

The STARK TRUTH About the STARK LAW: Part I

The law addresses a wide range of services and financial relationships. Find out whether it affects you.

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The Stark statute has generated confusion and anxiety among physicians. Such reactions are understandable given how easy it is to violate the law and how severe the penalties are. This article is the first in a two-part series intended to defuse the confusion. It explains what the Stark statute is, how it differs from the anti-kickback statute and how you can determine whether it applies to you. It also defines some of the key terms used in the statute, and describes the standards for meeting the “group practice” definition and how the definition applies to two of the most notable exceptions to the statute (referrals for in-office ancillary services and to other physicians in the group). The second article will

focus on additional exceptions, such as those for lease arrangements and personal services contracts.

The basic prohibitions

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





The Stark statute applies only to physicians who refer Medicare and Medicaid patients for designated health services (DHS) to entities with which they (or an immediate family member) have a financial relationship.



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 “exceptions” described in the statute.



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Even referrals within a physician group are implicated by the statute.

patients to determine whether they meet any of the almost 20 detailed and complicated “exceptions” described in the statute (see “The exceptions” below).

Referrals and claims that violate the Stark statute are each punishable by a \$15,000 civil money penalty, any claim paid as the result of an improper referral is an overpayment, and circumvention schemes are punishable by a \$100,000 civil money penalty.

The Stark statute became effective on Jan. 1, 1995, but it was not until Jan. 4, 2001 – six years later – that the government released any final regulations interpreting the statute. Fortunately, the regulations are not as restrictive as they could have been, given the way the statute is written. Unfortunately, only part of the statute and several exceptions are interpreted in the regulations. This does not mean that the rest of the statute is not in force; it simply means there are many questions about the exceptions that remain unanswered. Final regulations were expected last summer, but they have not yet been published.

The Stark analysis

To determine whether the Stark statute applies to a particular arrangement, ask yourself these three critical questions:

1. Does this arrangement involve a referral of a Medicare or Medicaid patient by a physician or an immediate family member of a physician?
2. Is the referral for a “designated health service”?

THE EXCEPTIONS

The almost 20 exceptions to the Stark statute address many different types of referrals, including the following:

- To other physicians in the group,
- For in-office ancillary services,
- Within prepaid health plans,
- To entities in which the physician is invested (including publicly traded entities, hospitals in Puerto Rico, rural providers and a hospital itself).

The statute also describes some other exceptions, such as when financial relationships include the following:

- Rental of office space and equipment,
- Bona fide employment relationships,
- Personal services arrangements,
- Physician recruitment.

KEY POINTS

- The Stark statute applies only to physicians who refer Medicare and Medicaid patients for designated health services to entities with which they (or an immediate family member) have a financial relationship.
- There are almost 20 exceptions to the Stark statute.
- To qualify for several exceptions, a practice must meet the statute’s definition of a “group practice.”

3. Is there a financial relationship of any kind between the referring physician or a family member and the entity to which the referral is being made?

To answer these questions, you’ll need to better understand some of the terminology used in these three questions and other parts of the statute. Then, if you determine that your answer to any question is “no,” Stark does not apply. If your answers to all three questions are “yes,” you’ll need to determine whether any of the exceptions apply to your situation.

Critical definitions

Although it is beyond the scope of this article to address all of the definitions in the Stark law, it is important to understand several core concepts that appear throughout the statute – referrals, designated health services, fair market value and volume or value of referrals:

- All of the following qualify as a “**referral**” under Stark: 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. Note that referrals within a physician group are also implicated by the statute.
 - The Stark law only applies to “**designated health services**,” which include 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.

Because these terms are not very precise, the regulators have established a list of DHS organized by CPT code.

For example, at the moment, nuclear medicine and PET scans are not included as imaging. If a service is not on the hit list, Stark

will not be violated. (The hit list is available online at <http://www.cms.hhs.gov/medicare/currentcodes.pdf>.)

