

The Federal Stark Law: Key Elements and Potential Penalties

This summary provides the key elements of the Federal Stark Law and potential penalties, found at 42 U.S.C. § 1395nn. If the Stark Law applies, one of the exceptions listed below must be met (see 42 C.F.R. § 411.355-357). Note, individual states may also have their own version of the Stark Law that should be considered.

Key Elements:

1. A physician cannot
2. Refer to an entity
3. For designated health services payable by Medicare or Medicaid
4. Where there is a financial relationship between the entity and the physician (or member of the physician's immediate family)
 - Includes direct or indirect ownership/investment interests and direct or indirect compensation arrangements
5. Unless an exception applies
 - General Exceptions – 42 C.F.R. § 411.355
 - Ownership Exceptions – 42 C.F.R. § 411.356
 - Compensation Exceptions – 42 C.F.R. § 411.355

Designated Health Services: Defined as the following items or services:

- Home health
- Radiation therapy
- Hospital (inpatient & outpatient)
- Prosthetics, orthotics, and prosthetic devices & supplies
- Occupational therapy
- Durable medical equipment ("DME") & supplies
- Radiology
- Outpatient prescription drugs
- Physical therapy
- Parenteral & enteral items
- Clinical lab
- Outpatient speech-language pathology

Potential Penalties:

- Non-payment or recoupment of payment
- Civil assessments up to 3 times the claimed amount
- CMPs up to \$15,000 per service
- Potential False Claims liability
- Exclusion from Federal health care programs

Meg Pekarske

Hospice Practice Group Leader

Partner | Madison

608.234.6014

meg.pekarske@huschblackwell.com