

The Anti-Kickback Statute (AKS) is a criminal law that prohibits the knowing and willful payment of "remuneration" to induce or reward patient referrals or the generation of business involving any item or service payable by the Federal healthcare programs (e.g., drugs, supplies, or health care services for Medicare or Medicaid patients).

The Physician Self-Referral Law, commonly referred to as the Stark law, prohibits physicians from referring patients to receive "designated health services" payable by Medicare or Medicaid from entities with which the physician or an immediate family member has a financial relationship, unless an exception applies. Financial relationships include both ownership/investment interests and compensation arrangements. For example, if you invest in an imaging center, the Stark law requires the resulting financial relationship to fit within an exception or you may not refer patients to the facility and the entity may not bill for the referred imaging services.

"Designated health services" are:

- clinical laboratory services;
- physical therapy, occupational therapy, and outpatient speech-language pathology services;
- radiology and certain other imaging services;
- radiation therapy services and supplies;
- DME and supplies;
- parenteral and enteral nutrients, equipment, and supplies;
- prosthetics, orthotics, and prosthetic devices and supplies;
- home health services;
- outpatient prescription drugs; and
- inpatient and outpatient hospital services.

For more information, see [CMS's Stark law Web site](#)

The Stark law is a strict liability statute, which means proof of specific intent to violate the law is not required. The Stark law prohibits the submission, or causing the submission, of claims in violation of the law's restrictions on referrals. Penalties for physicians who violate the Stark law include fines as well as exclusion from participation in the Federal healthcare programs.