

The STARK TRUTH About the STARK LAW: Part II



Alice G. Gosfield, JD

Find out whether one or more of the many exceptions to the Stark statute apply to you.

The Stark statute presents significant challenges to physicians – those with specific business interests as well as those whose sole focus is patient care. Understanding the law and knowing which, if any, of the many Stark exceptions apply to your arrangement is essential. Part I of this series explained the purpose of the Stark statute, how it differs from the anti-kickback statute and how you can determine whether it applies to you. It also defined some of the key terms used in the statute and described two

of the most notable exceptions. (See the overview on page 43.)

This article looks at the exceptions that are most important for family physicians to be aware of: non-

monetary compensation, preventive services, fair market value, hospital incidental benefits, hospital compliance training, risk-sharing arrangements, lease arrangements, bona fide employment relationships, personal services arrangements and physician incentive plans.

Nonmonetary compensation

The Stark regulations allow nonmonetary compensation to physicians from a referred-

to entity as long as the compensation is in the form of items or services rather than cash or cash equivalents and does not exceed an aggregate value of \$300 per year. The compensation must also meet the “volume or value of referrals” definition (see “An overview” on page 43), may not be solicited by the physician or the physician’s practice (including employees and staff members), and must not otherwise violate the anti-kickback statute. For example, this excep-

tion allows referred-to entities, such as imaging centers, to give holiday gifts to their referring physicians.

Preventive services

Preventive screening tests, immunizations

and vaccines are exempted from the Stark regulations as long as they meet the relevant frequency limits mandated by the Centers for Medicare & Medicaid Services (CMS) and are reimbursed by Medicare based on the fee schedule, and as long as the billing and claims submissions otherwise comply with federal law and the arrangement does not otherwise violate the anti-kickback statute.

Understanding the law and knowing which, if any, of the many Stark exceptions apply to your arrangement is essential.

Alice Gosfield is an attorney and principal of Alice G. Gosfield & Associates, PC, in Philadelphia, immediate past chairman of the Board of Directors of the National Committee for Quality Assurance, and a member of the Family Practice Management Panel of Consultants. Conflicts of interest: none reported.



Covered in FPM Quiz



Understanding the Stark statute and knowing which, if any, of the many Stark exceptions apply to your arrangement is essential.



The nonmonetary compensation exception allows nonmonetary compensation to physicians from a referred-to entity if the compensation is in the form of items or services rather than cash or cash equivalents.



Preventive screening tests, immunizations and vaccines are exempted from Stark if they meet a number of requirements, including not violating the anti-kickback statute.



The fair market value exception can apply to transactions that don't quite meet all of the requirements of one of the other exceptions.

Fair market value

This is a very broad catch-all exception. It pertains to any compensation resulting from an arrangement between an entity and a physician (or an immediate family member) or any group of physicians (regardless of whether the group meets the definition of a group practice) for the provision of items or services by the physician, family member or group as long as the arrangement is set forth in an agreement that meets all of the following criteria:

- It must be in writing and must cover only specific identifiable items or services.
- It must specify the time frame, which can be less than a year as long as the compensation remains the same for each period within a year.
- When compensation is fixed for at least a year, it must be stated specifically in advance, must be consistent with fair market value and must not take into account volume or value of referrals.
- The transaction must be commercially reasonable and further legitimate business purposes of the parties.
- It must meet a safe-harbor regulation under the anti-kickback statute, be explicitly approved by the Office of the Inspector General (OIG) under a favorable advisory opinion or must not violate the anti-kickback statute.
- The services must not involve the counseling or promotion of a business arrangement or other activity that violates state or federal law.

This exception can function as a safety net, applying to transactions that don't quite meet all of the requirements of one of the other exceptions. For example, if a hospital is looking to recruit a new physician to its community and has made payments to that physician's group as a recruitment subsidy or to cover transition expenses, the arrangement would not meet the recruitment exception, which allows payment only to the recruited physician. However, if the payments from the hospital to the group meet the six criteria of this fair market value exception, the payments would be allowed.

