there is anything one can take away from this summer of regulatory activity, it's that the Centers for Medicare and Medicaid Services (CMS) and the Office of Inspector General (OIG) for the U.S. Department of Health & Human Services have united to wage a parallel attack on per-click lease arrangements between diagnostic testing facilities and referring physicians.

**CMS Revisions to the Stark Law**

Under the Stark Law, if a physician or a member of a physician's immediate family has a financial relationship with an entity, the physician may not make referrals to that entity for the furnishing of certain designated health services (DHS) payable by Medicare, unless an exception applies. Radiology and other imaging services are DHS, as are hospital services. For example, if an orthopedic surgery group owns an MRI unit and leases the unit to a hospital on a per-procedure basis, the lease arrangement would need to qualify for protection under the equipment-lease exception to the Stark Law before the surgeons could refer patients to the hospital for MRI scans or any other DHS.

On August 19, 2008, CMS published the FY 2009 Hospital Inpatient Prospective Payment System final rule. This final rule implements significant changes to the Stark Law regulations. This includes changes to the office space and equipment lease exceptions that will, beginning in October of next year, prohibit per-click leases and changes to the definition of a DHS entity that limit the ability of referring physicians to enter into “under arrangements” structures with hospitals, IDTFs, or other DHS entities.

**Future of Per-Click Arrangements**

Back in January of 2001 when CMS published the Stark II (Phase I) regulations, CMS crafted the office space and equipment rental exceptions to permit “time-based or unit-of-service-based payments, even when the physician receiving the payment has generated the payment through a DHS referral.” Little did CMS know that opening the door to this payment methodology would create the monster which it is now trying to slay. By giving per-click leases the stamp of approval under the strict liability Stark Law, CMS unwittingly contributed to the proliferation of lease arrangements similar to the MRI lease described above.

CMS has now completely reversed its previous position on per-unit-of-service payments. The agency now views per-click leases as being “inherently susceptible to abuse because the physician lessor has an incentive to profit from referring a higher volume of patients to the lessee.” As a result, the final rule revises the exceptions for rental of office space and equipment and also the exceptions for fair-market-value compensation and indirect compensation arrangements to specify compensation for the rental of office space or equipment may not be determined using a formula based on:

- Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred between the parties.

This new limitation becomes effective October 1, 2009, and will apply to both existing and future lease arrangements. As a result, the orthopedic surgery group in our example above would need to modify the MRI lease arrangement with the hospital to provide for a flat lease rate (e.g., $X per month) instead of the current rate of $X per MRI. We note that the new prohibition on per-unit lease payments applies not only to situations in which the referring physician leases space or equipment to a DHS entity but also to situations in which the referring physician is the party leasing office space or equipment from a DHS entity. For example, if the orthopedic surgeon was leasing an MRI unit from a hospital or imaging center, the lease arrangement would need to be priced on a flat fee rather than a per-scan basis.

**Restricting Under-Arrangements Services**

Medicare permits hospitals to furnish services to beneficiaries under arrangements with third-party vendors. The vendor has a contractual relationship with the hospital under which the hospital bills Medicare for the vendor’s service and subsequently reimburses the vendor. In recent years under-arrangements joint ventures between hospitals and referring physicians have been used to furnish imaging, ambulatory surgery, cardiac catheterization, and other services to hospitals.

CMS expressed concern that hospital outpatient services furnished through an
under-arrangements vendor owned by referring physicians create a risk of overutilization. CMS questioned whether such arrangements were solely a circumvention scheme designed for the purpose of enabling a physician to make money on referrals and to secure higher hospital reimbursement rates, particularly when the services furnished by the joint venture were previously directly furnished by the hospital.

In an effort to curtail the use of under-arrangements joint ventures, CMS in the final rule expanded the definition of a DHS 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, it is now possible through writing one order for a Medicare patient to receive DHS that a physician can actually make a referral to two different DHS entities. Each of the referrals would need to be protected under an exception to the Stark Law if the physician has a financial relationship with each DHS entity.

