

MEDICARE-MEDICAID PHYSICIAN SELF-REFERRAL PROHIBITIONS (STARK LAWS)

NOTE: Analysis of potential physician self-referral issues is very complex and fact-specific. The Stark law and how it is interpreted changes frequently. Almost all of the exceptions to the laws and regulations prohibiting self-referral require compliance with multiple specific conditions. Physicians are well-advised to seek legal advice before assuming that their ownership or investment interests or compensation arrangements with referral sources do not violate the Stark laws. The Legal Resource Center of the Washington State Medical Association (www.wsma.org) can assist you in identifying attorneys experienced in Stark and other self-referral questions.

What are the Stark laws?

Stark I, a federal law which became effective on January 1, 1992, prohibits a physician from referring patients for Medicare covered services to a clinical laboratory with whom the physician has a financial relationship.¹

Stark II, a federal law which became effective on January 1, 1995, expands the physician referral prohibitions of Stark I to include Medicaid and to embrace 10 other designated health services.² Stark II prohibits a physician from making a referral of a Medicare or Medicaid patient to an entity for the provision of certain “designated health services,” if the physician, or an immediate family member of the physician, has a financial relationship (whether through an ownership or investment interest or a compensation arrangement) with the entity.³

Stark II also prohibits an entity providing designated health services from billing for any designated health services furnished pursuant to a prohibited referral.⁴

Further, Stark II requires each entity which provides designated health services to report information concerning the entity’s ownership, investment and compensation arrangements.⁵

The Centers for Medicare and Medicaid Services (CMS) released Phase III of their final regulations (Stark III) on September 5, 2007.⁶ Stark III is a response to comments CMS received on Phase II. Stark III addresses the entire group of regulations regarding self-referral, and expands upon, but does not alter, concepts that were introduced in Stark I and II.⁷

¹ Ethics in Patient Referral Act of 1989, Omnibus Budget Reconciliation Act of 1989 (OBRA 1989), Pub. L. No. 101-239, § 6204, 103 Stat. 2106 (1989) (codified at 42 U.S.C. § 1395nn).

² Pub. L. No. 103-66 § 13562, 107 Stat. 312 (1993).

³ 42 U.S.C. § 1395nn(a)(1)(A).

⁴ 42 U.S.C. § 1395nn(a)(1)(B).

⁵ 42 U.S.C. § 1395nn(f).

⁶ 72 Fed. Reg. 51012, *et. seq.* (2007).

⁷ 72 Fed. Reg. 51013 (2007).

What are designated health services?

The “designated health services” encompassed in the Stark laws and regulations include:⁸

- Clinical laboratory services.*
- Physical therapy, occupational therapy, and outpatient speech-language pathology services.*
- Radiology services, including x-rays, magnetic resonance imaging, computerized axial tomography scans, positive emission tomography, ultrasound services, and nuclear medicine.*
- Note that with regard to certain imaging services, including MRI, CT, and PET scans, the referring physician must provide written notice (which must meet certain requirements set forth in regulations) to the patient at the time of the referral that the patient may receive the same service from a person other than the referring physician or the physician’s group.⁹
- 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.

*The list of CPT and HCPCS codes for the specific services that are considered DHS under the above categories that are followed by an asterisk is updated annually in the physician fee schedule final rule and on the CMS website.¹⁰

Are there any exceptions to the self-referral prohibitions of the Stark laws?

Yes. Stark sets forth a number of statutory and regulatory exceptions to the physician self-referral prohibitions. The Stark statutory and regulatory exceptions include:

⁸ 42 U.S.C. § 1395nn(h)(6); 42 C.F.R. § 411.351.