• 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 established 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.

• Many of the Stark exceptions also 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. However, in an almost counterintuitive interpretation of the law, the regulations explicitly state that time-based or unit-of-service-based payments are allowed “even when the physician receiving the payment has generated a payment through a DHS referral.”¹ For example, if a group of pulmonologists leases an X-ray machine from a group of family physicians who otherwise refer to the pulmonologists, the rent paid to the family physicians generating the referrals can be paid on a “per click” basis. In this type of situation, the amount paid to the physician who is making the referral will not violate the Stark statute as long as the

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To qualify for several exceptions, a practice must meet all of the elements of the Stark statute’s definition of a group practice.

STARK VS. THE ANTI-KICKBACK 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:

- The Stark statute pertains only to physician referrals under Medicare and Medicaid (“physicians” includes chiropractors and dentists but not midlevel providers, such as nurse practitioners and physician assistants); the anti-kickback statute is far broader and affects anyone engaging in business with a federal health care program.
- The Stark statute does not require bad intent (i.e., a tainted financial relationship violates the Stark law regardless of good intentions); the anti-kickback statute requires intent, but it must be specific intent (i.e., not just intent that might merely be inferred from a pattern of behavior).
- The Stark statute exceptions define the boundaries of permissible behavior. The statute is a prohibition that can only be overcome by complying explicitly with an exception. The anti-kickback “safe harbor” regulations describe transactions that may tend to induce referrals but don’t necessarily violate the law. The safe harbor regulations state clearly that transactions that don’t meet a safe harbor don’t necessarily violate the statute; a prosecutor will evaluate the facts and circumstances to make that determination.
- A Stark violation is punishable by civil money penalties; an anti-kickback violation is punishable by exclusion from federal health care programs, criminal penalties of up to \$25,000 in fines or up to five years in jail (or both) and a \$50,000 civil money penalty for each violation.

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.



A group practice must involve at least two or more physicians who are legally organized in a partnership, professional corporation, foundation, nonprofit corporation or other similar association.



A group must also function as a unified business, with centralized decision making; consolidated billing, accounting and financial reporting; and centralized utilization review.



Cost centers are allowed as long as the accounting methods used to create them do not produce profit sharing or compensation that reflects the volume or value of DHS referrals.



Physicians in a group may share in the overall profits of the group and may be paid a productivity bonus, as long as certain standards are met.

payment per unit is at fair market value and does not change during the term of the contract that establishes the relationship.

Defining "group practice"

Another critical term in the Stark statute is "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. These are the keys to being considered a group practice under Stark:

- **A group practice must involve at least two or more physicians who are legally organized in a partnership, professional corporation, foundation, nonprofit corporation or other similar association.**

A sole proprietorship with employees, which is not "legally organized" as a group, cannot qualify as a group practice under the definition.

- **Each physician who is a member of the group (including shareholders, partners and employees but not independent contractors) must provide 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.** For example, if a family practice group hired a part-time ob/gyn just to perform colposcopies, which are not designated health services, and the ob/gyn does more than just colposcopies in his or her own practice, this full-range-of-service test would not be met and the group would not qualify as a group practice under the definition. Consequently, all of the group's DHS referrals would violate the Stark statute.

- **The group must function as a "unified business."** A unified business requires (1) centralized decision making by a body of the practice that maintains effective control over the group's assets and liabilities including budgets, compensation and salaries; (2) consolidated billing, accounting and financial reporting; and (3) centralized utilization review. In essence, a practice must operate out of one financial identity to meet the standards for a unified business. However,

this does not mean that the group cannot have cost centers, for example, by office location. Cost centers are allowed, provided the accounting methods used to create them do not produce profit sharing or compensation that reflects the volume or value of DHS referred by the physicians. Generally, the Stark statute requires that no physician may be compensated in a way that rewards referrals; however, physicians may share in the "overall profits of the group" and may be paid a "productivity bonus" for their own services or services "incident-to" their services, as long as certain standards are met (see "When profit sharing and productivity bonuses exist," on page 31).

