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**Health Law Fundamentals:
Fraud and Abuse Laws
and
HIPAA (Privacy Rule)**

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TABLE OF CONTENTS

A.	The Stark Statute	1
B.	The Anti-Kickback Statute	7
C.	HIPAA	11

COMPARISON OF THE ANTI-KICKBACK STATUTE AND STARK LAW*

	THE ANTI-KICKBACK STATUTE (42 USC § 1320a-7b(b))	THE STARK LAW (42 USC § 1395nn)
Prohibition	Prohibits offering, paying, soliciting or receiving anything of value to induce or reward referrals or generate Federal 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 services entity from submitting claims to Medicare for those services resulting from a prohibited referral
Referrals	Referrals from anyone	Referrals from a physician
Items/ Services	Any items or services	Designated health services
Intent	Intent must be proven (knowing and willful)	<ul style="list-style-type: none"> No intent standard for overpayment (strict liability) Intent required for civil monetary penalties for <i>knowing</i> violations
Penalties	Criminal: <ul style="list-style-type: none"> Fines up to \$25,000 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 Potential \$50,000 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 <i>knowing</i> violations Potential \$15,000 CMP for each service Civil assessment of up to three times the amount claimed
Exceptions	<i>Voluntary</i> safe harbors	<i>Mandatory</i> exceptions
Federal Health Care Programs	All	Medicare/Medicaid

*This chart is for illustrative purposes only and is not a substitute for consulting the statutes and their regulations.

A. The Stark Statute

Commonly known as the Stark statute, The Ethics in Patient Referrals Act, Section 1877 of the Social Security Act (42 U.S.C. §1395nn), restricts referrals by physicians to providers of certain **“designated health services” (“DHS”)** under the Medicare and Medicaid programs and prohibits designated health services entity from submitting claims to Medicare for services resulting from prohibited referrals. The Stark regulations are located in Title 42 of the Code of Federal Regulations §411.350 - §411.389.

1. DHS

The following items or services are DHS:

- (a) Clinical laboratory services;
- (b) Physical therapy services;
- (c) Occupational therapy services;
- (d) Outpatient speech-language pathology services;
- (e) Radiology and certain other imaging services;
- (f) Durable medical equipment and supplies;
- (g) Parenteral and enteral nutrients, equipment, and supplies;
- (h) Prosthetics, orthotics, and prosthetic devices and supplies;
- (i) Home health services;
- (j) Outpatient prescription drugs; and
- (k) Inpatient and outpatient hospital services.

The Centers for Medicare and Medicaid Services maintain and annually update a **List of Current Procedural Terminology (CPT)/Healthcare Common Procedure Coding System (HCPCS) Codes (Code List)**, which identifies all items and services included within certain DHS categories. The updated Code List is published in the Federal Register as an addendum to the annual Physician Fee Schedule final rule. The DHS categories defined by the Code List are: clinical laboratory services; physical therapy services, occupational therapy services, outpatient speech-language pathology services, radiology and certain other imaging services, and radiation therapy services and supplies. The 2015 Code List is available for download at: https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/List_of_Codes.html

The following DHS categories are **defined at 42 C.F.R. §411.351 without reference to the Code List**: 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; and inpatient and outpatient hospital services.

2. Exceptions

Unless an exception applies, Stark prohibits a physician from making referrals for certain designated health services (“DHS”) payable by Medicare or Medicaid to an entity with which he or she (or an immediate family member) has a financial relationship (ownership, investment, or compensation) and also prohibits the entity from presenting or causing to be presented claims to Medicare for the referred services.

Stark establishes specific exceptions, based on whether the physician’s financial relationship is one of **ownership or compensation**. Stark exceptions follow:

General Exceptions Related to Ownership/Investment and Compensation Arrangements (411.355)

- Physician Services
- In-Office Ancillary Services
- Services Furnished by an Organization to Enrollees
- Academic Medical Centers
- Implants Furnished by an ASC
- EPO and Other Dialysis-Related Drugs
- Preventive Screening Tests, Immunizations, and Vaccines
- Eyeglasses and Contact Lenses Following Cataract Surgery
- Intra-Family Rural Referrals

Exceptions Related to Ownership or Investment Interests (411.356)

- Publicly-Traded Securities
- Mutual Funds
- Specific Providers (Rural Providers, Hospitals in Puerto Rico, “Whole” Hospitals)

Exceptions Related to Compensation Arrangements (411.357)

- Rental of Office Space
- Rental of Equipment

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