The physician self-referral or “Stark” law, first enacted by Congress in 1989, and amended many times since, was intended to prevent overutilization that was perceived to stem from arrangements in which physicians benefited financially from their referrals for ancillary services by, for example, having an ownership interest in the entity that furnished the service or having a portion of compensation tied to the number of referrals. As originally enacted, the law applied only to clinical diagnostic laboratory tests. Congress amended the law in 1993 and 1994 to add additional services which include, among other things, therapy services and imaging.

The Centers for Medicare and Medicaid Services has promulgated a number of regulations over the years implementing the Stark law as it continually tries to close loopholes in the regulatory framework. As a result, this has become one of the most complex areas of Medicare compliance and is the source of much confusion. This article is intended to help Academy members identify situations in which the Stark law might be implicated as well as clarify those situations where Stark is probably not an issue. However, it is not a substitute for legal advice and we recommend that Academy members consult with legal counsel with respect to their specific arrangements.

Three Questions to Ask When Analyzing a Possible Stark Issue

Essentially, the Stark law prohibits a **physician** from making a **referral** for a **designated health service** paid for by Medicare to an entity with which the physician has a **financial relationship** unless an exception to the Stark law applies. The terms in bold all have specific definitions with the Stark regulatory framework as explained below.

When analyzing whether an arrangement implicates the Stark law, it may be helpful to ask the following questions:

1. **Is there a referral by a physician?** Referral is broadly defined to include any request by a physician, or the ordering or certifying of the need for any designated health service. It includes a referral for a consultation if the result of the consultation is the ordering by the consulting physician of designated health services. A referral, for Stark law purposes, does not include a referral for a service the referring physician **personally performs**. A **physician** includes doctors of medicine, osteopathy, dental surgery or dental medicine, podiatric medicine, optometry or a chiropractor. Mid-level practitioners such as nurse practitioners or physician assistants are **not** physicians for purposes of the Stark law prohibitions.

2. **Is the referral for a designated health service?** Designated health services (DHS) are

   - Clinical laboratory services
   - Physical, occupational and speech therapy
   - Radiology and certain other imaging services (includes MRIs, CT Scans, nuclear medicine, ultrasound) but with exceptions for imaging that is integral to another medical procedure
   - Radiation therapy services and supplies
• Durable medical equipment and supplies
• Parenteral and enteral nutrients, equipment and supplies
• Prosthetics, orthotics and prosthetic devices and supplies
• Home health services
• Outpatient prescription drugs
• Inpatient and outpatient hospital services

Services such as EMGs, nerve conduction studies and EEGs are not designated health services if done in the physician office setting. However, they would be DHS, if performed in the hospital since DHS includes all inpatient and outpatient hospital services. However, as noted above, if the service is personally performed by the physician, it is not considered a referral for Stark law purposes.

3. Does the referring physician have a financial relationship with the entity performing the service?

• Financial relationship with own practice: A physician is considered to have a financial relationship with his or her own practice, regardless of whether the physician is an owner, employee or contractor. Thus, referrals for DHS to be performed by the physician’s practice group must fit within an exception to the Stark law.

• Financial relationship with hospital: Examples of financial relationships with hospitals include
  • Serving as a medical director to a hospital
  • Renting space in a hospital-owned physician office building
  • Payment by a hospital to a physician for providing “on-call” services
  • Payment by a hospital to a physician owner’s group for services provided to hospital patients (e.g. intra-operative monitoring). Note that the relationship with the group practice is attributed to physician owners.
  • Employment by the hospital

Note: A physician does not have a financial relationship with a hospital simply by having privileges at the hospital and admitting patients.

If the answers to the above three questions are all yes, and any services are billed to Medicare, the Stark law is implicated. This means that the referral must fit within a Stark law exception.
Exceptions Relevant to Services Furnished in the Physician’s Office

The Stark law exception for “in-office ancillary services” protects both ownership and compensation relationships between a physician and his or her own group. This exception has a number of components and can be extremely complex to apply. Criteria relevant to this exception include

- Whether the arrangement meets the “same building” or “centralized building” test
- Whether the physician practice meets the Stark law definition of a “bona fide group practice” test which includes, among other things,
  - Requirements related to how income from DHS is distributed
  - Special rules for profit sharing and productivity bonuses
  - Meeting requirements that “substantially all” services billed by the group by provided by “members” of the group

This exception essentially prohibits physicians from being paid directly for DHS that they order but do not perform personally; however, physicians are allowed to receive indirect benefit through productivity bonuses and profit sharing arrangements provided they are properly structured. There is also a de minimis exception, which may apply if Medicare revenue from DHS is insubstantial.

Employees of a group practice who are not owners, may also qualify for the employment exception. There are also limited exceptions that apply to physicians practicing in rural areas.

Exceptions Relevant to Relationships with Hospitals

Depending on the nature of the arrangement, there are exceptions for

- Rental of office space
- Rental of equipment
- Employment relationships
- Personal service arrangements
- Physician recruitment
- E-prescribing and Electronic Health Records

The general rule, for most of these exceptions, is that the compensation between the parties must reflect “fair market value.” However, each exception has its own unique criteria which must all be met in order for the exception to apply.

“Stand in the Shoes” and “Under Arrangement” Rules of Attribution

In an effort to close perceived loopholes in the Stark law regulatory framework, CMS recently adopted two amendments to the Stark law regulations, referred to as the “stand in the shoes” rule and the “under arrangement” rule.
The “stand in the shoes” rule construes a physician owner of a medical practice to stand in the shoes of the practice itself, so that any financial relationship between the practice and another DHS entity is attributed to the individual physician. Thus, for example, if the practice has an agreement to provide services to a hospital, each physician owner will be deemed to have the same financial relationship with the hospital, as if the physician owner had entered into the arrangement directly with the hospital. Thus, the physician “stands in the shoes” of the practice. This change was intended to eliminate a perceived loophole that exempted arrangements where excessive compensation was paid to a practice entity rather than to a physician directly.

The “under arrangement” rule, which became effective on October 1 of this year, defines a DHS entity to include any entity that provides DHS under arrangement to another entity. As a result, if a hospital contracts with a physician-owned joint venture to purchase a service, which the hospital then bills “under arrangement,” the joint venture is now considered to be a DHS entity. If a physician owner of the joint venture refers a patient to the hospital for a service ultimately provided by the joint venture, the physician owner will be deemed to have made a prohibited referral to the joint venture under Stark. There is no exception available to protect these types of arrangements.

These changes could impact certain intra-operative monitoring (IOM) arrangements between neurologists and hospitals if the neurologist orders the IOM service. If the service is ordered by another physician not in the same practice, then the Stark restriction may not apply.

Similarly, if a neurologist has an interest in a sleep lab and the sleep lab has an arrangement with a hospital to perform sleep studies, such arrangements could now pose compliance risks under Stark if the neurologist refers a patient to the hospital which in turn contracts with his/her sleep lab for sleep studies.

Neurologists who believe their arrangements may be impacted by the “stand in the shoes” or “under arrangements” amendments should have the arrangement reviewed by legal counsel familiar with the Stark law.

Stark Law Penalties

Penalties for violating the Stark law include civil monetary penalties of up to $15,000 per claim and exclusion from the Medicare program. A physician who violates the Stark law may also be liable under the False Claims Act for having “caused” improper claims to be submitted by the DHS entity.