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# Complete Healthcare Compliance Manual
# Physician Self-Referral Law (Stark Law)

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**Fast Facts**

**Title of law**: Limitation on certain physician referrals (commonly called the Stark Law or Physician Self-Referral Law)

**Categories**:

- Medicare
- Medicaid
- Fraud and abuse

**U.S. Code**: 42 U.S.C. § 1395nn

**Year enacted**: 1989

**Major amendments**:

- Omnibus Budget Reconciliation Act of 1990 (Stark I)
- Omnibus Budget Reconciliation Act of 1993 (Stark II)
- Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations, 85 Fed. Reg. 77,492 (December 2, 2020)

**Enforcement agencies**: U.S. Department of Justice (DOJ), Centers for Medicare & Medicaid Services (CMS), U.S. Department of Health & Human Services (HHS)

**Link to full text of law**: https://www.govinfo.gov/content/pkg/USCODE-2010-title42/pdf/USCODE-2010-title42-chap7-subchapXVIII-partE-sec1395nn.pdf

**Applies to**: Physician referrals for health services in which the referring physician has some financial relationship with the referred entity.

## What Is the Physician Self-Referral Law (Stark Law)?

The Physician Self-Referral Law/Stark Law (referred to as Stark Law in this article) prohibits a physician from making referrals for certain designated health services payable by Medicare to an entity with which they (or an

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immediate family member) have a financial relationship, unless an exception applies. It also prohibits the entity from presenting (or causing to be presented) claims to Medicare for those referred services. There are a number of specific exceptions and grants to the law, and the U.S. Department of Health & Human Services (HHS) secretary has the authority to create regulatory exceptions for financial relationships that do not pose a risk of program or patient abuse. The exceptions include:

- **Physician services**: Permits physicians to refer to other physicians who are members of the same group practice or under the supervision of a physician in the same group practice.
- **In-office ancillary services**: Permits a group medical practice to make referrals for in-office ancillary services, such as laboratory or radiology services.
- **Services furnished by an organization to enrollees**: Physicians can refer patients to organizations that provide prepaid health services to enrollees, including approved health maintenance organizations (HMOs) and competitive medical plans (CMPs), plans approved by the Centers for Medicare & Medicaid Services (CMS), and other plans identified by the Stark Law.
- **Academic medical centers**: Physicians can refer patients to academic medical centers the physician has a financial relationship with, if the physician:
    - Is a "bona fide" employee of the medical center,
    - Is licensed in the state where the medical center is located,
    - Is a faculty member of the facility,
    - Provides paid clinical teaching services at the center, and
    - Refers the patient to an academic medical center that is approved under the Stark Law.
- **Implants furnished by an ambulatory surgery center (ASC)**: Physicians can refer patients to have certain implant procedures done at an ASC by a physician who belongs to the same medical group.
- **Eyeglasses and contact lenses after the patient has cataract surgery**: Applies when Medicare approved the eyeglasses or contact lenses.
- **Erythropoietin (EPO) and other prescription drugs for dialysis patients who need outpatient treatment**: Applies to referrals for specified drugs (preapproved) that are given in an end-stage renal disease (ERSD) facility.
- **Preventive services**: Vaccines, immunizations, and screening tests covered by Medicare are generally allowed if they are given prudently.
- **Intra-family rural referrals**: Some referrals in rural areas are permitted if the services are for an immediate family member and there are no nearby facilities or people that can provide the same service.
- **Fair market compensation**: Applies when a compensation arrangement is in writing, specifies a timeframe and the compensation to be provided, involves a commercially reasonable transaction, and meets the safe harbors under the Anti-Kickback Statute.
- **Indirect compensation**: Permits indirect compensation arrangements between a physician and an entity if the compensation received by the referring physician is of fair market value, does not take into account the value or volume of referrals, and is set out in writing and signed by the parties.