⁹ 42 C.F.R. § 411.355(b)(7)

¹⁰ *Id.*

- Physicians' services provided personally by, or under the personal supervision of, another physician in the same group practice as the referring physician.¹¹
- In-office ancillary services.¹²
- Services provided within certain prepaid health plans.¹³
- Certain services provided within a faculty practice plan associated with a hospital, institution of higher education, or medical school with an approved medical residency program.¹⁴
- Implants furnished by an ambulatory surgery center.¹⁵
- EPO and other dialysis-related drugs.¹⁶
- Preventive screening tests, immunization, and vaccines.¹⁷
- Eyeglasses and contact lenses following cataract surgery.¹⁸
- Intra-family rural referrals.¹⁹
- Ownership or investment interests in certain publicly traded investment securities and mutual funds.²⁰
- Ownership of investment interests in hospitals in Puerto Rico,²¹ rural providers who meet certain conditions,²² and hospitals outside of Puerto Rico if:²³
 - The referring physician is authorized to perform services at the hospital;
 - The hospital was not a specialty hospital from December 8, 2005 through June 7, 2005;

¹¹ 42 U.S.C. § 1395nn(b)(1), 42 C.F.R. § 411.355(a).

¹² 42 U.S.C. § 1395nn(b)(2), 42 C.F.R. § 411.355(b).

¹³ 42 U.S.C. § 1395nn(b)(3), 42 C.F.R. § 411.355(c).

¹⁴ 42 U.S.C. § 1395nn(h), 42 C.F.R. § 411.355(e).

¹⁵ 42 C.F.R. § 411.355(f).

¹⁶ 42 C.F.R. § 411.355(g).

¹⁷ 42 C.F.R. § 411.355(h).

¹⁸ 42 C.F.R. § 411.355(i).

¹⁹ 42 C.F.R. § 411.355(j).

²⁰ 42 U.S.C. § 1395nn(c); 42 C.F.R. § 411.356.

²¹ 42 U.S.C. § 1395nn(d)(1).

²² 42 U.S.C. § 1395nn(d)(2).

²³ 42 U.S.C. § 1395nn(d)(3).

- The ownership or investment is in the whole of a hospital, not merely a subdivision; and
- The hospital met certain statutory requirements by September 22, 2012.²⁴
- Payments made for certain office space²⁵ and equipment rentals.²⁶
- Payments made by an employer to an employee who has a true (“bona fide”) employment arrangement with the employer.²⁷
- Payments made under certain personal service arrangements.²⁸
- Payments made under certain physician incentive plans, involving such things as withholds, capitation, and bonuses, which may have the effect of reducing or limiting services a physician provides to enrolled individuals.²⁹
- Remuneration by hospitals which is unrelated to the provision of designated health services.³⁰
- Certain hospital physician recruitment incentives.³¹
- Payments made in connection with isolated financial transactions, such as a one-time sale of property or practice.³²
- Certain group practice arrangements with a hospital which were in effect before December 19, 1989.³³
- Payments by a physician for items or services furnished at a price consistent with fair market value.³⁴
- Bona fide charitable donations made by a physician (or immediate family member).³⁵
- Nonmonetary compensation up to \$300 per calendar year.³⁶

²⁴ As outlined in 42 U.S.C. § 1395nn(i)(1).

²⁵ 42 U.S.C. § 1395nn(e)(1)(A); 42 C.F.R. 411.357(a).

²⁶ 42 U.S.C. § 1395nn(e)(1)(B); 42 C.F.R. 411.357(b).

²⁷ 42 U.S.C. § 1395nn(e)(2); 42 C.F.R. § 411.357(c).

²⁸ 42 U.S.C. § 1395nn(e)(3); 42 C.F.R. § 411.357(d).

²⁹ 42 U.S.C. § 1395nn(e)(3)(B); 42 C.F.R. § 411.357(d)(2).

³⁰ 42 U.S.C. § 1395nn(e)(4); 42 C.F.R. § 411.357(g).

³¹ 42 U.S.C. § 1395nn(e)(5); 42 C.F.R. § 411.357(e).

³² 42 U.S.C. § 1395nn(e)(6); 42 C.F.R. § 411.357(f).

³³ 42 U.S.C. § 1395nn(e)(7); 42 C.F.R. § 411.357(h).

³⁴ 42 U.S.C. § 1395nn(e)(8); 42 C.F.R. § 411.357(i).

³⁵ 42 C.F.R. § 411.357(j).

³⁶ 42 C.F.R. § 411.357(k).