Here is an example of how it works. A cardiologist and a hospital partner to jointly own and operate a cardiac CTA imaging center (the JV). The JV has an under-arrangements relationship to perform cardiac CTAs for hospital patients. The technical component is billed by the hospital under its name and billing number. The cardiologist refers a Medicare patient to the JV and the hospital bills for the cardiac CTA. Under the current Stark regulations, the cardiologist would only be making a referral to the hospital since it is the only entity billing Medicare for the services. But under the revised regulations, the cardiologist will be making a referral to two entities. First, the cardiologist will be referring a patient to the hospital since it submits a claim to Medicare for the cardiac CTA. Second, the cardiologist will be referring a patient to the JV since the JV is the entity that performed the cardiac CTA. Because there is no exception that can be used to protect such referrals to the JV, the arrangement would need to be dissolved or restructured.

OIG Advisory Opinion 08-10

Shortly after CMS published the changes to the Stark Law, the OIG launched a parallel attack on space and equipment leases under the federal anti-kickback statute. On August 26, 2008, the OIG published Advisory Opinion 08-10 which addressed a proposal by a physician group practice that owns a cancer-treatment center (the Center) to lease to urology groups on a block-time basis (e.g., Mondays 8 am - 5 pm) for a fixed monthly fee the space, equipment, and personnel services necessary for the urology groups to bill Medicare and other third-party payors for intensity-modulated radiation therapy (IMRT) provided to their patients at the cancer center. The lease payments were structured to meet all the requirements of the space, equipment rental safe harbors to the anti-kickback statute. The urology groups would bill and collect for the IMRT services under their own billing number and keep the difference between the fees collected from the billings and the amount of lease fees paid to the Center.

The OIG noted although the lease arrangement might be able to meet the safe harbors for space rental, equipment rental, and personnel services and management contracts, the OIG was, nevertheless, concerned it could potentially violate the anti-kickback statute because:

1. The urology groups would be expanding into a line of business that is dependent upon their own patient referrals.
2. The urology groups would essentially be contracting for turnkey IMRT services so they would be incurring very little real business risk. In fact, the amount of time leased to each group could be determined based on historical usage patterns so as to further minimize risk.
3. The Center is an established independent provider of the IMRT capable of providing, billing, and collecting all reimbursement for the services on its own (and, in fact, used to provide IMRT to the urology group patients and separately bill for those services).

The OIG repeated its longstanding concerns about joint ventures in which all or most of the business of the joint venture would be derived from one of the venture participants. The OIG concluded even if each of the separate components of the lease arrangements satisfied the safe harbors, the nature of the overall arrangement continues to pose a risk to the federal healthcare programs because the OIG cannot exclude the possibility that the arrangement is designed to permit the Center to do indirectly what it cannot do directly — that is, pay the urology groups a share of the profits from their IMRT referrals. The OIG concluded the proposed lease arrangement could potentially generate prohibited remuneration under the anti-kickback statute and the OIG could potentially impose administrative sanctions on the parties.

Conclusion

The changes to the Stark Law regulations to prohibit the use of per-click leases for office space and equipment and to expand the definition of an entity to include any entity that performs the DHS significantly curtail the ability of referring physicians to enter into per click or turnkey lease arrangements with diagnostic testing centers. Moreover, Advisory Opinion 08-10 has dealt a second swift blow to turnkey lease arrangements. These developments provide major ammunition to imaging centers that want to fend off referring physicians who seek self-referral profit from part-time lease arrangements.

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FOOTNOTES
5. See OIG's Special Fraud Alert on Joint Venture Arrangements (59 FR 65362, 65363 (Dec. 19, 1994) and OIG's Special Advisory Bulletin on Contractual Joint Ventures (68 FR 23148 (Apr. 30, 2003)).