

## Stark III

The Stark Law governs physician self-referral for Medicare and Medicaid patients. The law is named for United States Congressman Pete Stark, who sponsored the initial bill.

The latest round of Stark regulations, Phase III, took effect December 4, 2007. However, the effective date of certain “stand in the shoes” provisions has been delayed until December 4, 2008 to give the Centers for Medicare and Medicaid Services the chance to review their unintended impact.

The Stark law, also known as the physician self-referral law, prohibits a physician from making referrals for certain "designated health services" payable by Medicare to an entity with which he or she has a financial relationship, unless an exception applies. It also prohibits the entity from filing claims with payers for those referred services.

Specific examples of arrangements covered by Stark include: physicians who have contracts with hospitals for clinical programs, physicians who have been recruited by a hospital, physicians or group practices that have joint venture relationships with diagnostic facilities or an ambulatory surgery center, and faculty practice plan physicians with arrangements with an academic medical center.

The latest changes generally are intended to fine-tune the existing prohibitions. The following discussion will highlight selected key elements of these regulations. It is an overview of selected topics and is not an exhaustive review of the new regulations.

The delay involves the application of the Phase III “stand in the shoes” provisions in the academic medical center (AMC) setting or similar settings such as a nonprofit integrated health care system in which each affiliated organization qualifies for exemption from federal income taxation under section 501(c)(3) of the Internal Revenue Code (for purposes of this final rule, referred to as an “integrated section 501(c)(3) health care system”) where “support payments” or other similar monetary transfers are common. It has been asserted that under Phase III, support payments that previously did not trigger application of the physician self-referral

law will need to satisfy the requirements of an exception if, for example, a DHS entity component (for example, a hospital) of an AMC transfers funds to the faculty practice plan component of the AMC. Specifically, in the situation where a physician stands in the shoes of his or her faculty practice plan, the compensation arrangement between the AMC component providing the support payment and the faculty practice plan will be considered to be a direct compensation arrangement between the component and the physician. If the component making the support payment is a DHS entity to which the physician refers Medicare patients, the arrangement between the component and the faculty practice plan would need to satisfy the requirements of a direct compensation arrangement exception if the physician were to continue referring Medicare patients to the component for DHS. A similar analysis applies in the case of an integrated section 501(c)(3) health care system that includes both a hospital affiliate and a nonprofit physician practice affiliate. According to the comments received by HHS, it is unlikely that the requirements of any available exception could be satisfied given the nature of support payments.

In order to evaluate fully the impact of the Phase III “stand in the shoes” provisions on remunerative relationships within AMCs and nonprofit integrated health care systems that, prior to Phase III, did not trigger application of the physician self-referral laws, HHS is delaying the effective date until December 4, 2008 as to provisions relating to the following compensation arrangements between the following physician organizations and entities ONLY:

- With respect to an AMC as described in § 411.355(e)(2), compensation arrangements between a faculty practice plan and another component of the same AMC; and
- With respect to an integrated section 501(c)(3) health care system, compensation arrangements between an affiliated DHS entity and an affiliated physician practice in the same integrated section 501(c)(3) health care system.

### **Additional Background**

The Stark law applies if a physician is referring Medicare beneficiaries or Medicaid recipients to an entity for the following 10 categories of designated health services, commonly referred to as "DHS":

- Clinical laboratory services
- Physical therapy, occupational therapy and speech-language pathology services

- Radiology and certain other imaging services (including ultrasound, MRI, CT and PET)
- 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 payable by Medicare Part B
- Inpatient and outpatient hospital services.

Each year CMS publishes an updated "List of codes" in the Federal Register to clearly define the first four categories of DHS.

The primary test for arrangements that might be covered by the Stark regulations involves two questions: first, is there a direct or indirect financial relationship between the referring physician and the entity furnishing DHS and second, is there a referral for DHS from the physician to the entity? If the answer to both questions is "yes," the Stark regulations are violated unless an exception applies.

A financial relationship is either a) a direct or indirect ownership or investment interest in any entity that furnishes DHS, or b) a compensation arrangement with a DHS entity. A physician may have a financial arrangement with a DHS entity even though the financial relationship is entirely unrelated to the furnishing of DHS.

An ownership or investment interest may be direct or indirect and may be through equity, debt or other means. This includes an interest in an entity that holds an interest in a DHS entity. For example, a physician who holds a membership interest in a limited liability company that owns and operates an MRI facility has an ownership interest in a DHS entity.

