Another round of Stark law changes coming your way as early as October 1, 2008

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Sweeping changes to the Stark regulations will force many arrangements between physicians and hospitals, particularly hospital/physician joint ventures, to undergo significant restructuring.

On August 19, 2008, the Centers for Medicare & Medicaid Services (CMS) finalized several significant changes to the Stark rules, as part of the 2009 final hospital inpatient prospective payment system rule (IPPS Rule).[1] The Stark rules implement the Stark law, which prohibits a physician from making referrals for certain designated health services (DHS) payable by Medicare to an entity with which the physician has a financial relationship unless a Stark law exception applies.[2] Similarly, the entity to which the DHS is referred in that circumstance may not bill for the DHS.

The Stark rule changes made in the final IPPS Rule will have a major impact on relationships between physicians and hospitals. Some of this impact will occur as early as October 1, 2008, and the rest will take effect on October 1, 2009. This article highlights some aspects of the changes. These changes will be the focus of a Wisconsin Medical Society educational program to be offered in October. Some of the changes provide more flexibility than the rules proposed last year;[3] other changes are more restrictive.

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Percentage-Based Compensation Formulae

Percentage-based compensation arrangements for *space and equipment rental* charges will be a thing of the past, as of October 1, 2009. In the final IPPS rule, CMS amended the exceptions for rental of office space, rental of equipment, fair market value, and indirect compensation arrangements to prohibit the use of compensation formulae based on a percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in the leased office space or leased equipment. CMS initially proposed a much broader prohibition under which percentage-based compensation formulae would only be permitted for personally performed physician services. However, in the final rule, CMS took a more targeted approach to address its concerns with percentage-based compensation in the context of lease arrangements.

Unit-of-Service ("Per-Click") Payments in Lease Arrangements

The final IPPS rule significantly limits the use of "per-click" payments in the context of lease arrangements. Specifically in the final rule, effective October 1, 2009, CMS revised the space and equipment lease exceptions, the fair market value exception, and the exception for indirect compensation arrangements to prohibit per-click payments to a physician lessor, where the payments reflect services provided to patients referred by the physician to the lessee. CMS further stated that the per-click prohibition applies regardless of whether the physician is the lessor or whether the lessor is an entity in which the referring physician has an ownership or investment interest. Moreover, CMS stated that the prohibition could also apply in situations where the lessor is a DHS entity that refers patients to a physician lessee or a physician organization lessee.

"Stand in the Shoes" Provisions

CMS has opted to simplify the physician "stand in the shoes" analysis, effective October 1, 2008. Stand in the shoes essentially means that if physician organizations contract with an entity such as a hospital, the physicians are deemed to have made that contract as well. The upshot is a limited ability to take advantage of the indirect compensation exception to the Stark prohibition. However, under the finalized "stand in the shoes"analysis, only physicians who have an *ownership or investment interest* in a physician organization will now be deemed to stand in the shoes of the physician organization for purposes of compliance with

Stark law. Physicians with other compensation links to their organizations (such as employment) will not stand in the organization's shoes. CMS also made 2 important clarifications regarding the stand in the shoes analysis:

1. Physicians who have only titular ownership are not required to stand in the shoes of their physician organizations. CMS considers an ownership or investment interest to be titular where the physician is not able to claim or is not entitled to any of 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.
2. The stand in the shoes requirement does not apply to an arrangement that satisfies the requirements of the Academic Medical Center exception to the rules.

Services Provided "Under Arrangements"

Starting October 1, 2009, entities (including physicians) that provide services to hospitals "under arrangements" (ie, the hospital *bills* for the services but has an arrangement for the other entity to *provide* the services) will now be considered DHS entities *themselves* for Stark law purposes. Prior to the final IPPS rule, only the person or entity that billed for DHS was considered to be "furnishing" the DHS. However, in the final IPPS rule, CMS amended the definition of "entity" to clarify that a person or entity is considered to be furnishing DHS if it is the person or entity that has (1) performed the DHS (even if another entity bills for the services as DHS) or (2) presented a claim for Medicare benefits of the DHS. As a result of this change, physicians will be limited in their ability to refer patients to "under arrangement" service providers in which they have an ownership or investment interest.

Amendments to Agreements — Set in Advance

Under the Stark law, CMS requires compensation in a hospital-physician arrangement to be "set in advance," in writing, in a manner that will not vary over the course of the agreement. Under the new rule, CMS takes the position that amendments to the compensation provision of an agreement will be consistent with the set in advance requirement as long as:

1. All of the requirements of an applicable exception are satisfied.
2. The amended rental charges or other compensation is determined before the amendment is implemented and the formula is sufficiently detailed so that it can be verified objectively.
3. The formula for the amended rental charges does not take into account the volume or value of referrals or business generated by the referring physician.
4. The amended rental charges or compensation remains in place for at least 1 year from the date of the amendment.

CMS further clarified that this interpretation applies to all of the Stark law exceptions for compensation arrangements that include a 1-year term requirement for satisfying the exception.

Conclusion

These topics and other aspects of the Stark rules will be covered in more depth in the Society's October educational programs, which are being held October 14 in Wausau, October 15 in Green Bay, October 21 in Waukesha, and October 22 in Madison. The authors will also provide a Stark Law Primer and an update on the anti-markup rule. More information about the programs can be found at www.wisconsinmedicalsociety.org/education.

End Notes

1. IPPS rule. Available at: http://edocket.access.gpo.gov/2008/pdf/E8-17914.pdf. Accessed August 28, 2008.
2. Under the Stark Law, DHS entities are those providing any of the following "designated health services": clinical laboratory services, occupational and physical therapy services, radiology services, DME and supplies, prosthetics, orthotics and prosthetics devices and supplies, outpatient prescription drugs, radiation therapy services and supplies, parenteral and enteral nutrients equipment and supplies, home health services, and inpatient hospital services.
3. Lyons L, Katayama A. Per-click, under arrangement, mark-up, and other dirty words. *WMJ.* 106:5;280-284.

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