

Final phase of the

STARK REGULATIONS

takes effect:

HOW WE GOT HERE

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The third and final phase of physician self-referral regulations—called the Stark Laws in reference to Rep. Pete Stark (D-CA), who introduced the legislation that originally called for banning self-referrals—became effective on December 4, 2007. This article is intended to bring surgeons up to date on the rules and their effects on surgical practices.

Background

The first Stark Law (Physician Self-Referral Law, Sec. 1877 of the Social Security Act, 42 U.S.C. § 1395nn) was enacted in 1989 with the intent of prohibiting physicians from referring Medicare patients to laboratory service facilities in which they had a financial interest, a practice termed “self-referral.” This restriction, known as Stark I, became effective January 1, 1992. In 1993, legislation passed to extend the Stark I Laws to services provided to Medicaid patients and amended the original law to include additional health care services considered to be particularly susceptible to overuse because of physicians’ financial interests. These amendments went into effect January 1, 1995, and are referred to as Stark II Laws.

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Regulatory issues addressed in Stark II, Phase I, II, and III

Regulatory issue	Stark II, Phases I and II	Stark II, Phase III
Safe harbor provision	CMS created a voluntary “safe harbor” provision for calculating fair market value of hourly payments to physicians for their services. The safe harbor provision reduces or eliminates a party’s liability under the law when actions are performed in good faith.	Phase III eliminates the safe harbor provision; however, CMS will continue to scrutinize all fair market value arrangements.
Physician recruitment	The recruit’s medical practice must relocate. Under the rule, the recruited physician will be deemed to have been relocated if the physician’s medical practice moves at least 25 miles or if at least 75% of the recruited physician’s revenues are provided to new patients not seen at the previous practice site.	Phase III expands the “geographic area served by the hospital” test to include the area comprising all the contiguous zip codes from which the hospital’s inpatients are drawn. It allows group practices to impose practice restrictions and permits practices to offer more generous income guarantees to a physician recruited to take the place of a deceased, retiring, or relocating physician. It also adds provisions exempting certain physicians from the relocation requirement.
Intra-family rural referrals	Phase II created a new exception for cases in which no other entity furnishes the designated health service (DHS) within 25 miles of the patient’s home. If the patient is receiving at-home care, the exception applies if no DHS entity is available “in a timely manner in light of the patient’s condition.”	Phase III modifies the exception to include an alternative distance test based on transportation time (45 minutes) from the patient’s residence. This new alternative test requires case-by-case analysis of the conditions existing at the time of the referral (for example, snow blocking access to roads).
Personal service arrangements	The exception covers services provided by the referring physician or his or her immediate family member and/or employees, but not contractors. A personal service contract can mean any kind of services personally performed and can be between a DHS entity and an individual and may include equipment that the physician needs to provide services.	Phase III changes the personal service arrangements exception to include a provision that permits a holdover personal service arrangement for services provided after the terms of the contract expires, extending for up to six months such arrangements that otherwise meet the requirements of the personal services exception.

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Regulatory issues addressed in Stark II, Phase I, II, and III (continued)

Regulatory issue	Stark II, Phases I and II	Stark II, Phase III
Nonmonetary compensation	Items or services not exceeding an aggregate of \$300, provided they are not solicited by a physician, do not take into account the value of referrals and do not violate the anti-kickback statute. In phase II, the \$300 limit of nonmonetary compensation will be updated annually for inflation and displayed on the CMS self-referral Web site after September 30 of each year.	Phase III makes two substantive changes to the nonmonetary compensation exception by (1) allowing physicians to repay certain excess nonmonetary compensation within the same calendar year to preserve compliance with the exception, and (2) allowing entities without regard to the \$300 dollar limit to provide one medical staff appreciation function (such as a party) for the entire medical staff per year.
Professional courtesy	The professional courtesy provision provides for a new and narrow exception to allow the provision of certain free or discounted health care items or services. Phase II defines professional courtesy as “the provision of free or discounted health care items or services to a physician or his or her family members or staff.” Certain requirements must be met before the exception applies, and CMS cautions that these arrangements should be examined to determine whether they violate the anti-kickback statute or the civil monetary penalties laws.	Phase III modifies the professional courtesy exception by deleting the requirement that an entity notify an insurer when the professional courtesy involves the whole or partial reduction of any coinsurance obligation.
Definition of referral	In Phase I, HCFA excluded from the definition those services personally performed by the physician, explaining that it is not possible for a physician to make a referral to himself or herself for services that he or she provides.	Phase III further clarifies that there are few, if any, situations in which a referring physician could personally furnish durable medical equipment (DME), because this would require the physician be enrolled in Medicare as a DME supplier and personally perform all of the duties of a supplier.
“Stand in the shoes” <i>CMS has delayed enactment of this provision for academic medical centers and 501(c)(3) health care systems.</i>	Phase II’s definition of a referring physician states that the physician may be treated as “standing in the shoes” of his or her wholly owned professional corporation and does not apply to group practices.	Phase III added the definition for physician organizations, which means a physician, including a professional corporation in which the physician is the sole owner, a physician practice, or a group practice.

The Stark II Laws prohibit physicians from making referrals for a designated health service (DHS) payable by Medicare or Medicaid to entities with which they or members of their immediate family have a financial relationship. A financial relationship means either an ownership interest or a compensation arrangement. For the purposes of the Stark Law, a DHS falls within one of 11 categories, including inpatient and outpatient services; clinical laboratory services; home health; prosthetics, orthotics, and prosthetic devices; and supplies. The law is wide-ranging; for example, a physician's practice or group may be an entity to which referrals are prohibited. Penalties for violating the Stark Law include denial of payment for the services, civil penalties, or even exclusion from the Medicare or Medicaid programs.

On January 4, 2001, the Health Care Financing Administration (HCFA), now known as the Centers for Medicare & Medicaid Services (CMS), issued the first phase of the Stark II final regulations, also known as Stark II, Phase I. These rules addressed the general prohibition, general exceptions applicable to both ownership or investment interests and compensation arrangements, new exceptions that are applicable only to compensation arrangements, and definitions. Stark II, Phase I only applied to referrals of Medicare beneficiaries and went into effect January 4, 2002, one year after publication.

CMS issued Phase II of the final regulations on March 26, 2004. Phase II addressed provisions of the Stark Law not addressed in Phase I and provided additional regulatory exceptions and responses to public comments on Phase I regulations.

The current system

Finally, on August 27, 2007, CMS released the long-awaited Phase III rules. Under the statute, physicians cannot refer Medicare patients to facilities in which they have a financial interest unless the business arrangement meets one of a number of exceptions. Phase III final regulations were published September 5, 2007, and became effective December 4, 2007. Generally, Phase III responds to comments on Phase II and addresses the entire regulatory scheme. Phase III does not contain any sweeping changes to the

Stark Laws. No new exceptions are extended to physicians, hospitals, and other providers implementing business and referral arrangements. However, Phase III does revise and clarify some regulatory language in a few areas in hopes of simplifying compliance. Phases I, II, and III of the rulemaking are intended to be integrated and read together as a whole. The accompanying chart (pages 23-24) provides highlights of all three phases of Stark II. [Q](#)