law in order to refer patients to a provider that contracts with an entity performing DHS and is directly or indirectly owned by the same physician. *See* Figure 1.

Figure 1



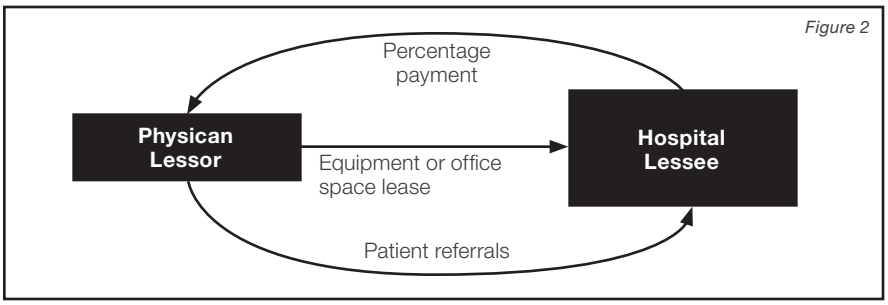
CMS declined to further define the phrase *"performed the DHS,"* and instead stated that the phrase should be interpreted as having "its common meaning." CMS noted in the preamble to the Final Rule, however, that the agency does not consider an entity engaged in the following activities to be "performing" DHS: (1) leases or sells space or equipment used for the performance of the DHS; (2) furnishes supplies that are not separately billable but are used in the performance of DHS; or (3) provides management, billing services, or personnel to an entity that is performing the DHS. With the exception of the foregoing, physician-owned entities deemed to be performing DHS "under arrangements" for another entity, and physicians having ownership/investment interests in, or compensation arrangements with, such entities will be prohibited from making DHS referrals to such entities unless an exception applies. In fact, both the relationship between the physician and the physician-owned entity, and the relationship between the physician and the entity billing for the services, must meet an applicable Stark Law exception.

Relationships to consider when analyzing the impact of the Stark Law "under arrangements" revisions include: (1) physician ownership in an entity that furnishes non-DHS services and also provides these services as inpatient or outpatient services "under arrangements" for a hospital; and (2) physician ownership in an entity that bills for DHS and also provides DHS "under arrangements" for a health care provider.

Take Away: Physician-owned "under arrangements" relationships not meeting one of the Stark Law ownership exceptions are prohibited as of October 1, 2009. Parties should consider how to restructure or unwind noncompliant arrangements. Parties should consider a more narrow arrangement under which the entity does not "perform" the services, while also keeping in mind the restrictions on per-click leasing arrangements addressed below.

Percentage-Based Arrangements

A second revision in the Final Rule limits the ability of health care entities to utilize percentage-based compensation formulas to determine rental charges for the lease of office space and equipment. Percentage-based leases compensate a lessor based upon a percentage of revenues generated through the utilization of the leased equipment or office space. The Final Rule limits a physician's ability to benefit from referrals in percentage-based arrangements by ending these arrangements. *See* Figure 2.

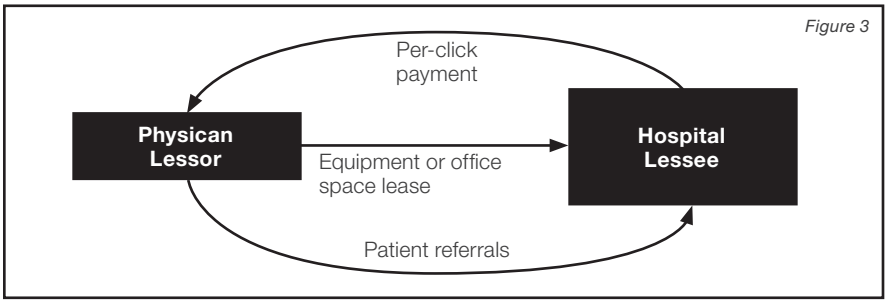


The Final Rule prohibits office space and equipment lease arrangements that determine rent based upon a percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed, or business generated by the use of the space or equipment. CMS expressed concern that such rental charge calculations create an incentive for the lessor to increase referrals to the lessee, and that fluctuating rental payment under a percentage-based formula may not represent fair market value. The new regulations only address percentage-based compensation formulas for rental charges in leases, however; such arrangements are still permitted for a physician's personally performed services and for non-professional services. This includes management and billing arrangements so long as the arrangements are not bundled with office space or equipment leases.

Take Away: Physician and physician group office space and equipment lease arrangements should be examined to ensure that the compensation terms comply with the percentage-based compensation restrictions in the Final Rule.

Per-Click Arrangements

A third revision in the Final Rule limits the ability of health care entities to utilize per-unit or per-click rental payment methodologies (*i.e.*, the owner is paid for each use of the leased space or equipment) to satisfy the requirements of either space or equipment lease exceptions. *See* Figure 3. This means that the prohibition applies when the physician is the lessor, or when the physician is the lessee of space or equipment. While CMS stressed its interest in restricting per-click arrangements with physician lessors, the Final Rule adopted a symmetrical approach by applying the prohibition to both physician lessees and other entity lessees. This prohibition also applies to the fair market value and indirect compensation arrangement exceptions.



CMS was careful to note, however, 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. Leasing equipment or space on a per-use basis for services rendered to patients referred by others is not prohibited.

Take Away: Existing lease arrangements should be examined in order to identify any arrangements that will require restructuring prior to the October 1, 2009 deadline.

Conclusion

To comply with the October 1, 2009 effective date, we encourage health care providers impacted by changes to the Stark Law regulations to take steps to ensure that any services provided "under arrangements" are in compliance. We also encourage health care providers to review office space and equipment leases involving physicians or their immediate family members in order to ensure compliance with the new rules governing compensation terms.

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* We provided a full discussion of the Stark Law changes in the Final Rule in an earlier memorandum entitled, "Significant Stark Law Changes Adopted in the 2009 IPPS Final Rule," August 22, 2008, which is available at *http://www.reedsmith.com/publications/search_publications.cfm?widCall1=customWidgets.content_view_1&cit_id=21137*

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