

2017 Stark Law Compliance: What You Should Know



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GENERAL OVERVIEW ON STARK LAW

Stark Law, made up of three separate provisions, governs physician self-referrals for Medicare and Medicaid patients. Essentially, if the physician has a financial relationship with an entity (such as a hospital), that physician **may not** make a referral to that entity for the furnishing of designated health services for which payment may be made under Medicare/Medicaid, unless the arrangement falls under one of the Stark Law Exceptions. This law **only** applies directly to physicians, whereas medical professionals, such as athletic trainers, are governed by other "Anti-Kickback Statutes".

WHAT ARE DESIGNATED HEALTH SERVICES (DHS)?

- Clinical laboratory services
- Physical therapy, occupational therapy and speech-language pathology services
- Radiology and other imaging services
- Radiation therapy services and supplies
- Durable medical equipment (DMEs)
- Parenteral and enteral nutrients, equipment and supplies
- Prosthetics, orthotics, devices and supplies
- Home health services
- Outpatient prescription drugs
- Inpatient and outpatient hospital services

To stay compliant with Stark Law, compensation models to physicians should **not be** based on these services.

STARK EXCEPTIONS

Commonly used exceptions include:

- Rental of office space or equipment
- Physician recruitment
- Personal service and fair market value (FMV) exceptions
- Isolated transactions
- Bona-fide employment
- ***New in 2016: Assistance to compensation of non-physician practitioner (NPP)***
- ***New in 2016: Time share arrangements***

It is important to note that the *Assistance to Compensation of NPP* exception only applies to those who provide services of primary care and mental health.

Common elements to meet Stark exceptions include a signed, written agreement that specifies the services or property of the exception. The arrangement must be commercially reasonable and compensation must meet fair market value. Finally, the agreement of compensation should be set in advance and not take into account the volume or value of DHS referrals that would be generated between the parties.

Personal Service Exception

This Stark exception applies to arrangements with medical directors, independent physicians and “call coverage” physicians. To meet this exception, the arrangement must:

- Be in writing
- Duration of agreement to be of at least one (1) year in length
- Compensation set in advance without taking into account potential referral income
- Cumulative services contracted for must be commercially reasonable
- Expiration of 1-year term may have indefinite holdover rules

WHY THE NEW 2016 CHANGES?

The two new exceptions to the Stark Law (*Assistance to Compensation of NPP and Time Share Arrangements*) were put in place in an effort to reduce the burden on health care organizations through writing requirements, term requirements and holdover requirements specific to those two exceptions. Specifically, the *Assistance to Compensation of NPP* exception, recruitment of both primary care and mental health professionals should result in an increase of those practices becoming more easily accessible throughout the United States.

STARK LAW COMPLIANCE STEPS

Auditing and Monitoring

An ongoing evaluation process is important to a successful compliance. This ongoing evaluation includes not only whether agreements between the physician and entity are in fact current and accurate, but also whether the agreement demonstrates fair market value, commercial reasonableness and not taking into account DHS referrals. These are the three most used principles to prove non-compliance against an entity. Therefore, an audit is an excellent way to ascertain what, if any, problem areas exist and focus on the risk areas that are associated with those problems.

A baseline audit should include a list of all existing financial arrangements of the entity, as well as a compliance checklist for each type of financial agreement (personal service, rental of office space, bona-fide employment, etc.) It is recommended to collect existing documentation for each arrangement, such as contracts, time records, policies, and documentation supporting fair market value and commercial reasonableness. Interviews with those responsibilities for executing the physician contract process is recommended in order to verify the information documented. When reviewing the compliance checklists, look for information that would prove to support the entity following fair market value, commercial reasonableness, and not taking into account DHS referrals. Following the audit, identify action items needed to correct any potentially non-compliant arrangements and document that process.

*It is recommended that all financial arrangements be evaluated by legal counsel **with experience in medical law** to determine risk of Stark Compliance.*

Common Financial Arrangements

Common financial arrangements an entity may have with physicians include but are not limited to:

- Employment arrangements
- Personal service arrangements
 - Call coverage
 - Medical directors
 - Consulting services
- Office/equipment leases

Common Issues with Stark Compliance

Common non-compliance issues with Stark Law have included technical non-compliance measures with an exception, such as lack of documentation, non-signed contracts, non-exclusivity use of rental space, failure to accurately describe services rendered, or duties and/or compensation changed without changing the terms in writing. Additionally, lack of documentation to support fair market value, commercial reasonableness, or not taking into account DHS referrals have been reported as a common issue.

Additional Risk Mitigation Strategies

It is recommended that the process of financial arrangements of physicians be formalized with a centralized approval process, with a plan to audit and monitor all physician compensation arrangements. Policies and procedures for self-disclosure along with education for Stark compliance training are additionally recommended. Financial arrangements between entities and physicians should be made as simple as possible, and drafted to fit within the chosen Stark exception. Finally, it is recommended that all financial arrangements be evaluated by legal counsel **with experience in medical law** to determine risk of Stark compliance.

Key Terms Takeaway

Commercial Reasonableness: There is no statutory or regulatory definition in Stark law, however, the Center for Medicare and Medicaid Services (CMS) has commented on the commercial reasonableness standard both subjectively and objectively. Essentially, one should ask themselves, "Would the parties agree to this deal if there were no referral made?"

Fair Market Value (FMV): Stark Statute has defined FMV as, "The value in arm's length transactions, consistent with the general market value..." (1877 (h)(3) of the Social Security Act)

Additional Resources

<http://starklaw.org/>

<https://www.cms.gov/>

Wolfe, J. N. (2016, November 30). *New 2017 Stark Law Compliance*. Lecture.

Visit nata.org for more information on Practice Advancement.

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