- **Substantially all of the services of the physicians who are members of the group must be provided through the group and billed under a billing number assigned to the group; and amounts received must be treated as receipts of the**

group. This requires using a single taxpayer identification number. Yet simply having one tax ID number is not enough. Smaller groups that want to merge to take advantage of the ancillary revenues allowed under the Stark statute often say, "We want to operate just as we did but under one tax ID number," or, "We want a group practice without walls." However, these desires are unrealistic under the law. A group must function as a real group to meet the Stark definition of a group practice.

- **The group's overhead expenses and income must be distributed in a manner that is established before payment is received for the services that create the overhead expense or income.** Let's say the decision is made that each physician will have assessed against his or her gross revenues 25 percent of the fixed overhead of the group and 100 percent of the salary of the nurse assigned to him or her. If the physician's revenues are lower than expected, the group cannot lower the percentages applied to monies already received but can adjust for the rest of the year as long as the methodologies don't reflect the volume or value of DHS referrals.

- **When taken as a whole, the amount**

To qualify for several exceptions, a practice must meet all of the elements of the Stark statute's definition of a group practice.

of time physician members of the group (excluding independent contractors) spend in work dedicated to the group must average 75 percent. This standard is intended to weed out virtual groups, partially integrated groups and groups in which physicians do not have their core activities dedicated to the group. For example, if five physicians work full time with the group and one works half time with the

group and half time with the university, the average for the group would be an acceptable 91.7 percent. However, if two family physicians, two internists and an ob/gyn form a women's health practice and hire a breast surgeon, a radiologist and a gynecologic oncologist to each spend one day a week with the practice, the overall percentage would only be 70 percent, meaning the practice could not internally refer for

WHEN PROFIT SHARING AND PRODUCTIVITY BONUSES EXIST

Although the Stark statute does not allow physicians to be compensated in a way that rewards referrals, physicians in a group may share in the "overall profits of the group" and may be paid a "productivity bonus" for their own services or services "incident-to" their services, as long as certain standards are met.

When profit sharing exists, a group that meets the statute's group practice definition must distribute a share of the overall profits from the designated health services (DHS) to the entire group or to a component of the group that consists of at least five physicians. These "pods" of five may be aggregated on any basis the group chooses (e.g., by location, specialty or seniority), as long as the compensation does not reward volume or value of referrals directly. The Stark regulations set forth three profit-sharing models: (1) a per capita or per-physician division of profits (e.g., each physician could be paid an equal share of the profits), (2) a distribution of DHS profits based on the distribution of the group practice's revenues attributed to non-DHS services (e.g., profits could be distributed based on the volume of each physician's evaluation and management (E/M) services since E/M visits are not DHS), or (3) any distribution of DHS revenues if the group practice's DHS revenues are less than 5 percent of the total revenues and no physician gets more than 5 percent of his or her total compensation from that allocation. Groups are not required to use these particular methods; any method is acceptable as long as it is reasonable, objectively verifiable and indirectly related to referrals.

A physician can receive dollar-for-dollar credit as a productivity bonus for services that are provided by the physician or by ancillary personnel that are an integral although incidental part of the physician's service to the patient. When incident-to services are performed, one physician member of the group must be in the office suite unless the services are diagnostic, in which case the rules on diagnostic services supervision pertain. Since Medicare services that are billed "incident-to" are always billed as if the physician performed them, they require the treating physician's provider number. For example, a family physician who orders and interprets a chest X-ray may be given direct productivity credit for the associated technical component revenues. However, a family physician who refers a patient to a cardiologist in the group to perform an echocardiogram may not get credit for the technical component of that echocardiogram since the service is incident-to the cardiologist's interpretation. Services of nurse practitioners, physician assistants, psychologists or others that are billed on their own numbers, even if those revenues are assigned to the physician group, are not incident-to services and may not be attributed directly to the treating physician. However, those revenues may be shared in the overall profit distribution. (For more information on the incident-to requirements, see "The Ins and Outs of 'Incident-To' Reimbursement," *FPM*, November/December 2001, page 23, and for more information on diagnostic services, see "Diagnostic Testing and Medicare: How to Get Paid Without Getting in Trouble," *FPM*, June 2003, page 14.)

