### Changes to Stark - Are you still in compliance?

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Stark compliance is not something that any physician can simply check off a to-do list, never to think of again. Instead, compliance with these complex regulations must be analyzed and re-analyzed with each revision or pending effective date. Stark bans physician self-referral of designated health services under Medicare unless one of the exceptions contained within the law are met. October 1, 2009 was yet another one of these times where Stark demands that physicians re-evaluate their contracts and business arrangements. If you failed to do so, it is imperative that you act immediately to ensure continued compliance.

On October 1, 2009, significant changes to Stark went into effect relating to percentage-based leases, "per click" payments and "under arrangements" relationships. Since Stark is a strict liability statute, physicians cannot claim ignorance of these changes as a defense if they are found to be noncompliant.

## 1. Percentage-Based Leases

Previously under Stark, the rental of office space or equipment did not constitute a financial relationship even if payments were based on the revenue earned from the space or equipment (as long as the lease agreement was in writing and met specific criteria). As of October 1, 2009, Centers for Medicare and Medicaid Services (CMS) closed this "loophole" in light of their concern that such percentage-based leases created an unacceptable risk for patient abuse.

Under the new regulations, any office or equipment lease which bases the payment amount on a percentage of revenue creates a financial relationship between the parties. As a result, any referral between parties to a percentage-based lease may trigger liability under Stark, potentially subjecting physicians to civil monetary penalties of \$15,000 per violation, refund of Medicare payment related to such referrals, exclusion from the Medicare program, and false claims liability exposure. Therefore, physicians should immediately have their leases reviewed to ensure continuing compliance with Stark.

Moreover, this may not be the last change we see relating to percentage-based compensation. While it is still permissible to use percentage-based compensation for management or billing services, CMS has left the door open to further revise the regulations if needed in the future. Thus, physicians must remain mindful of any upcoming changes.

#### 2. Per-Click Leases

As with percentage-based leases, "per-click" payments for use of office space or equipment also can create a financial relationship between the parties. The term "per-click" refers to payments per use of the space or equipment to the extent that the charges reflect referrals between the parties. Notably, non-physicians may continue to lease equipment and space on a "per click" basis. Also, physicians are still allowed to lease equipment or space on a per use basis for services referred by others; however, if the physician-lessor is also referring patients to use the equipment an alternative leasing arrangement that meets a Stark exception must be put in place.

While CMS declined to prohibit all time-based leasing arrangements, CMS has indicated that it will interpret the "per click" regulations broadly and has stated that certain arrangements – such as "on demand" rental agreements, leasing of small blocks of time (such as a single four hour block per week) or an extended block of time beyond what the lessee can reasonably use – are problematic and may be covered by the revised language. Therefore, any physician who is party to any time-based rental arrangements should also have these contracts reviewed for compliance.

# 3. Services Provided "Under Arrangements"

Prior to these recent changes, Stark allowed many joint ventures between hospitals and physicians where physicians were able to refer to the joint venture without meeting a Stark exception because, if only the hospital was billing Medicare for the service, then only the hospital was considered to be providing designated health services. This is no longer the case. As of October 1, 2009, an entity is considered to be providing a designated health service if the entity bills for the service or performs the service. Now, it is possible that a single referral is actually going to two separate entities – the entity that is billing for the service and the entity that is actually performing the service. If the referring physician has a financial relationship with either party, a Stark exception must exist or there is a violation.

#### Conclusion

CMS gave significant time for physicians to comply with these three changes to Stark. However, many physicians remain unaware of the need to review existing arrangements. If a violation is found, physicians should contact legal counsel and carefully consider the next steps that should be taken, since retention of Medicare reimbursement received from an improper arrangement could create liability under the recently revised Federal False Claims Act. Moreover, even for physicians who do not participate in the Medicare program, there may be implications under Michigan's version of the Stark law, which applies to all payors.

If you have not evaluated your contracts and business arrangements to ensure compliance, do not wait any longer. Each violation of Stark means the possibility of more denied payments and more \$15,000 penalties. Now is the time to make sure that you are complying with Stark, until – of course – it changes again.



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