



UT Health Law CLE 2023

Fundamentals of Healthcare: Stark Law,
Anti-Kickback Statute and HIPAA

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Two Primary Federal Fraud and Abuse Statutes



- **Stark Law**
 - Civil Statute
 - Prohibits Physician Referrals to entities with which they have a financial interest
- **Anti-Kickback Statute**
 - Criminal Statute
 - Prohibits Payments for Referrals
- **State Laws**

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- H.R. 5198 introduced on August 10, 1988 by Representative Fortney “Pete” Stark (D-Cal.) Eventually Stark I and the 1993 amendments, known as Stark II, were born. Since then, there have been numerous updates to the law.
- Initially created to:
 - Limit impermissible physician self-referrals by providing “bright line” rules as to the types of arrangements that are permissible and prohibited.
 - Impose penalties severe enough to provide incentive for self-enforcement in the industry.

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42 U.S.C. § 1395nn

A physician may not refer a Medicare or Medicaid patient to an entity for furnishing “designated health services” if the physician or an immediate family member has a financial relationship with that entity, unless an exception is present.

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Designated Health Services



Why are **Designated Health Services** special?

- 1) Clinical laboratory services
- 2) Physical therapy services
- 3) Occupational therapy services
- 4) Radiology services, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services
- 5) Radiation therapy services and supplies
- 6) Durable medical equipment and supplies
- 7) Parenteral and enteral nutrients, equipment, and supplies
- 8) Prosthetics, orthotics, and prosthetic devices and supplies
- 9) Home health services
- 10) Outpatient prescription drugs
- 11) Inpatient and outpatient hospital services

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Stark Penalties



- Up to \$15,000 per item or service
- \$100,000 for circumvention scheme
- \$50,000 Civil Monetary Penalties for each act
- 3 times remuneration paid
- Exclusion from Medicare / Medicaid
- Some organization make self- disclosures

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