

Understanding the Stark Law: Compliance Essentials for Healthcare Practices

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The Physician Self-Referral Law, more commonly known as the Stark Law, is very important in keeping our healthcare system as conflict-free as possible. It states that if you are a physician and you have a patient who is on Medicare, you cannot refer that patient to any entity for “designated health services” (DHS) if you have a financial interest in the entity to which you are referring.

Prohibited Self-Referrals and Financial Relationships

Doctors cannot refer patients covered by Medicare to places where they or their immediate family members have a financial interest. They sure can't do it legally. And yet the Department of Justice (DOJ) and Department of Health and Human Services (HHS) continue to bring cases against doctors, alleging that they have done just this. Services to which doctors can't refer under these conditions are called designated health services (DHS). They include inpatient and outpatient hospital care; imaging; lab tests; and services that involve physical therapy and durable medical equipment.

The Stark Law covers financial relationships that include not just direct ownership but also compensation arrangements of various kinds, such as payment for services, office leasing, or other financial arrangements that tie together physicians and DHS providers. If a Stark Law violation is uncovered, the penalties can be steep, running as high as unfathomable fines and the kick to a medical practice that could easily put it out of business: being excluded from Medicare. And repayment of claims found to be in violation can also result in a hefty bill that might be called a fine but in effect is restitution to the taxpayer.

A significant legal case involved a medical center that received penalties because its doctors were referring patients for imaging services to a business in which they had a financial interest. The center got into compliance by restructuring the financial relationship between the physicians and the imaging services business.

Exceptions That Allow Compliant Financial Arrangements

Stark Law has strict prohibitions, but it also has specific exceptions that allow certain financial relationships to exist under certain conditions.

One crucial exception is the in-office ancillary services exception, which permits physicians to provide certain designated health services—like lab tests or imaging—within their practices if the services are supervised and billed properly.

Another critical exception to consider is the Bona Fide Employment Exception. This exception allows physicians to receive compensation through employment agreements. To comply, however, the payments need to reflect fair market value, and they must not be linked to the volume of referrals that the physician might send to the residential care facility.

For instance, one clinic effectively formed its in-office lab services under the In-Office Ancillary Services Exception to the Stark Law, which allows certain lab services to be performed in a physician's office under specific conditions. This particular clinic set up its services in a way that allowed it to comply with the Stark Law and bill for those lab services without running afoul of the regulations.

Proper Documentation for Stark Law Compliance

Keeping meticulous records of all monetary dealings with doctors is crucial for ensuring that Stark Law is followed and that an audit could be passed without problems.

Every financial arrangement—including leases, employment contracts, and service agreements—should be documented in writing. These arrangements must outline the services provided, specify payment terms, and ensure that compensation aligns with fair market value.

When depending on a Stark Law exception, practices must maintain meticulous documentation that demonstrates compliance. This includes assessments of fair market value and a full accounting of all contract terms. Practices must not only keep these documents current; they should also review them regularly to ensure that they reflect any changes in compensation, services, or market conditions that are bound to occur over time.

A healthcare organization steered clear of Stark Law penalties by keeping the most copious documentation on all its physician compensation arrangements. This allowed the organization not only to show, but also to demonstrate, that it followed fair market value requirements.

Conducting Compliance Audits to Mitigate Risks

Stark Law compliance risks can be identified and addressed through routine audits. Healthcare practices can avoid the expense of enforcement actions by reviewing their financial arrangements and ensuring that they comply with legal requirements.

Non-compliant financial relationships can be found and corrected before they lead to penalties by conducting regular audits. These audits help find and fix problems in three concentration areas: ownership interests, compensation arrangements, and compliance with exceptions to Stark Law.

A big part of risk management is ensuring that compliance policies are correct and up to date, and that staff members are properly trained. Programs should underscore the importance of not getting into conflicts of interest and knowing when the law allows certain actions that might otherwise appear unethical and would, if misunderstood, lead to a risk judgment. If the auditors find any problems, the first step is to take the obvious corrective action—fix the compliance problem.

A hospital that engaged in consistent auditing of its physician pay arrangements was able to identify and fix compliance issues before they became significant problems, allowing the facility to avoid some hefty penalties and paybacks.

Legal Risks and Potential Penalties for Non-Compliance

Not following the Stark Law can lead to very serious financial and legal results, including being booted out of the Medicare program and facing some hefty fines. Here are some frequent violations and the associated risks:

- **Self-Referral Is Prohibited:** Physicians may not refer patients for designated health services (DHS) to entities in which they have a financial interest. If they do, and if they do it knowingly, they can get (1) a monetary penalty; (2) a several-times-the-amount-of-the-penalty civil fine; or (3) exclusion from the Medicare program.
- **Meeting the Exception Criteria:** If a financial arrangement satisfies fully the applicable Stark Law exception, then legal and financial penalties cannot be imposed.
- **Insufficient Documentation:** Poor record-keeping heightens the likelihood of audits and makes it difficult to demonstrate

compliance.

- **Unfair Market Value Arrangements:** If financial relationships involve payments that are above or below fair market value, practices may be required to make certain repayments and could face additional fines.

Ensuring Ongoing Compliance

Healthcare practices that bill Medicare must comply with the Stark Law if they wish to avoid serious regulatory consequences. Eluding the Stark Law's grasp typically demands a three-part strategy. First, attempts to stay within the law's confines should lead to the structuring of financial arrangements in accordance with the Stark Law's many exceptions. Second, the law's compliance should be documented in detail, with the documentation designed clearly not to mislead. Third, the arrangement's actual compliance should be audited routinely.