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The overhead expenses and income of a group must be distributed in a manner that is established before payment is received for the services that create the overhead expense or income.



The Stark regulations set forth three profit-sharing models, but groups are not required to use them as long as what they do use is reasonable, objectively verifiable and indirectly related to referrals.



A physician can receive a productivity bonus for patient services that are provided by the physician or incident-to the physician's service.



The amount of time physician members of the group spend in work dedicated to the group must average 75 percent.



This is intended to weed out virtual groups, partially integrated groups and groups in which physicians do not have their core activities dedicated to the group.



To refer patients to your own nurses or technicians for in-office ancillary services, your group must qualify as a group practice and meet the three standards for in-office ancillary services.



In-office ancillary services must be furnished by the referring physician, by a physician in the same group practice or by individuals who are "directly supervised" by one of those physicians.

any Medicare or Medicaid DHS. But if the part-time physicians were independent contractors, the group would qualify. Note that just because a physician works part time does not necessarily mean he or she counts as part time. For example, if a family practice group hires two physicians who only work 50 percent of the time but all of their professional time is devoted to the practice, they each count as 100 percent rather than 50 percent.

Exception: Referrals for in-office ancillary services

To refer patients to your own nurses or technicians for in-office ancillary services, such as X-rays, your group must qualify as a group practice under the Stark definition. These three standards must be met as well:

• **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**

DOES IT VIOLATE STARK?

? A family physician invests in an imaging center to which he does not refer Medicare or Medicaid patients. However, he does refer to an orthopedist who orders an MRI from the center. Does this violate Stark?

Yes, because the orthopedist's order is a downstream referral for a designated health service (DHS).

? A pulmonologist opens an office in a building owned and occupied by a multispecialty group that includes family physicians, and she enters into a lease arrangement in which she uses the office only when the building owners have patients for her to see for evaluations and pulmonary function tests (PFTs). Do the family physicians' referrals to the pulmonologist violate Stark?

No, because neither evaluations nor PFTs are DHS.

? A multispecialty group with multiple offices sets up a new office to house all of its diagnostic testing, including clinical laboratory services, X-ray and physical therapy. There are no other physician offices at this new location. All the physicians in the group refer patients to it, and the services are provided by nonphysicians. The profits are shared among the physician shareholders based on the locations where they work (each of which has at least five shareholders) and are divided based on the number of evaluation and management (E/M) services each physician renders by comparison with his or her peers at that location. Does this violate Stark?

No. This arrangement qualifies for the in-office ancillary services exception. The ancillary services office is considered a centralized location under the Stark statute, and no physician supervision of the services is required. The profit sharing in this arrangement does not reflect volume or value of referrals for DHS.

? A family physician group installs an X-ray machine for the convenience of its patients. Nonphysicians do the X-rays, and the family

physicians bill and receive direct credit in their compensation plan for the technical component of the service (regardless of whether they were in the office to supervise). They send the films to a radiologist who performs and bills for the interpretation. Does this violate Stark?

No. This arrangement qualifies for the in-office ancillary services exception. The technical components are provided incident-to the physician's treatment of the patient, and, for this service, there is no requirement that a physician be on premises.

? Three small physician groups form one partnership to share office expenses and some ancillary service expenses, such as for clinical laboratory and X-ray services. The groups share ownership of the equipment and hire technicians to perform the services, which are all provided in the same building. Two of the groups bill using the number assigned to the partnership, but two physicians in the third group bill all of their services on their own numbers. Does this violate Stark?