A compensation arrangement is any arrangement involving remuneration, direct or indirect, between a physician and the DHS entity. "Remuneration" is any *payment or other benefit* made directly or indirectly, overtly or covertly, in cash or in kind. A compensation arrangement includes space and equipment leases; arrangements between a physician and a DHS entity in which the physician provides professional services, medical director services or management services; a physician recruitment arrangement between a hospital and a physician; an "under arrangements" contractual joint venture between a

physician and a hospital; and any other type of arrangement involving remuneration between a physician and a DHS entity. There are compensation regulations that govern the calculation and payment of bonuses and specify that compensation must generally be fair market value, reasonable, set in writing and often set in advance.

The Stark law is very broad in its limits on financial and referral arrangements, but there are exceptions, and certain arrangements can exist if they comply with the regulations. The Stark law establishes exceptions to both ownership interests and compensation arrangements. Generally, two elements are extremely important for an exemption to be considered valid: first, compliance with all aspects of the regulation must be documented, and second, all financial arrangements must be at fair market value rates.

### **Physician Services Exception**

A physician will presumably always have a compensation arrangement with his or her own practice and will often also have an ownership interest. There are exceptions for referral and compensation arrangements within group practices.

Physician services within a group practice are an exception to both the compensation and ownership arrangement prohibitions when the physician services are provided personally (or under the personal supervision of) another physician in the same group practice as the referring physician.

While this aspect of group practice operations is fairly straightforward, the Stark regulations are very complex when it comes to consideration of referral and compensation arrangements for "incident to" services and in-office ancillary services. For in-office ancillary services to be allowed under Stark they must satisfy very specific conditions regarding the provider of the services, where the services are provided and billing arrangements. The intent is to ensure that ancillaries are provided within a true group practice.

### **Bona Fide Employment Arrangements Exception**

There is a compensation exemption within the Stark regulations for true employment relationships. The exception is met when: (1) the employment is for identifiable services, (2) the amount of the remuneration under the employment is consistent with the fair market value for the services and generally is not determined in a manner that takes into account the volume or value of any referrals by the referring physician, and (3) the remuneration is

provided pursuant to an agreement that would be commercially reasonable even if no referrals were made to the employer.

### **Space and Equipment Lease Exceptions**

Lease arrangements for office space and equipment leases are considered a form of compensation and therefore they are targeted by the Stark regulations. These leases are allowed when the following conditions are satisfied: the lease is set out in writing; is signed by the parties and specifies the items covered; the space or equipment leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease and is used exclusively by the lessee when being used by the lessee; the lease provides for a term of at least one year; the rental charges over the term of the lease are set in advance; are consistent with fair market value; and are not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.

### **Personal Services Arrangement Exception**

The personal services exemption deals with physicians or family members who have independent contractor relationships with health care providers, as contrasted to employee relationships. The exemption permits a physician to refer patients to an entity with which the physician has a personal services arrangement when the following conditions are satisfied: the arrangement is set out in writing that generally specifies the services covered by the arrangement; the contracted services are reasonable and necessary for the legitimate business purposes of the arrangement; the term of the arrangement is for at least one year; and the compensation to be paid over the term of the arrangement is set in advance and does not exceed fair market value. The latest Phase III regulations make some changes to the definition of fair market value, which may affect contracts currently in place.

### **Physician Recruitment Exception**

Part of the Stark regulations limits recruitment arrangements between hospitals and doctors. Some of the key requirements of these arrangement are: the arrangement must be in writing and signed by the parties; the arrangement cannot be conditioned upon hospital referrals from the physician; the hospital does not determine, directly or indirectly, the amount of remuneration to the physician based upon the volume or value of actual or anticipated referrals by the physician or the amount of other business done by the parties.

The physician must be allowed to establish hospital privileges at any other hospitals and to refer business to any other entity.

There are many other conditions that must be satisfied, including conditions that apply to income guarantees and recruited physicians who are employed in a group practice.

## **Penalties**

The basic sanction for violation of the Stark regulations is nonpayment for DHS referred by a physician with an improper financial relationship with the DHS entity.

The Stark regulations also provide a civil monetary penalty of up to \$15,000 for each bill or claim for a service known to be improper. A civil penalty of up to \$100,000 can also be imposed for each arrangement or scheme that a physician or health care entity knows or should have known has a principal purpose of assuring prohibited referrals.

The Stark regulations are separate from the Anti-kickback statute which makes it a crime to pay or receive remuneration of any kind for referral. Stark is also separate from the False Claims Act that prohibits submitting a false claim to the government.

In addition many states have their own laws that apply to referrals, ownership and compensation arrangements. Some of these state-mandated requirements are stricter than the Stark requirements.

Health care is one of the most highly regulated industries, as shown by the Stark regulations. A qualified attorney can assist with the interpretation of the regulations and qualified accountants can assist with financial matters such as the determination of fair market value and the treatment of income from arrangements between provider organizations.