

Stark Exceptions

Exceptions to the Stark Law Prohibition

The Stark statute applies only to physicians who refer Medicare and Medicaid patients for specific services ("designated health services," or DHS) to entities with which they (or an immediate family member) have a "financial relationship." While many of the exceptions to the Stark law prohibition contained in the Stark II Regs rely upon a fact specific analysis and the application of certain defined terms, in brief, these exceptions, as contained in the Stark II Regs, are set forth below:

Physician Services

Physician services that are furnished (i) personally by another physician who is a member of the referring physician's group practice or (ii) under the supervision of another physician who is a member of the referring physician's group practice are exempt for the self-referral prohibition. Notwithstanding, the Stark II Regs contain a detailed analysis as to what constitutes a "group practice" and who qualifies as part of the referring physician's group practice under this exception.

In-Office Ancillary Services

Certain services that are furnished personally by (i) the referring physician, (ii) a physician who is a member of the same medical group as the referring physician, or (iii) an individual who is supervised by the referring physician or by another physician in the group, if the services are furnished either (x) in the same building in which the referring physician generally practices, and the receipt of DHS is not the primary reason the patient contacted the referring physician, or (y) in a centralized building that is used exclusively by the referring physician's group practice, are excepted from the Stark law prohibition so long as the medical group bills for the services using its provider number or the physician rendering services bills using his or her provider number.

Although the in-office ancillary services exception existed in a similar form under the 1998 proposed rule, a noteworthy change in the Stark II Regs is an additional exception that allows physicians to provide their patients canes, crutches, walkers, folding manual wheelchairs, and blood glucose monitors in-office so long as certain additional requirements are met.

Additionally, the Stark II Regs provide a new special exception for physicians whose principal medical practice consists of treating patients in their homes.

Services Furnished by an Organization to Enrollees

Otherwise prohibited physician referrals are permitted if they are made to organizations providing services to enrollees of prepaid health plans that contract with HCFA to provide services to Medicare beneficiaries.

Clinical Laboratory Services Furnished in an Ambulatory Surgical Center (ASC) or End-Stage Renal Disease Facility (ESRD), or by a Hospice

If the charges for the DHS are included in the ASC rate, the ESRD composite rate, or as part of the per diem hospice rate, the referral for the DHS shall be excepted from the Stark law prohibition.

Academic Medical Centers

In accordance with this new exception, referrals for DHS may be made by physicians with a financial relationship to an academic medical center if the referring physician (i) is a bona fide employee of the academic medical center, (ii) is licensed to practice medicine in the state, (iii) has a bona fide faculty appointment at the affiliated medical school, and (iv) provides either substantial academic or clinical teaching services for which he or she receives compensation. Furthermore, the physician's total compensation must be set in advance, be fair market value, and not violate the federal anti-kickback statute. The academic medical center must also meet certain requirements with respect to its organizational structure and use of funds.

Implants in Ambulatory Surgery Centers

Implants, including, but not limited to cochlear implants, intraocular lenses, and other devices are excepted from the self-referral prohibition if they are furnished by the referring physician or a member of his or her medical group, the device is implanted during a surgical procedure performed in the same ASC where the implant is furnished, and the arrangement complies with the federal anti-kickback statute.

EPO and Other Dialysis-Related Outpatient Prescription Drugs Furnished in or by an End-Stage Renal Disease Facility

Certain outpatient prescription drugs identified on HCFA's website (updated annually) that are EPO and other dialysis-related drugs and are administered in or by an ESRD facility are exceptions to the Stark law prohibition.

Preventive Screening Tests, Immunizations, and Vaccines

Certain screening tests, immunizations and vaccines identified on HCFA's website (updated annually) that are subject to HCFA-mandated frequency limits and are reimbursed by Medicare, are excepted from the Stark law prohibition.

Eyeglasses and Contact Lenses Following Cataract Surgery

For those instances when Medicare covers eyeglasses and contact lenses following cataract surgery, a physician may refer a patient for such services to an entity in which the physician has a financial relationship if the patient referral does not violate the federal anti-kickback statute and all billing and claims submissions comply with federal and state law.

No Knowledge of Prohibited Referral

Under this exception, an entity will not be deemed to have provided prohibited DHS if the entity did not know or have reason to suspect the identity of the referring physician.

Electronic Prescribing Items and Services

This exception was mandated by the Medicare Prescription Drug, Improvement and Modernization Act of 2003, which created the drug benefit under Medicare Part D. It applies to non-monetary remuneration provided by a hospital to members of its medical staff or by a group practice to physicians who are members of the group practice (consisting of items and services in the form of hardware, software or information technology and training services) “necessary and used solely” to receive and transmit electronic prescription information. In order to qualify under this exception, the following conditions must be satisfied:

- (1) Items and services must be provided by a hospital to a physician who is a member of its medical staff or by a group practice to a physician who is a member of the group;
- (2) The items and services must be provided as part of, or used to access, an electronic prescription drug program that meets the applicable standards under Medicare Part D at the time the items and services are provided;
- (3) The donor (or a person on the donor’s behalf) must not take any action to limit or restrict the use or compatibility of the items or services with other electronic prescribing or electronic health record systems;
- (4) For items or services that are of the type that can be used for any patient without regard to payor status, the donor must not restrict, or take any action to limit, the physician’s right or ability to use the items or services for any patient;
- (5) Neither the physician nor the physician’s practice can make the receipt of items or services, or the amount or nature of the items or services, a condition for doing business with the donor;
- (6) Neither the eligibility of the physician for the items or services, nor the amount or nature of items or services, can be determined in a manner that takes into account the volume or value of referrals or the business generated between the parties;
- (7) The arrangement must be set forth in a written agreement that is signed by the parties, specifies the items and services being provided and the donor’s costs of

the items and services, and covers all the electronic prescribing items and services to be provided by the donor; and

(8) The donor must not have actual knowledge of, and must not act in reckless disregard or deliberate ignorance of, the fact that the physician possesses or has obtained items or services equivalent to those provided by the donor.