Hospital incidental benefits

The Stark regulations explicitly permit hospitals to provide their medical staffs with

KEY POINTS

- The Stark statute can affect those with specific business interests as well as those whose sole focus is patient care.
- Final regulations on the last phase of the statute were expected to be published in the summer of 2003 but are not out yet.
- All of the statute and its exceptions, including those parts that have not yet been interpreted, are still in effect.

incidental benefits in the form of items or services (not including cash or cash equivalents) under the following circumstances:

- The item or service is used on the hospital's campus.
- The compensation is offered to all members of the medical staff but only during periods when the medical staff members are making rounds or performing other duties that benefit the hospital or its patients.
- The compensation is provided by the hospital and used by the staff members only on the hospital's campus.
- The compensation is reasonably related to the provision of medical services at the hospital or designed to facilitate (indirectly or directly) their delivery.
- The compensation is consistent with the types of benefits offered to medical staff members by other hospitals in the region or comparable hospitals in comparable regions.
- Each occurrence of the benefit is worth less than \$25.

- The compensation does not violate the anti-kickback provision and is not determined in a manner that takes into

account the volume or value of referrals.

For example, this exception explicitly allows free meals to hospital staff members when they are at the hospital and free parking for staff members who are coming to treat or see their patients in the hospital.

Hospital compliance training

This exception allows hospitals to provide compliance training to a physician or his or her family members who practice in the community as long as the training is held in

The fair market value exception can function as a safety net.

AN OVERVIEW

Following are some highlights from the first article in this series (“The Stark Truth About the Stark Law: Part I,” *FPM*, November/December 2003, page 27). See the article for more detailed information, including how the Stark statute applies to a list of real-world vignettes.

What the Stark statute is ... and isn't

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.” The lists of designated health services and financial relationships addressed by the statute are extraordinarily broad. To ensure you're not violating Stark, you must evaluate any economic benefits you receive from entities to which you refer Medicare and Medicaid patients to determine whether they meet any of the almost 20 detailed and complicated “exceptions” described in the statute.

One of the major misunderstandings about the Stark statute is that it is the same as the anti-kickback statute. Not only are they not the same law, they have a very different scope and are in two different titles of the Social Security Act. Yet, in every situation where the Stark statute applies, the anti-kickback statute applies too. If you survive the Stark analysis, you should conduct an anti-kickback analysis; if you don't survive the Stark analysis, an anti-kickback analysis is irrelevant because you shouldn't proceed with the transaction at all.

Key definitions

Understanding these key terms used in the statute is necessary to understand the exceptions to the statute:

- **Referral:** Any physician request for a service, item or good payable under Part B; a referral for a consultation and all the services ordered as a result of the consultation; and a prescription for a course of treatment using DHS. Referrals within a physician group are also implicated by the statute.
- **Designated health services:** This includes many of the ancillary services family physicians provide, such as clinical laboratory services, outpatient prescription drug services and physical and occupational therapy and imaging services (e.g., MRI, CT, ultrasound). Other examples of DHS include durable medical equipment and supplies; home health services; inpatient and outpatient hospital services; radiation therapy; parenteral and enteral nutrient equipment and supplies; and prosthetics, orthotics and prosthetic devices and supplies.
- **Fair market value:** Many of the Stark exceptions require that whatever financial relationship exists reflects fair market value. Financial terms that are negotiated between the parties would not necessarily meet this standard. Fair market value must be estab-

lished by reference to other prices for the same services in the community and agreed upon by both parties in an arm's-length transaction. The value must also be consistent with the “general market value,” which is the price an asset would bring as a result of bona fide bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business or compensate the other party.