- Fair market compensation.³⁷
- Medical Staff non-cash incidental benefits from a hospital to a member of the Medical Staff used on the hospital campus (such as low-cost meals for physicians) or used away from campus to access hospital information (such as pagers or internet access).³⁸
- Risk-sharing arrangements between a physician and a managed care organization (MCO) or independent physician organization (IPO) for services provided to enrollees of a health plan.³⁹
- Compliance training for physicians (or to the physicians' immediate family member or office staff).⁴⁰
- Certain indirect compensation arrangements.⁴¹
- Referral services.⁴²
- Obstetrical malpractice insurance subsidies.⁴³
- Professional courtesy to physician or physician family members under certain circumstances.⁴⁴
- Retention payments in underserved areas.⁴⁵
- Access to community-wide information systems.⁴⁶
- Electronic prescribing items and services.⁴⁷
- Certain arrangements involving temporary non-compliance.⁴⁸
- Electronic health records items and services.⁴⁹

³⁷ 42 C.F.R. § 411.357(l).

³⁸ 42 C.F.R. § 411.357(m).

³⁹ 42 C.F.R. § 411.357(n).

⁴⁰ 42 C.F.R. § 411.357(o).

⁴¹ 42 C.F.R. § 411.357(p).

⁴² 42 C.F.R. § 411.357(q).

⁴³ 42 C.F.R. § 411.357(r).

⁴⁴ 42 C.F.R. § 411.357(s).

⁴⁵ 42 C.F.R. § 411.357(t).

⁴⁶ 42 C.F.R. § 411.357(u).

⁴⁷ 42 C.F.R. § 411.357(v).

⁴⁸ 42 C.F.R. § 411.353(f).

⁴⁹ 42 C.F.R. § 411.357(w).

- Other financial relationships which the Department of Health and Human Services (DHHS) determines do not pose a risk of program or patient abuse and specifies in regulations.⁵⁰

Most of the Stark statutory and regulatory exceptions contain multiple enumerated requirements which must be met in order to come within the exception. Under Stark, physician referrals of Medicare and Medicaid patients for designated health services to an entity with whom the physician, or an immediate family member of the physician, has a financial relationship are absolutely prohibited unless the ownership or investment interest or the compensation arrangement squarely fits within all of the enumerated requirements of one of the Stark exceptions.⁵¹

What are the penalties for violating the Stark laws?

The sanctions for violations of the Stark laws include:

- No payment for a designated health service furnished pursuant to a prohibited referral.⁵²
- Repayment of all amounts improperly billed.⁵³
- Civil money penalties of up to \$15,000 per each improperly billed service.⁵⁴
- Civil money penalties of up to \$100,000 against any physician or entity that enters into any circumvention arrangement or scheme which the physician or entity knew or should have known has a principal purpose of assuring referrals.⁵⁵
- Civil money penalties of up to \$10,000 each day for which a required report has not been made.⁵⁶
- Exclusion from participation in Medicare or Medicaid.⁵⁷
- Assessment of not more than three times the amount claimed for each item or service improperly claimed.⁵⁸

⁵⁰ 42 U.S.C. § 1395nn(b)(4).

⁵¹ 42 U.S.C. § 1395nn(a)(1); 42 C.F.R. § 411.353(a).

⁵² 42 U.S.C. § 1395nn(g)(1).

⁵³ 42 U.S.C. § 1395nn(g)(2).

⁵⁴ 42 U.S.C. § 1395nn(3).

⁵⁵ 42 U.S.C. § 1395nn(4).

⁵⁶ 42 U.S.C. § 1395nn(5).

⁵⁷ 42 U.S.C. § 1395nn(4); 42 U.S.C. § 1320a-7a(a).

⁵⁸ 42 U.S.C. § 1395nn(4); 42 U.S.C. § 1320a-7a(a).

Does compliance with the Stark laws ensure compliance with the Medicare-Medicaid anti-kickback law or Washington's anti-rebate law?

No. See **MEDICARE-MEDICAID FRAUD AND ABUSE AND ANTI-KICKBACK PROVISIONS**; and **REBATES**.

Where can physicians find more information concerning the Stark laws?

The federal government website related to physician self-referral, under the Centers for Medicare & Medicaid Services is: <http://www.cms.hhs.gov/PhysicianSelfReferral>.