

Stark I and II & Regulatory Phases I, II, III

A. General prohibition against referrals

Stark prohibits a physician from making a *referral* for certain *designated health services* (DHS) to an *entity* which the physician (or immediate family member) has a *financial relationship*, unless one of the listed 36 exceptions apply. 42 C.F.R. § 411.353. The C.F.R. (which has not been updated with Phase III) can be found at http://www.access.gpo.gov/nara/cfr/waisidx_06/42cfr411_06.html. The Phase III regulations can be found on the CMS website at <http://www.cms.hhs.gov/PhysicianSelfReferral/Downloads/CMS-1810-F.pdf>. An ABA article summarizing Phase III can be found at <http://www.abanet.org/health/esource/Volume4/01/Wachler-Dresevic.html>.

B. Key terms in Stark

There are several key terms in determining when Stark applies to a referral. Those terms are:

1. Referral - A request by a physician for an item or service under Medicare
2. DHS - Includes: clinical laboratory services, physical therapy, occupational therapy, imaging, radiation therapy
3. DHS entity - Organization receiving payment from CMS (shall be referred to as “Hospital” for remainder of this outline)
4. Financial relationship - Includes ownership or investment interests (either direct or indirect) and compensation arrangements between the referring physician (“Physician”) and the Hospital

In order to be prohibited by Stark, a referral must satisfy all of the above terms. If a referral satisfies these terms, it may still be permissible under one of the 36 listed exceptions described below.

C. Implementation history of Stark and regulations

In 1989 Congress enacted a self-referral statute (42 U.S.C.S. § 1395nn), commonly known as “Stark I”. Stark I is a reference to the statute’s primary sponsor, Congressman Fortney “Pete” Stark. Congress revised Stark I in 1993 and the revision is commonly referred to as “Stark II”. Two years after Stark II was passed, the Health Care Financing Administration (“HCFA”) published final regulations on *Stark I* on August 14, 1995 (60 Fed. Reg. 41914). In 2001, HCFA finally addressed Stark II by publishing Phase I of the final regulations. (66 Fed. Reg. 856). The Centers for Medicare and Medicaid Services (CMS) published Phase II of the final regulations of Stark II on March 26, 2004 (69 Fed. Reg. 16054). On September 5, 2007, CMS published the final regulations for Phase III of Stark II.

The following is a summary of the implementation dates of Stark and its regulations:

	<u>Year</u>
Stark I	1989
Stark II	1993
Phase I regulations of Stark I	1995
Phase I regulations of Stark II	2001
Phase II regulations of Stark II	2004
Phase III regulations of Stark II	2007

References to Stark for the remainder of this outline shall mean all of the above.

C. Organization of Stark (including Phases I, II, III)

Stark is organized in the Code of Federal Regulations (C.F.R.) by scope, definitions, exceptions, and reporting requirements. Specifically, Stark is divided into the following nine different sections in the C.F.R.:

1. **Scope** of regulations (42 C.F.R. § 411.350);
2. **Definitions** of terms used in Stark (§ 411.351);
3. **Group practice** definition and compensation rules (§ 411.352). This definition is important in determining if a referral is covered under the “in-office ancillary services” exception or the “physician services” exception (i.e. referrals are permissible within a group practice);
4. **General prohibition** against Physician making referrals to Hospital (§ 411.353);
5. **Financial relationship** between Physician and Hospital (§ 411.354);
6. **Exceptions** when the Physician has certain ownership or compensation agreements with the Hospital (§ 411.355). This section (§ 411.355) includes the following specific exceptions:
 - a) Physician services (i.e. referrals within a group practice);
 - b) In-office ancillary services (i.e. referrals incident to treatment);
 - c) Services furnished by an organization to enrollees;
 - d) Reserved;
 - e) Payments to Physician by an academic Hospital;
 - f) Payments to Physician for implants from an Ambulatory Surgical Center that is partially owned by the Physician;
 - g) Erythropoietin and dialysis drugs;
 - h) Preventative screenings;
 - i) Eyeglasses and contact lenses following cataract surgery; and
 - j) Referrals to a rural Hospital that employs the Physician’s family member;
7. **Exceptions** for ownership interests of Physician (§ 411.356). This section (§ 411.356) includes the following exceptions:

- a) Publicly traded securities (i.e. Physician can own stock of publicly traded Hospital);
- b) Mutual funds which contain Hospital stock; and
- c) Physician who has ownership interest in a Hospital (must be whole Hospital and not a subdivision);