- **Volume or value of referrals:** Many of the Stark exceptions require that any compensation involved be calculated in a manner that does not take into account the volume or value of referrals between the parties.
- **Group practice:** To qualify for several exceptions, such as referrals for in-office ancillary services and referrals to other physicians in the group, a practice must meet all of the elements of the Stark statute's definition of a group practice, which requires among other things that at least two or more physicians are legally organized and that each member of the group provides substantially his or her normal full range of DHS and other services in the group practice through the joint use of shared office space, facilities, equipment and personnel.

Exceptions

Following are two of the most notable exceptions to the Stark statute:

- **In-office ancillary services exception.** To meet this exception, a group must qualify as a group practice under the Stark definition, and in-office ancillary services must be furnished personally by the referring physician, by a physician who is in the same group practice or by individuals who are “directly supervised” by one of those physicians; must be provided in a building in which the referring physician or another member of the group practice furnishes physician services unrelated to DHS or in another building that is used by the group practice for “the centralized provision of the group's designated health services”; and must be billed by the physician performing or supervising them, by a group practice of which that physician is a member under a billing number assigned to the group, or by an entity that is wholly owned by such physician or such group practice.
- **Referrals for physician services within the group exception.** Referrals from one physician to another for physician services must be provided personally by or under the personal supervision of another physician in the same group practice.

SPEEDBAR®



Hospitals may provide their medical staffs with incidental benefits in the form of items or services under the hospital incidental benefits exception.



The hospital compliance training exception allows hospitals to provide compliance training to physicians as long as the training is held in the local community.



Many of the Stark exceptions require that any compensation involved be calculated in a manner that does not take into account the volume or value of referrals between the parties.



Two of the most notable exceptions to the Stark statute are for in-office ancillary services and referrals for physician services within the group.



The risk-sharing arrangements exception allows withholds, bonuses and risk pools as long as the compensation involved pertains to services provided to enrollees of a health plan.



To meet the lease arrangements exception, a lease must be “commercially reasonable in the absence of referrals between the parties,” among other things.



The bona fide employment relationship exception and the personal services arrangements exception apply to physicians engaged in administrative relationships with entities to which they refer.



The bona fide employment relationship exception explicitly allows productivity bonuses based on services performed personally by the physician.

the local community. “Compliance training” refers to training in the basic elements of a compliance program or specific training on the requirements of federal health care programs (e.g., billing, coding, reasonable and necessary services, documentation and unlawful referral arrangements).

Risk-sharing arrangements

This new exception allows withholds, bonuses and risk pools as long as the compensation involved pertains to services provided to enrollees of a health plan (regardless of whether the compensation comes from a managed care organization or an independent physicians’ association) and does not violate the anti-kickback statute or any other law or regulation. Most risk-sharing arrangements would meet this exception.

Lease arrangements

Lease arrangements between family physicians and entities to which they refer for designated health services (DHS) can implicate the Stark statute. This is particularly true when physicians lease equipment to a hospital or when a hospital leases space (or equipment) to physicians. To meet the lease exception for rental of office space or equipment, an arrangement must meet the following requirements:

- The parties involved must sign a written lease that specifies the premises covered by the lease.
- The space rented or leased must not exceed that which is reasonable and necessary for the legitimate purposes of the lease, and it must be used exclusively by

the lessee when the lease is in effect. This is intended to counter the risks of abuse, such as a physician entering into a lease arrangement for a space that far exceeds the amount he or she would be using simply to funnel money back to a referral source.

- The rent calculation for common areas, such as a waiting room or parking lot, must be based on a pro rata share of expenses.
- The rental charges must be set in advance, must be consistent with fair market value and must not be determined in a manner that takes into account the volume or value of referrals between the parties.

The preceding requirements are all consistent with the anti-kickback statute. The Stark statute includes one other requirement as well:

- The lease must be “commercially reasonable in the absence of referrals between the parties.” For example, if a mobile diagnostic services provider rents space in a family practice office to offer ultrasound testing (which is a DHS) and the only patients treated are Medicare and Medicaid beneficiaries referred by the family practice, the lease would not meet this requirement. However, if the mobile diagnostic services provider is simply performing pulmonary function tests or EKGs (which are not DHS), this criterion would not matter and the lease could proceed under the anti-kickback statute.

