



Stark Law Compliance for ASC's

Richard Bays JD, MBA, RN

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OBJECTIVES

- What is The Stark Law
- Penalties for Violating Stark Law
- Relationship to the Federal Anti-Kickback Law
- What is a Designated Health Service
- ASC Safe Harbors
- Stark Analysis for your ASC

What is The Stark Law
42 USC § 1395nn



What is The Stark Law

42 USC § 1395nn

Section 1877 of the Social Security Act (The Act) (42 U.S.C. 1395nn), also known as the Physician Self-Referral law and commonly referred to as the Stark Law which:

1. Prohibits a physician from making referrals for certain Designated Health Services (DHS) payable by Medicare to an entity with which they (or an immediate family member) have a financial relationship (ownership, investment, or form of compensation), unless an exception applies.
2. Prohibits the entity from presenting (or causing to be presented) claims to Medicare (or billing another individual, entity, or third party payer) for those referred services.

What is The Stark Law

42 USC § 1395nn

Section 1877 of the Social Security Act (the Act) (42 U.S.C. 1395nn), also known as the Physician Self-Referral law and commonly referred to as the Stark Law which:

3. Establishes a number of specific exceptions and grants the Secretary the authority to create regulatory exceptions for financial relationships that do not pose a risk of program or patient abuse.

The law is named for United States Congressman Pete Stark, who sponsored the initial bill.



What is The Stark Law

The Stark statute applies only to physicians who refer Medicare and Medicaid patients for specific services ("Designated Health Services," or DHS) to entities with which they (or immediate family member) have a "financial relationship."

The lists of designated health services and financial relationships addressed by the statute are extremely broad.

The Stark Law

The Stark statute became effective on Jan. 1, 1995, but it was not until Jan. 4, 2001 that the government released any final regulations interpreting the statute.

Penalties for Violating Stark Law



Penalties for Violating Stark Law

Referrals and claims that violate the Stark statute are each punishable by a \$15,000 Civil Money Penalty.

Any claim paid as the result of an improper referral is an overpayment.

Circumvention schemes are punishable by a \$100,000 Civil Money Penalty.

Penalties for Violating Stark Law

\$15,000 Penalty that may be imposed for claims violations

\$100,000 Fine that may be imposed for "circumvention schemes"

Exclusion from Medicare possible for claims violations



Relationship to the Federal Anti-Kickback Law



ANTI-KICKBACK STATUTE

Relationship to the Federal Anti-Kickback Law

STARK VS. THE ANTI-KICKBACK STATUTE

One of the major misunderstandings about the Stark statute is that it is the same as the anti-kickback statute.

Not only are they not the same law, they have a very different scope and are in two different titles of the Social Security Act.

Relationship to the Federal Anti-Kickback Law

STARK VS. THE ANTI-KICKBACK STATUTE

The Stark statute pertains only to physician referrals under Medicare and Medicaid; the anti-kickback statute is far broader and affects anyone engaging in business with a federal health care program.

Note: "Physicians" includes chiropractors and dentists but not midlevel providers, such as nurse practitioners and physician assistants.

Relationship to the Federal Anti-Kickback Law

STARK VS. THE ANTI-KICKBACK STATUTE

The Stark statute does not require bad intent (i.e., tainted financial relationships violate the Stark law regard less of good intentions).

The anti-kickback statute requires intent, but it must be specific intent (i.e., not just intent that might merely be inferred from a pattern of behavior).

Relationship to the Federal Anti-Kickback Law

STARK VS. THE ANTI-KICKBACK STATUTE

The Stark statute exceptions define the boundaries of permissible behavior. The statute is a prohibition that can only be overcome by complying explicitly with an exception.

The anti-kickback "safe harbor" regulations describe transactions that may tend to induce referrals but don't necessarily violate the law. The safe harbor regulations state clearly that transactions that don't meet a safe harbor don't necessarily violate the statute; a prosecutor will evaluate the facts and circumstances to make that determination.

Relationship to the Federal Anti-Kickback Law

STARK VS. THE ANTI-KICKBACK STATUTE

A Stark violation is punishable by Civil Monetary Penalties while an anti-kickback violation is punishable by exclusion from federal health care programs, criminal penalties of up to \$25,000 in fines or up to five years in jail (or both) and a \$50,000 Civil Monetary Penalty for each violation.