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- **Nonmonetary exemptions**: Applies to the payment of nonmonetary compensation to a physician of up to $300 per year if the physician did not solicit the compensation and it does not take into account the volume or value of referrals.
- **Rental of office space and/or equipment**: Physicians can rent out office space and equipment if the lease is in writing, the term is at least for one year, the lease is commercially reasonable, and other conditions are met.
- **Bona fide employee relationship**: An employer can pay a physician or family member if the physician/family member is a true bona fide employee with the employer, the compensation is fair, it's clear what services the physician/family member is providing, and other factors are met.
- **Physician incentive plan**: Incentive plants are permitted if they do not limit necessary medical services to eligible patients.
- **Physician recruitment**: Hospitals can pay physicians to persuade them to work for the hospital if the agreement is in writing and does not require the physician to refer patients to the hospital, the amount of the payment is not related to the value or volume of referrals, and the physician can obtain staff privileges at other hospitals.
- **Charity**: A physician may donate to an approved Internal Revenue Service tax-exempt charity as long as the donation is not based on the value or volume of referrals.
- **Medical staff incidental benefits**: Hospitals can provide noncash benefits to medical staff as long as the value of the benefit is less than $25, is provided at the hospital to all members of the medical staff, is comparable to benefits given by other hospitals, and all other conditions are met.[5]

## History

The Stark Law—named after its sponsor Congressman Pete Stark—was enacted by Congress in 1989 as the Ethics in Patient Referrals Act. The original intent of the law was to prohibit physicians from referring Medicare patients to clinical labs that a physician had a financial or ownership interest in. In 1993 and 1994, Congress expanded the prohibition to include aspects of physician self-referral to the Medicaid program. In 1997, Congress added a provision that permitted the HHS secretary to issue written advisory opinions as to whether a referral other than clinical laboratory services is prohibited by the act. In late 2020, HHS published two new rules in order to reduce regulatory burdens without increasing the risk of abuse of the federal healthcare system and to promote coordinated and value-based care for patients. "Coordinated care" refers to patient care spanning across care settings in both the federal healthcare programs and the commercial sector.

## Related Laws

Like its sister laws, the Anti-Kickback Statute (AKS) and the False Claims Act (FCA), the Stark Law was enacted to preserve federal healthcare programs from undue waste by bad actors who look to leverage public funds for personal gain. Thus, there is significant overlap between the three laws.

## Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)

The AKS provides for criminal and civil liability for "knowing and willful" renumeration for the purpose of rewarding patient referrals for services provided by a federal healthcare program. Both the AKS and the Stark Law prohibit renumeration for patient referrals; however, the Stark Law only provides for civil liability and does

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provide for strict liability (i.e., no knowing or willful requirement) for sanctions (i.e., denial of payment or requirement of refunds).[6]

For more information on this law, please see the "Anti-Kickback Statute" article in this chapter.

### False Claims Act, 31 U.S.C. §§ 3729–3733

The FCA makes it illegal for a person or entity to submit claims for payment to the government that the claimant knows are false or fraudulent. Similarly, the Stark Law makes it illegal for physicians to "present or cause to be presented" claims that constitute as self-referrals under the law and do not fall under any exception. Although the FCA does not specifically apply to healthcare and does include a "knowing" requirement, violations under the Stark Law do expose healthcare organizations to dual liability under the statutes if the FCA's conditions are met.[7]

For more information on this law, please see the "False Claims Act" article in this chapter.

## Physician Self-Referral Law (Stark Law) Compliance Risks

### Risk Area: General Prohibition on Physician Self-Referrals

> a. Prohibition of certain referrals
>
> 1. In general
>
> Except as provided in subsection (b)..., if a physician (or an immediate family member of such physician) has a financial relationship with an entity specified in paragraph (2), then—
>
> A. the physician may not make a referral to the entity for the furnishing of designated health services for which payment otherwise may be made under this subchapter, and
>
> B. the entity may not present or cause to be presented a claim under this subchapter or bill to any individual, third party payor, or other entity for designated health services furnished pursuant to a referral prohibited under subparagraph (A).
>
> 2. Financial relationship specified
>
> For purposes of this section, a financial relationship of a physician (or an immediate family member of such physician) with an entity specified in this paragraph is—
>
> A. except as provided in subsections (c) and (d)..., an ownership or investment interest in the entity, or
>
> B. except as provided in subsection (d)..., a compensation arrangement (as defined in subsection (h)(1)...) between the physician (or an immediate family member of such physician) and the entity.

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> An ownership or investment interest described in subparagraph (A) may be through equity, debt, or other means and includes an interest in an entity that holds an ownership or investment interest in any entity providing the designated health service.[8]

**Context**: The Stark Law provides a general prohibition against physicians referring Medicare or Medicaid patients to an entity to provide designated health services if the physician or the physician's immediate family members have a financial stake in the referred entity. Designated health services include the following:[9]

- Clinical laboratory services;
- Physical therapy;
- Occupational therapy;
- Radiology services;
- 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; and
- Outpatient speed-language pathology services.