These same requirements pertain to equipment leases, although Stark also permits equipment leases that incorporate per-click or per-study payments (see part I of this series). For example, if a large primary care group with multiple locations purchases mobile imaging equipment that it makes available to a rural hospital and that members of the group use when their patients are in the hospital, the Stark statute would be implicated. Why? Because the physicians have a financial relationship with the equipment for which the hospital would be billing the technical components. However, under these circumstances, the regulators are not concerned that the primary care practice has an investment in the equipment that creates a financial relationship with the hospital. The trans-

action is considered legitimate as long as the rent paid by the hospital to the practice for the use of the equipment is consistent with fair market value, even if it’s calculated on a per-study or per-click basis.

Many family physicians are engaged in meaningful administrative relationships with entities to which they refer.

Bona fide employment relationship

Many family physicians are engaged in meaningful administrative relationships with entities to which they refer (e.g., being a medical director or a department chair or performing certain services for a home health agency by which they’re employed).

There are two exceptions in the Stark statute relevant to these relationships: the bona fide employment relationship exception and the personal services arrangements exception (described later).

The bona fide employment relationship exception allows payments of any amount by an employer to a physician or an immediate family member for providing covered services where the individual has a bona fide employment relationship as long as the following requirements are met:

- The employment is for identifiable services.
- The payment is consistent with fair market value and does not take into account volume or value of referrals.
- The arrangement is established in a contract that would be commercially reasonable even if no referrals were made to the employer.

This exception explicitly allows productivity bonuses based on services performed personally by the physician. However, unlike the productivity bonuses allowed under the group practice definition (see part I of this series), a productivity bonus under this provision may not include revenues from incident-to services.

Personal services arrangements

This exception allows a physician to be engaged in a contract that makes him or her, in essence, an independent contractor to the referred-to entity. The following requirements are necessary to meet this exception:

- The arrangement must be in writing,

signed by the parties specifying the services and covering all the services provided by the physician or immediate family member.

- The services must not exceed those that are reasonable and necessary.
- The contract must have a term of at least one year.

The regulators' failure to publish a complete set of regulations has contributed to many misperceptions about Stark.

- The compensation must not take into account the volume or value of referrals.

- The services must not involve counseling or promotion of a business

arrangement or activity that violates state or federal law.

This exception applies to most straightforward, fair market value, fixed-rate (e.g., \$10,000/year) personal services.

Physician incentive plans

The Stark statute allows physician incentive plans as long as no compensation between an entity and a physician or physician group is exchanged that may directly or indirectly have the effect of reducing or limiting medically necessary services to enrollees. These physician incentive plan requirements are what prevent hospitals from trying to lower their expenses by paying physicians part of the money saved from DRG payments (gainsharing arrangements).

The bright side

The regulators' failure to publish a complete set of regulations to date has contributed to many misperceptions associated with the Stark statute. However, because the regulatory interpretations that do exist liberalize parts of an otherwise daunting statute and define "group practice," there is much to be pleased about. Still, you should become familiar with the factors that may implicate the Stark statute and, because of the complexity of the law, obtain appropriate legal advice when there are financial relationships associated with designated health services provided to Medicare and Medicaid patients. **FPM**

*Send comments to
fjmedit@aafp.org.*

THE STATUS OF STARK

Only part of the Stark statute and several exceptions are interpreted in the regulations, which has contributed to many of the misperceptions associated with this law. Final regulations on the last phase of the statute were expected to be published in the summer of 2003 but are not out yet. Despite this, all of the statute and its exceptions, even those exceptions that have not yet been interpreted (investments, lease arrangements, personal services arrangements, bona fide employment relationships, physician recruitment, isolated transactions, physician purchases of services and others) are still in effect.