Civil Monetary Penalty (CMP) - any penalty, fine, or other sanction that: (1) is for a specific amount, or has a maximum amount, as provided by federal law; and (2) is assessed or enforced by an agency in an administrative proceeding or by a federal court pursuant to federal law.

Relationship to the Federal Anti-Kickback Law

STARK VS. THE ANTI-KICKBACK STATUTE

In every situation where the Stark statute applies, the anti-kickback statute applies also.

If the Stark analysis fails, an anti-kickback analysis is irrelevant because you shouldn't proceed with the transaction at all.

What is a Designated Health Service



What is a Designated Health Service

Stark Law - Prohibits a physician from making referrals for certain Designated Health Services (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship (ownership, investment, or compensation), unless an exception applies.

What is a Designated Health Service

The following items or services are DHS:

1. Clinical laboratory services.
2. Physical therapy services.
3. Occupational therapy services.
4. Outpatient speech-language pathology services.
5. Radiology and certain other imaging services.
6. Radiation therapy services and supplies.
7. Durable medical equipment and supplies (DME).
8. Parenteral and enteral nutrients, equipment, and supplies.
9. Prosthetics, orthotics, and prosthetic devices and supplies.
10. Home health services.
11. Outpatient prescription drugs.
12. Inpatient and outpatient hospital services.

What is a Designated Health Service

Stark Law - Prohibits a physician from making referrals for certain designated health services (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship (ownership, investment, or compensation), unless an exception applies.

ASC's are NOT a Designated Health Service (DHS)

ASC Safe Harbors



ASC Safe Harbors

The Anti-Kickback Statute contains certain exceptions, known as safe harbors, which allow conduct that would otherwise violate the statute.

The Safe Harbor for investments in ASCs has four categories:

1. Surgeon owned ASCs;
2. Single specialty ASCs;
3. Multi-specialty ASCs; and
4. Hospital/physician ASCs.

Safe Harbor protection requires full compliance with all of the standards of any one category.

ASC Safe Harbors

The standards require, in part, that each physician investor:

- (1) be in a position to refer patients directly to the ASC and perform surgery on such referred patients;
- (2) derive at least one-third of his medical practice income from procedures he performs at the ASC and
- (3) perform at least one-third of the procedures (that may be performed in an ASC setting) at the investment entity ASC if the investment is in a multi-specialty ASC.

ASC Safe Harbors-Exceptions

Exceptions to the Stark Law

Generally, there are three types of exceptions:

1. For ownership/investment interests (§411.356)
2. For compensation arrangements (§411.357)
3. For certain "services" (§411.355)

Stark Analysis for your ASC



Stark Analysis for your ASC

Self-Referral Disclosure Protocol (SRDP) under the Patient Protection and Affordable Care Act

Section 6409 of the Patient Protection and Affordable Care Act (ACA) was signed into law by the President on March 23, 2010.

Section 6409(a) of the ACA required the Secretary (in cooperation with the Inspector General) of the Department of Health and Human Services to establish a Medicare Self-Referral Disclosure Protocol ("SRDP") that sets forth a process to enable providers of services and suppliers to self-disclose actual or potential violations of the physician self-referral statute.

Stark Analysis for your ASC

Self-Referral Disclosure Protocol (SRDP) under the Patient Protection and Affordable Care Act

The SRDP requires health care providers of services or suppliers to submit all information necessary for CMS, on behalf of the Secretary, to analyze the actual or potential violation of Section 1877 of the Social Security Act.

Section 6409(b) of the ACA, gives the Secretary of DHHS the authority to reduce the amount due and owing for violations of Section 1877 of the Act.

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Self-Referral Disclosure Protocol (SRDP) under the Patient Protection and Affordable Care Act

The SRDP is intended to facilitate the resolution of only matters that, in the disclosing party's reasonable assessment, are actual or potential violations of the physician self-referral law.

A disclosing party should make a submission under the SRDP with the intention of resolving its overpayment liability exposure for the conduct it identified.

As provided in the physician self-referral law, no payment may be made for Designated Health Services that are provided in violation of the physician self-referral law.

