Risks and Costs You Can't Afford to Ignore
Stark Law Basics and Anti-Markup Rules

By Andrew B. Wachler

STARK LAW BASICS
The Stark II ban on physician self-referral generally makes it unlawful for a physician to refer Medicare or Medicaid patients for designated health services (DHS) to an entity with which the physician (or an immediate family member) has a financial relationship. A financial relationship consists of either an ownership or investment interest in an entity through equity, debt, or other means, or a direct or indirect compensation arrangement with an entity. A compensation arrangement is defined to include any arrangement involving any remuneration between a physician and an entity. Remuneration can be direct or indirect, overt or covert, in cash or in kind.

Stark II broadly defines the term "referral" to include a request by a physician for an item or service payable under Medicare or Medicaid (including the request by a physician for consultation with another physician and any test or procedure ordered or performed by such other physician), or a request by a physician for the establishment of a plan of care that includes the provision of a DHS.

In addition to prohibiting referrals by the physician with whom the entity has a financial relationship, Stark II prohibits the entity from presenting or causing to be presented a claim for payment under the Medicare or Medicaid programs for any such referred DHS unless the arrangement falls within an exception.

DHS include the following services: clinical laboratory, physical and occupational therapy, radiology, radiation therapy, DME, parenteral and enteral nutrition, prosthetics and orthotics, home health, outpatient prescription drugs, and inpatient and outpatient hospital.

Stark issues come up regularly when dealing with in-office ancillary services, mobile diagnostic arrangements, and physician relationships with any referral source, such as other physicians, hospitals, DME companies, and Independent Diagnostic Testing Facilities (IDTFs).

In order to allow for certain arrangements that the government determines to have less potential for abuse, numerous exceptions were created. Each exception contains very specific criteria, which if met, will protect a provider from being held liable for a Stark violation. Because Stark is a strict liability statute, the government does not look at intent, but rather looks at whether the provider strictly adheres to the criteria set forth in an exception.

NEW DENIAL CODE FOR STARK VIOLATIONS

The Centers for Medicare and Medicaid Services (CMS) recently informed providers of a new denial code that will be used to deny claims on the basis of a Stark violation. In addition to denial of payment, severe fines can be imposed on

providers who violate the regulations, including imposition of a $15,000 per service civil monetary penalty and imposition of a $100,000 civil monetary penalty for each arrangement considered to be a circumvention scheme.

Any analysis under the Stark regulations must also include analysis of the anti-kickback statute and related state laws. It is important for billing companies to be aware of these laws to protect clients and their own potential liability. While providers may look to billing companies for guidance in this area, it is very complex and billing companies should not counsel clients on these topics without first seeking the counsel of an experienced healthcare attorney.

THE ANTI-MARKUP BILLING LIMITATION

The Anti-Markup Rule is a payment limitation imposed on certain Medicare Part B diagnostic services performed by a physician who does not "share a practice" with the billing provider.

A typical example of a situation that could involve the Anti-Markup Rule is a situation where a physician performs the technical component of an X-ray at his or her office and then sends the X-ray to an offsite radiologist for interpretation.

In order to determine whether the physicians "share a practice," one of two alternative tests must be met. The first test is called the "substantially all services" test. Under this test, if the performing physician (i.e., the physician supervising the technical component or performing the professional component), furnishes substantially all (i.e., "at least 75 percent") of his or her professional services through the billing physician, then the providers will be considered to "share a practice" and the anti-markup provisions will not apply.

If the performing physician does not meet the "substantially all" criteria, then the arrangement can be analyzed under the "site of service" test. Under this analysis, technical components conducted or supervised and professional components performed in the "office of the billing physician or supplier" by a physician owner, employee, or independent contractor of the billing physician are not subject to anti-markup payment limitations. The "office of the billing physician or other supplier" is defined as any medical office space, regardless of the number of locations, in which the ordering physician regularly furnishes patient care. This definition includes space located in the "same building" in which the ordering physician regularly furnishes patient care, i.e., the interior of a building with the same street address.

If the Anti-Markup Rule payment limitation applies, the billing physician may not exceed the *lowest* of the following:

1) The performing supplier's net charge to the billing physician;
2) The billing physician or suppliers actual charge; or
3) The fee schedule amount for the test that would be allowed if the performing supplier billed directly .

For purposes of the Anti-Markup Rule, "net charge" must be determined without regard to the cost of any equipment or space leased to the performing

supplier by or through the billing physician. Overhead, such as the administrative costs associated with billing the service, also cannot be considered.

Depending on the arrangement between the billing and performing provider, the “net charge” can be calculated based upon a fixed fee or based upon salary and benefits of the performing provider. The billing entity is encouraged to maintain documentation of the information and methodology used to arrive at the “net charge” amount.

It is important for billing companies to understand this rule so that they can submit an accurate claim. Instructions for properly billing diagnostic tests subject to the Anti-Markup Rule pricing limitation can be found in CMS Transmittal 445, dated February 13, 2009, available on the CMS website at: http://www.cms.hhs.gov/Transmittals/downloads/R445OTN.pdf.

Importantly, the technical and professional components of claims that are subject to the Anti-Markup Rule must be billed separately, rather than globally, and must include anti-markup amount information.

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