Electronic Health Records Items and Services

An additional new Stark law exception goes beyond electronic prescription information and extends more generally to electronic health records (“EHR”) defined to mean “a repository of consumer health status information in computer processable form used for clinical diagnosis and treatment for a broad array of clinical conditions.” This exception applies to non-monetary remuneration (consisting of items and services in the form of software or information technology and training services) “necessary and used predominantly” to create, maintain, transmit, or receive EHR, provided all the following conditions are satisfied:

- (1) The items and services are provided by a provider entity, as defined in the Stark law, to a physician;
- (2) The software is interoperable at the time it is provided to the physician. Interoperable means “able to communicate and exchange data accurately, effectively, securely, and consistently with different information technology systems, software applications, and networks, in various settings; and exchange data such that the clinical or operational purpose and meaning of the data are preserved and unaltered.” Software is deemed to be interoperable if a certifying body recognized by the Secretary has certified the software no more than twelve months prior to the date it is provided to the physician.
- (3) The donor, or any person on the donor’s behalf, does not take any action to limit or restrict the use, compatibility or interoperability of the items or services with other electronic prescribing or EHR systems;
- (4) Before receipt of the items or services, the physician pays 15% of the donor’s cost for the items and services and the donor does not finance the physician’s payment or loan funds to be used by the physician to pay for the items and services;
- (5) Neither the physician nor the physician’s practice makes the receipt of items or services, or the amount or nature of the items or services, a condition for doing business with the donor;
- (6) Neither the eligibility of a physician for the items or services, nor the amount or nature of the items or services, can be determined in a manner that directly takes into account the volume or value of referrals or other business generated between the parties;
- (7) The arrangement is set forth in a written agreement that is signed by the parties, specifies the items and services being provided, the donor’s cost of the items and services, and the amount of the physician’s contributions, and covers all the EHR items and services to be provided by the donor; and

- (8) The donor does not have actual knowledge of, and does not act in reckless disregard or deliberate ignorance of, the fact that the physician possesses or has obtained items and services equivalent to those provided by the donor;
- (9) For items or services that are of the type that can be used for any patient without regard to payor status, the donor does not restrict, or take any action to limit, the physician's right or ability to use the items or services for any patient;
- (10) The items and services do not include staffing of physician offices and are not used primarily to conduct personal business or business unrelated to the physician's medical practice;
- (11) The EHR software contains electronic prescribing capability that meets the applicable standards under Medicare Part D at the time the items and services are provided;
- (12) The arrangement does not violate the Anti-Kickback statute or any federal or state law or regulation governing billing or claims submission
- (13) The transfer of the items or services occurs and all conditions are satisfied on or before December 31, 2013.

Exceptions to the Meaning of "Compensation Arrangement"

In addition to the exceptions set forth above, which apply to prohibited referrals due to a physician's ownership interest in or compensation relationship with an entity, the Stark II Regs list additional exceptions that apply to prohibited referral arrangements based exclusively upon a physician's compensation arrangement with an entity. In other words, the following arrangements are not considered prohibited "financial relationships" under Stark law.

Non-monetary Compensation Up to \$300

In accordance with this exception, the payment of non-monetary compensation to a physician up to \$300 per year does not create a "financial relationship" between a physician and an entity if the physician did not solicit the remuneration, the arrangement does not violate the federal anti-kickback statute, and the compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated by the physician.

Fair Market Value Compensation

Perhaps the most useful exception is the exception for fair market value compensation. Under the terms of this exception, if a compensation arrangement is in writing, specifies the timeframe for services, specifies the compensation that will be provided, involves a commercially reasonable transaction, meets a safe harbor under the federal anti-kickback statute, and the services to be performed do not involve the counseling or promotion of an illegal business activity, then the compensation generated under such arrangement will not be treated as creating a "financial relationship" between a physician and an entity. It is noteworthy that under this exception, the duration of the arrangement may be for any

term, provided that the parties enter into only one such arrangement in the course of the year.

Medical Staff Incidental Benefits

Under this exception, hospitals may provide the members of their medical staffs with compensation in the form of items or services (excluding cash) when the compensation is used on the hospital's campus so long as the compensation is not based on the volume or value of referrals, it is offered only during periods when the medical staff members are making rounds or performing other duties that benefit the hospital, it is reasonably related to the provision of medical services, each occurrence is of low value (less than \$25), and it is consistent with the types of benefits offered by other hospitals within the same local region.

Risk Sharing Arrangements

Similar to the exception for services to enrollees above, under this new exception, compensation exchanged between a physician and an entity pursuant to a risk sharing arrangement (including, but not limited to, withholds, bonuses, and risk pools) shall not qualify as a "financial relationship" for purposes of Stark.

Compliance Training

Compliance training provided by a hospital to a physician who practices in the hospital's local community or service area shall not be considered to constitute a "financial relationship" between the hospital and physician, provided the training is held in the local community or service area.

Indirect Compensation Arrangements

Under this exception, indirect compensation arrangements between a physician and an entity shall not be considered "financial relationships" for purposes of Stark if the compensation received by the referring physician is fair market value for services and items actually provided, does not take into account the value or volume of referrals or other business generated by the physician, the arrangement is set out in writing and signed by the parties, the writing specifies the services covered by the arrangement (except for a bona fide employment relationship, which does not have to be set out in writing, but must be commercially reasonable), and the arrangement does not violate the federal anti-kickback law.