42 U.S.C. § 1395nn(a)(2) describes a "financial relationship" as either ownership or an investment interest, or a compensation arrangement between the physician and the entity. However, the law does provide for exceptions discussed in later sections of the law.

### Risk Area: Reporting Requirements

> f. Reporting requirements
>
> Each entity providing covered items or services for which payment may be made under this subchapter shall provide the Secretary with the information concerning the entity's ownership, investment, and compensation arrangements, including—
>
> 1. the covered items and services provided by the entity, and
> 2. the names and unique physician identification numbers of all physicians with an ownership or investment interest (as described in subsection (a)(2)(A)), or with a compensation arrangement (as described in subsection (a)(2)(B)), in the entity, or whose immediate

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> relatives have such an ownership or investment interest or who have such a compensation relationship with the entity.
>
> Such information shall be provided in such form, manner, and at such times as the Secretary shall specify. The requirement of this subsection shall not apply to designated health services provided outside the United States or to entities which the Secretary determines provides services for which payment may be made under this subchapter very infrequently[10]

**Context**: The Stark Law requires facilities providing designated healthcare services to disclose to the HHS secretary their ownership and investment information, as well as any compensation agreements they have with other entities or physicians.

### Risk Area: Sanctions and Penalties for Noncompliance

> g. Sanctions
>
> 1. Denial of payment
>
>    No payment may be made under this subchapter for a designated health service which is provided in violation of subsection (a)(1).
>
> 2. Requiring refunds for certain claims
>
>    If a person collects any amounts that were billed in violation of subsection (a)(1), the person shall be liable to the individual for, and shall refund on a timely basis to the individual, any amounts so collected.
>
> 3. Civil money penalty and exclusion for improper claims
>
>    Any person that presents or causes to be presented a bill or a claim for a service that such person knows or should know is for a service for which payment may not be made under paragraph (1) or for which a refund has not been made under paragraph (2) shall be subject to a civil money penalty of not more than $15,000 for each such service. The provisions of section 1320a–7a of this title (other than the first sentence of subsection (a) and other than subsection (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1320a–7a(a) of this title.
>
> 4. Civil money penalty and exclusion for circumvention schemes
>
>    Any physician or other entity that enters into an arrangement or scheme (such as a cross-referral arrangement) which the physician or entity knows or should know has a principal purpose of assuring referrals by the physician to a particular entity which, if the physician

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directly made referrals to such entity, would be in violation of this section, shall be subject to a civil money penalty of not more than $100,000 for each such arrangement or scheme. The provisions of section 1320a–7a of this title (other than the first sentence of subsection (a) and other than subsection (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1320a–7a(a) of this title.

5. Failure to report information

   Any person who is required, but fails, to meet a reporting requirement of subsection (f)...is subject to a civil money penalty of not more than $10,000 for each day for which reporting is required to have been made. The provisions of section 1320a–7a of this title (other than the first sentence of subsection (a) and other than subsection (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1320a–7a(a) of this title.

6. Advisory opinions

   A. In general

      The Secretary shall issue written advisory opinions concerning whether a referral relating to designated health services (other than clinical laboratory services) is prohibited under this section. Each advisory opinion issued by the Secretary shall be binding as to the Secretary and the party or parties requesting the opinion.

   B. Application of certain rules

      The Secretary shall, to the extent practicable, apply the rules under subsections (b)(3) and (b)(4)...and take into account the regulations promulgated under subsection (b)(5) of section 1320a–7d of this title in the issuance of advisory opinions under this paragraph.

   C. Regulations

      In order to implement this paragraph in a timely manner, the Secretary may promulgate regulations that take effect on an interim basis, after notice and pending opportunity for public comment.

   D. Applicability

      This paragraph shall apply to requests for advisory opinions made after the date which is 90 days after August 5, 1997, and before

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> the close of the period described in section 1320a–7d(b)(6) of this title.[11]

**Context**: Stark Law violations may result in certain prohibitions, sanctions, and civil penalties. Violating physicians may be prohibited from being reimbursed by Medicare or Medicaid, or from billing patients or other providers for services. A physician may also be banned from participating in Medicare and Medicaid entirely. Civil penalties include up to $15,000 per isolated violation, and up to $100,000 for violations considered as "circumvention schemes," which are often illegal referral arrangements resulting in multiple individual violations. Lastly, entities that fail to report their ownership, investment, and compensation arrangements under 42 U.S.C. § 1395nn(f) are subject to fines up to $10,000.

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