8. **Exceptions** applicable to compensation arrangements between the Physician and the Hospital (§ 411.357). This section (§ 411.357) includes the following specific exceptions:

- a) Office space rental by Physician from Hospital;
- b) Rental of equipment by Physician from Hospital;
- c) Employment relationships between Physician and Hospital;
- d) Personal services relationships between Physician and Hospital;
- e) Recruitment of Physician by Hospital;
- f) Isolated transactions between Physician and Hospital;
- g) Other arrangements between Physician and Hospital;
- h) Arrangements with hospitals;
- i) Payments by Physician to Hospital;
- j) Charitable donations by Physician to Hospital;
- k) Non-monetary compensation from Hospital to Physician;
- l) Payments from Hospital to Physician which are fair market value (does not include leases);
- m) Incidental benefits to Physician's staff from Hospital;
- n) Risk sharing arrangements between Physician and Hospital;
- o) Compliance training provided by Hospital;
- p) Indirect compensation arrangements between Hospital and Physician;
- q) Referral services;
- r) Obstetrical malpractice insurance subsidies from Hospital;
- s) Professional courtesy (i.e. discounted health services from Hospital to Physician or Physician's family)
- t) Bonus payments to Physician in underserved areas;
- u) Community wide health information systems;
- v) Electronic prescribing items; and
- w) Electronic health records systems;

9. **Reporting requirements** (§ 411.361).

D. Summary of Phase III changes to Stark

1. Consultation exception not expanded
Stark has a 'consultation exception' which exempts referrals made from a pathologist, radiologist, and radiation oncologist. 42 C.F.R. § 411.351. CMS refused to expand this list to include anesthesiologists.

2. Physicians in group practices included in direct financial relationships
Stark evaluates 'financial relationships' as being either direct or indirect. 42 C.F.R. § 411.354(c). Phase III adds a section so that a referring physician "stands in the shoes" of their group practice or physician organization in determining if the physician has a direct or indirect financial relationship with the Hospital. 42 C.F.R. § 411.354(c). Adding this section eliminates some group practice referrals which were exempt from Stark because they were analyzed under the 'indirect financial relationships' test. See 42 C.F.R. § 411.354(b)(5). Current arrangements which violate this new provision are permissible but may not be renewed. For example, a lease between a group practice and a Hospital which no longer satisfies this exception may not be renewed when the lease expires.
3. In-Office Ancillary Services Exception
Phase III did not make any substantive changes but it is clear from the commentary that CMS is considering a future restriction.
4. Physician recruitment restrictions relaxed
Stark allows for a hospital to make a payment to a group practice for recruiting a physician to work in the area if certain conditions are met. 69 Fed. Reg. 16096 (2004). Phase III modifies this exception so that the group practice can put practice restrictions should the newly recruited physician subsequently leave the group practice. Examples of restrictions that can be inserted into the newly recruited physician's contract include: no moonlighting, no soliciting patients, and the physician paying liquidated damages if the contract is terminated early.
5. Non-monetary compensation under \$300 permissible under Stark
Stark allows non-monetary compensation of up to \$300 per year if certain conditions are met. See 42 C.F.R. § 411.357. Phase III modifies this exception by allowing: 1) physicians to repay some items within the same calendar year; and 2) DHS entities to provide one medical staff appreciation function for the entire staff per year. 42 C.F.R. § 411.357(k)(3) and (4).
6. Fair Market value compensation exception
Fair market compensation paid to a physician by a Hospital does not violate Stark if certain conditions are met. See 42 C.F.R. § 411.357(l). Phase III modifies this exception to include compensation paid to a physician and vice versa. *Id.* Phase III also clarifies that this exception does not apply to a lease.
In addition, Phase III eliminates the safe harbor applicable to hourly payments to physicians for their personal services. 72 Fed. Reg. 51015-51016 (2007).
7. Retention payments in undeserved areas
Stark allows for certain retention payments to a physician to keep their practice in an underserved area if the physician has an offer from an unrelated hospital at least 25 miles away. 42 C.F.R. § 411.357(t). Phase III modifies this exception to add rural health clinics as an entity able to make retention payments. Phase III also allows retention payments even if the physician does not have another offer if certain conditions are met.

8. Physician's cannot provide DME

Stark excludes services personally performed by the physician. Phase III clarifies that there are few, if any, situations where a physician can personally provide DME under this exception. 72 Fed. Reg. 51019-51020 (2007).

* The above information is not intended as legal advice and an attorney should be consulted for your specific situation.