Yes. Even though the three groups have a Medicare provider number and tax ID number for the partnership, they do not meet the Stark statute's definition of a group practice because not all of the services are billed through the partnership's numbers.

? A family physician's husband is a pathologist and shareholder in the only group in town that performs hospital laboratory services. The family physician refers her Medicare and Medicaid patients to this group for hospital laboratory services, and the pathologists bill Medicare for their own services. Does this violate Stark?

Yes, because the family physician and the pathologist are immediate family members. Stark would require that either the family physician not refer her Medicare and Medicaid patients to that group or that the husband not be a shareholder in the pathology group.

“directly supervised” by one of those physicians. Although the Stark statute uses the phrases “personal supervision” and “directly supervised,” the regulators have interpreted both of these to mean supervised to the extent otherwise required in the Medicare program. For example, since Medicare physical therapy does not require an on-premises physician for the services to be covered, “direct supervision,” according to Stark, does not actually require that a physician be in the office suite. A group could bill for Medicare physical therapy services when the services are provided by a physical therapist employee or an independent contractor who reassigns his or her right to payment to the group. However, if the services are not billed incident-to the physician, he or she cannot receive credit as the treating physician for those revenues. (For more information on the incident-to requirements, see “The Ins and Outs of ‘Incident-To’ Reimbursement,” *FPM*, November/December 2001, page 23.)

• **In-office ancillary services 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.”** For example, if a group practice has multiple offices and one of the physicians in the group wants to refer a patient for X-rays to be performed at a second office, group physicians at the second office must be performing other non-DHS services, such as basic patient office visits, pulmonary function tests and electrocardiograms. Also, since multiple “centralized locations” are allowed, a practice can have an office for a clinical lab, a building for imaging and a separate physical therapy clinic. However, if, rather than referring to the owners of advanced high-tech equipment such as MRI or CT machines, members of a group practice use the equipment themselves by renting space on a part-time basis at a location that uses the equipment, the group must provide its normal full range of services at the MRI or CT location to meet the standard for in-office ancillary services. This is intended to prevent a group practice from realizing profits on services with which they have relatively little operational connection.


• **In-office ancillary services 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. The “wholly owned” standard has led to problems when a group practice decides to operate a physical therapy business or a diagnostic testing arm of the group practice under a separate corporate identity. Unless the ownership in the group practice is the same as the ownership in the ancillary entity, the referrals will not meet the in-office ancillary services exception.

Exception: Referrals for physician services within the group

This exception is for referrals from one physician to another for physician services provided personally by or under the personal supervision of another physician in the same group practice. The phrase “in the same group practice” is not the same as “a member of the group practice.” In fact, the regulations state that an independent contractor physician can qualify in certain circumstances as being in the group practice even though, for purposes of determining whether the group meets the definition of a group, the independent contractor does not qualify as a “member” of the group. So a part-time, independent contractor physician can accept referrals within the group, supervise for the purpose of providing in-office ancillary services and be paid a productivity bonus.

Know the basics

The fundamental aspects of the Stark law discussed in this article are basic issues about which all family physicians treating Medicare and Medicaid patients should be knowledgeable. Because of the complexity of the law, it is important to obtain appropriate legal advice for any arrangement that could potentially violate the Stark statute. 

Editor’s note: Look for the second part of this series in an upcoming issue to learn about the exceptions related to lease arrangements and personal services contracts as well as some additional regulatory exceptions.

Send comments to fpmedit@aafp.org.

1. 66 Federal Register 876 (Jan. 4, 2003)

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And they must be billed by the physician performing or supervising them, by the physician’s group under its billing number, or by an entity that is wholly owned by the physician or group practice.



There is also a Stark exception for referrals from one physician to another for physician services provided personally by or under the personal supervision of another physician in the same group practice.



It is important to obtain appropriate legal advice for any arrangement that could potentially violate the Stark statute.