Stark Analysis for your ASC

Self-Referral Disclosure Protocol Settlements

Calendar Year	Number of Disclosures Settled	Range of Amounts of Settlements	Aggregate Amount of Settlements
2011	3	\$60 - \$579,000	\$709,060
2012	14	\$1,600 - \$584,700	\$1,236,200
2013	24	\$760 - \$317,620	\$2,468,348
2014	41	\$3,322 - \$463,473	\$5,175,168
2015	49	\$5,081 - \$815,405	\$6,706,458
Totals	131	\$60 - \$815,405	\$16,295,234

Source Note:

<https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral>

Stark Analysis for your ASC

The Stark analysis

To determine whether the Stark statute applies to a particular arrangement, ask yourself these three critical questions:

Stark Analysis for your ASC

1. Does this arrangement involve a referral of a Medicare or Medicaid patient by a physician or an immediate family member of a physician?
2. Is the referral for a "Designated Health Service"?

Stark Analysis for your ASC

3. Is there a financial relationship of any kind between the referring physician or a family member and the entity to which the referral is being made?

Stark Analysis for your ASC

To answer these questions, you'll need to examine the terminology used in these three questions and other parts of the statute. Then, if you determine that your answer to any question is "no," Stark does not apply.

If your answers to all three questions are "yes," you'll need to determine whether any of the exceptions apply to your situation.

Stark Analysis for your ASC

Exceptions to the Stark Law

Generally, there are three types of exceptions:

1. For ownership/investment interests (§411.356)
2. For compensation arrangements (§411.357)
3. For certain "services" (§411.355)

Stark Analysis for your ASC

ASC reimbursed procedures are not a DHS.

Therefore, the Stark law is generally inapplicable to physician ownership of an ASC.

However.....

Stark Analysis for your ASC

In a situation where a hospital and ASC enter into an under arrangement transaction and the ASC provides the surgical service to the hospital and in exchange, the hospital purchases the facility component of the surgical procedure from the ASC – we must take a 2nd look.

Hospital outpatient services are one of the categories of the Stark Law's Designated Health Services. Accordingly, a surgical procedure could be deemed a Stark Law DHS when billed by the hospital pursuant to an under arrangement transaction. In such instance, the hospital and the physicians will have an indirect compensation arrangement, which will need to be analyzed and structured in a manner that is compliant with the Stark law.

When In Doubt, Ask



STARK LAW VS. THE ANTI-KICKBACK STATUTE

COMPARISON OF THE ANTI-KICKBACK STATUTE AND STARK LAW*

	THE ANTI-KICKBACK STATUTE (42 USC § 1320a-7b(2))	THE STARK LAW (42 USC § 1395m)
Prohibition	Prohibits offering, paying, soliciting or receiving anything of value to induce or reward referrals or generate patient health care program business	<ul style="list-style-type: none"> Prohibits a physician from referring Medicare patients for designated health services to an entity with which the physician (or immediate family member) has a financial relationship, unless an exception applies Prohibits the designated health service entity from soliciting claims to Medicare for those services resulting from a prohibited referral
Patients	Referrals from services	Referrals from physicians
Trans	Any items or services	Designated health services
Intent	Intent must be proven (knowing and willful)	<ul style="list-style-type: none"> No intent required for overpayment (strict liability) Intent required for civil monetary penalties for knowing violations
Penalties	Criminal: <ul style="list-style-type: none"> Fines up to \$125,000 per violation Up to a 5 year prison term per violation Civil/Administrative: <ul style="list-style-type: none"> False Claims Act liability Civil monetary penalties and program exclusion Penalties \$10,000/CMP per violation Civil assessment of up to three times amount of kickback 	Civil: <ul style="list-style-type: none"> Overpayment refund obligation False Claims Act liability Civil monetary penalties and program exclusion for knowing violations Penalties \$10,000/CMP for each service Civil assessment of up to three times the amount claimed
Exceptions	Primarily safe harbors	Mandatory exceptions
Patients	All	Medicare/Medicaid
Health Care Programs	All	

Disclaimer

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Questions??

Richard Bays JD, MBA, RN, CPHQ
RBays@firmengroup.com
Houston/Dallas – 1.844.459.8866


