

New Stark Rules Bring Major Changes

On August 19, 2008, the Centers for Medicare and Medicaid Services (“CMS”) published the latest changes to the Stark Law. As you know, the Stark Law regulates the types of arrangements into which physicians may enter. Violations of the Stark Law bring hefty civil fines and penalties.

This latest set of changes to the regulations will affect many physician arrangements, requiring many to be restructured or terminated before the effective date of the applicable provisions on October 1, 2008 or October 1, 2009. It cannot be overly stressed how important compliance is with these new regulations. Our concern is that these regulations will have broader application than advertised and that unintended arrangements will be affected, particularly with respect to the first three changes discussed below.



“Under Arrangements” Under Siege

The final rule deals with a perception by CMS that “under arrangements” structures, through which a hospital provides certain services to its patients by contracting with another entity to furnish the service, are being used abusively to reward physicians for referring patients to the hospital.

As contemplated by CMS for Stark purposes, an “under arrangement” structure occurs when a hospital essentially outsources its technical needs, such as MRI, to a group of physicians who refer to the hospital. Typically, the group is paid a fee for the procedures done and the hospital is able to bill Medicare directly for such procedures. These arrangements currently permit physicians to be paid by the hospital for procedures performed, not just on the owner physician’s own patients, but on other providers’ patients, as well. The “abuse” that is perceived is that, according to CMS, there really is no need for these types of arrangements except to tie physicians to the hospital and obtain their loyalty and referrals.

The solution promulgated by CMS is to redefine the term “entity” to include under one definition both the entity that performs the service *and* the entity that bills for the service, treating them as an amalgamated unit for purposes of wrapping in the DHS into one entity. That being done, physician owners of the group that furnishes the service may not refer to the “under arrangements” service, and the combined “entity” is prohibited, absent an exception, from billing CMS for the service.

Because it will be difficult, if not impossible, for the “under arrangements” relationship to fit within a Stark exception with respect to physician owners of the group, this single change will likely require most “under

arrangements” relationships involving physicians to be restructured or terminated prior to the provision’s effective date of October 1, 2009.

Percentage-Based Payments

The Final Rule contains provisions that prohibit percentage-based payments for space and equipment leases. Specifically, compensation formulae for the rental of office space and equipment may not be 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 through the use of the leased equipment.

The final rule does not broadly proscribe percentage-based payments. Rather, the rule targets percentage-based payments for the lease of office space or equipment. CMS noted that it will continue to examine percentage-based compensation formulae in arrangements between designated health service entities and referring physicians (such as management or billing services) and may further restrict percentage-based approaches in a future rulemaking. The prohibition of percentage-based compensation for the rental of office space and equipment goes into effect on October 1, 2009.

Unit-of-Service (Per-Click) Arrangements

The new final rules prohibit per unit-of-service rental charges to the extent that such charges reflect services provided to patients referred by the lessor to the lessee. This prohibition applies where (i) the physician himself or herself is the lessor, (ii) an entity in which the referring physician has an ownership or investment interest is the lessor, or (iii) a DHS entity that refers patients to a physician lessee or a physician organization lessee is the lessor.

This change means that CMS will no longer permit, for example, an arrangement under which a hospital leases a MRI machine from a physician group on a per-click basis and receives referrals for MRI services from the physician who owns the machine. Any noncomplying arrangements must be restructured or terminated prior to the effective date of this change, October 1, 2009.

CMS did not impose any provision applicable to block-leasing arrangements. However, the agency stated that it believes such arrangements could be problematic, especially “on demand” rental agreements that are, according to CMS, effectively structured as per-click arrangements. CMS will continue to study block-leasing arrangements and may propose rulemaking in the future.

“Stand in the Shoes”

In one of the more promising changes wrought by these rules, CMS simplifies the “stand in the shoes” (SITS) doctrine for physicians and their physician organizations. Under current SITS doctrine, a physician is deemed to

stand in the shoes of his or her physician organization, which means any compensation arrangement between the physician organization and a DHS entity must satisfy a Stark exception for direct compensation arrangements. This requirement had potentially momentous implications for academic medical centers (“AMCs”) and nonprofit healthcare delivery systems (“IDSs”), and CMS had delayed its application to those entities pending consideration of that potential impact.

The new rules address many of the concerns raised with respect to SITS by providing that that only a physician who has an *ownership or investment interest* in his or her physician organization is deemed to stand in the shoes of the organization. Other physicians (*i.e.*, employees, independent contractors, and physicians whose ownership or investment interest is titular only) are *permitted* to stand in the shoes of their physician organizations, but are not required to do so.

The key for application of SITS is thus physician ownership. If, and only if, a physician holds an ownership interest in the physician organization involved in the relationship with the DHS entity, SITS applies and a direct compensation exception must apply. The new SITS rules should thus be welcome news for AMCs and IDSs, where physicians do not typically hold ownership interests in the physician organization. Arrangements that comply with the AMC exception now are explicitly exempted from the rules. Furthermore, the many AMCs and IDSs that currently rely on the indirect compensation arrangements provisions will be able to continue to do so under the new rules, because their physicians will not be required to stand in the shoes of their faculty practice plans or other physician organizations.

The SITS changes go into effect on October 1, 2008.

Conclusion

The foregoing descriptions are only partial overviews, and physicians must take care to ensure that their arrangements meet the requirements of the Stark Law. Other changes, such as signature requirements and criteria for the period of disqualification, are contained in these new regulations as well. The consequences of non-compliance are severe. That said, it is still possible for physicians to enter into mutually beneficial relationships with DHS entities; however, every such relationship should be reviewed by competent counsel to ensure its compliance with applicable law, including the Stark Law.

We will be happy to discuss these developments with you at your convenience.

For information on topics covered in this issue, please contact:

Sandra Herron 404.572.6965 sherron@pogolaw.com
Bruce Howell 214.721.8047 bhowell@pogolaw.com
Payal Cramer 404.572.5905 pcramer@pogolaw.com
Leah Stone 202.624.7240 lstone@pogolaw.com

This PoGo Alert is prepared by the Health Care Practice Group of Powell Goldstein LLP as a PoGo service. The information discussed is general in nature and may not apply to your specific situation. Legal advice should be sought before taking action based on the information discussed.

Atlanta ■ Washington ■ Dallas ■ Charlotte

One Atlantic Center
Fourteenth Floor
1201 West Peachtree Street, NE
Atlanta GA 30309
Tel: 404.572.6600
Fax: 404.572.6999

Third Floor
901 New York Avenue, NW
Washington DC 20001
Tel: 202.347.0066
Fax: 202.624.7222

JP Morgan Chase Tower
2200 Ross Avenue, Suite 3300
Dallas TX 75201
Tel: 214.721.8000
Fax: 214.721.8100

One Wachovia Center
Suite 3700
301 S. College Street
Charlotte NC 28202
Tel: 704.749.8999
Fax: 704.749.8990

www.pogolaw.com