

Governmental Regulations Affecting Medical Practices

What you need to know about the Anti-Kickback Act, Stark Law, and the False Claims Act.

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As compensation for professional services decreases and practice overhead increases, physicians have turned to ancillary services to maintain financial viability. As providers add new service lines and enter into relationships with hospitals and other entities, they face regulations that are easily violated if laws affecting these programs are not understood. This article provides an overview of legal constraints that may affect physician practices.

ANTI-KICKBACK ACT

The federal Anti-Kickback Act was intended to protect patients and federal health care programs by eliminating the corrupting influence of money on health

care decisions. Anyone who knowingly and willfully receives or pays anything of value to influence the referral of federal health care program business can be accountable under this law and may result in up to 5 years in prison, criminal fines of up to \$25,000, civil penalties up to \$50,000, and exclusion from participation in federal health care programs. Penalties may apply to all parties in the transaction. In addition, the tax-exempt status of a hospital or other exempt facility may be jeopardized for violations of the Anti-Kickback Act. As opposed to the Stark Law, the Anti-Kickback statute is a felony offense.

A flagrant example would be payment of cash by a surgeon to members of a family practice group in return

ANTI-KICKBACK CASE STUDIES

CASE 1. CASH PAYMENTS FOR REFERRALS

During an investigation of a clinical laboratory in Florida for massive Medicare fraud, it was discovered that the entity had been paying kickbacks to physicians in return for their referrals. Prosecutors accused primary care physicians of receiving nearly \$1 million in bogus consulting fees in return for their business. It was determined that the lab paid monthly fees between \$500 and \$1,500 to consulting physicians based on the volume of their referrals. Their duties were defined as "medical review" or "test review." In one case, the laboratory paid the annual fee for a physician's hunting lodge membership. Twelve of these providers were indicted for violating the federal Anti-Kickback law. Two of the physicians were convicted at trial and sentenced to prison terms in addition to monetary fines. The remaining 10 physicians pleaded guilty, and they faced probation and community service in addition to fines. All 12 physicians faced mandatory 5-year exclusion from Medicare and

Medicaid. The government did not contest the fact that the blood tests they had ordered were medically necessary.¹

CASE 2. BILLING FOR FREE SAMPLES

In one of the largest health care fraud settlements in history, TAP Pharmaceuticals (Lake Forest, IL), agreed to pay \$875 million to resolve civil and criminal charges based on marketing conduct and fraudulent drug pricing. TAP provided free samples of its drug Lupron to physicians who subsequently sought Medicare reimbursement for administering the free sample. Five physicians were charged and were alleged to have conspired to receive excessive Medicare reimbursements. TAP was also charged with giving physicians excessive gifts including trips to golf and ski resorts and free consulting services. Legal claims included conspiracy to defraud Medicaid, conspiracy to violate the prescription drug marketing act, and violations of the federal Anti-Kickback statute.²

for their referral of patients for operative procedures. A receipt of payment by a physician from another entity also constitutes a violation (see the sidebars for examples of physician culpability).

The Anti-Kickback Act is very broad and thus alarmed health care providers because they had the potential for prosecution for relatively innocuous arrangements. In 1987, Congress authorized the Office of the Inspector General (OIG) to design "safe harbors" for various arrangements that might have benefit but in which the participants could potentially face felony litigation. These safe harbors immunize certain payment and business practices from prosecution. They included such things as investments in ambulatory surgical centers (ASC), joint ventures in underserved areas, practitioner recruitment in underserved areas, subsidies for obstetrical malpractice insurance in underserved areas, and cooperative hospital services organizations.

In 2006, the OIG established a new safe harbor under the federal Anti-Kickback Act for certain arrangements related to electronic prescribing and electronic health records. It would protect hospitals and other entities that provide recipients, such as physician practices, with non-monetary remuneration in the form of computer hardware or software. These regulations became effective October 10, 2006.

STARK LAW

The Stark Law, also known as the Ethics in Patient Referrals Act, became effective January 1, 1992, and was known as Stark I after Fortney "Pete" Stark, representative from the state of California. It prohibits physicians from making referrals to entities in which that physician or an immediate family member has a financial relationship. The purpose behind the Stark Law was to prevent abuse in the medical system stimulated by a physician's financial gain when ordering unnecessary tests or treatments. Ownership interest can be direct or indirect, such as through a holding company. Penalties for violation of the Stark Law range up to \$15,000 for each service and exclusion from federal health care programs. Lack of knowledge of the provisions of the law does not preclude liability. The government defines the services called Designated Health Services (DHS) that are covered by this law. They include:

- Clinical laboratory services
- Physical therapy services
- Occupational therapy services
- Speech and language pathology services
- Radiology services including MRI and CT scans
- Radiation therapy services
- Durable medical equipment

- Parenteral and enteral nutrients, equipment, and supplies
- Prosthetics, orthotics, and prosthetic devices and supplies
- Home health services
- Outpatient prescription drugs
- Inpatient and outpatient hospital services

Nuclear medicine studies were previously exempted from the Stark Law, but this changed in January of 2007.

Of importance to the practicing physician is the existence of exceptions that do permit a physician's financial participation in DHS. However, understanding the com-

STARK CASE STUDIES

CASE 3. REFERRAL TO HEALTH CARE SYSTEM WITH FINANCIAL INTEREST

A physician owner of a medical clinic settled allegations that he violated the Stark Law by paying a fine of \$1.7 million. The government stated that patients were referred to a home health agency where the physician had a significant ownership interest.

In a similar case, a lawsuit was lodged against an orthopedic surgeon stating that the surgeon illegally referred patients to a home health care system in which he had a significant financial interest. The lawsuit stated that 48 patients were self-referred and this resulted in Medicare/Medicaid billings totaling \$250,000. The dollar amount of the settlement was not made public.³

CASE 4. UNDERCHARGING FOR OFFICE SPACE AND NURSING CARE

A physician group and a hospital in Rapid City, South Dakota, paid more than \$6.5 million in fines to settle allegations that they violated the Stark Law. They were alleged to have billed Medicare for services that resulted from referrals from physicians with whom it had improper financial relationships. The hospital allegedly rented office space to physicians at only 10% of the market value and undercharged physicians for nursing services. The entities did not meet the exception requirements to the Stark Law. Various compensation arrangements do fall under the exception requirements such as personal service agreements and leases, but they are generally required to be consistent with fair market value. The parties denied guilt and agreed to enter Corporate Integrity Agreements with the federal government to ensure future compliance.⁴

plexities of these exceptions is difficult. Examples include fair market value compensation arrangements, certain space and equipment rentals, and some types of incentive plans in the managed care setting.

One of the most widely used exceptions is that which applies to properly organized group practices. If the practice functions as a group and provides medical services to its patients, physicians in the group are permitted to engage in various ancillary services that fall under DHS. The service must be seen as an extension of the practice, and restrictions on the location of the facility and type of supervision must be met. Case 3 includes two examples of Stark Law violations.

In summary, the existence of three tenets constitute a Stark Law violation:

- The existence of a financial relationship between a physician or family member and another entity
- Proof that the physician referred a patient to the entity for a DHS
- An exception does not exist

One of the central tenets of the "in-office" exception is that physicians must not receive compensation based directly or indirectly on the volume of DHS referrals. In addition, the service supplied must generally be in the same building as the offices of the practice. However, it may be performed in another building if the practice owns or leases the space on a full-time basis. In-office ancillary services must be directly supervised. Case 4 is an example of an improper physician/hospital relationship that was alleged to have violated the Stark Law.

There are legal firms that specialize in Stark Law arrangements, and the Medical Group Management Association has a section of its Web site dedicated to understanding the law's complexities.

STARK LAW VERSUS ANTI-KICKBACK ACT

There is sometimes confusion regarding the differences between the Stark Law and the Anti-Kickback Act. The following points emphasize these differences:

- The Anti-Kickback statute includes criminal and civil penalties for entities or individuals that knowingly pay, offer, or receive financial remuneration to generate referrals covered under the CMS services, whereas the Stark Law results only in civil penalties.
- The Anti-Kickback statute encompasses all services covered under governmental programs, whereas the Stark Law refers to a list of DHSs.
- The Stark Law generally applies to physicians, whereas the Anti-Kickback statute is a more broadly encompassing statute.
- The Anti-Kickback Act generally requires a demonstration of intent to violate the law.

In some cases, financial arrangements between physi-

FALSE CLAIMS CASE STUDY

CASE 5. BILLING FOR UNNECESSARY OR UNPROVIDED SERVICES

A Roswell, Georgia obstetrician was accused of billing the Medicaid program for services that were never provided and services that were not medically necessary. He billed Medicaid for patients he had never seen and for sonograms that were not provided. In one case, he billed Medicaid for 92 sonograms on a single patient over a 3.5-year period. He pled guilty to defrauding Georgia's Medicaid program of more than \$1 million. He was sentenced to 5 years in prison, ordered to pay restitution of \$1,055,000, serve 500 hours of community service, surrender his medical license, and was banished from the Georgia Medicaid program.⁵

cians and hospitals may violate both the Stark Law and the Anti-Kickback Act.

FALSE CLAIMS ACT

The False Claims Act is sometimes referred to as the "Lincoln Law." The purpose of the law was to respond to fraud from companies selling supplies to the Union Army. One example of this was shipping boxes of sawdust to the military instead of guns. Under its provisions, private citizens known as "realtors" could sue offending companies, and they received 50% of the amount recovered. The government received the rest. These were the first whistle-blowers.

The law was revised and, in 1986, it prohibited any type of fraud against the US government. With regard to health care, it prohibits the deliberate submission of a false or fraudulent claim for payment from any federal health care program. In addition, "whistle-blowers" receive anywhere from 15% to 30% of monies recovered by the government. Attorneys representing these individuals or entities are guaranteed compensation for their regular hourly fees. Examples of false claims include:

- Claim for a service not reasonable and necessary
 - Claim for a service that was never provided
 - Claim for a service in which the diagnosis code has been knowingly listed incorrectly
 - Claim for a service provided by an unlicensed practitioner
 - Claim for a higher level of service than was provided
- CMS violations result in penalties of up to \$2,000 for each improper item or service. The practice is also liable

for civil penalty between \$5,500 and \$11,000 for each false claim and could be held liable for three times the amount of the claim. In the first 6 months of the 2005 fiscal year, settlements in judgments falling under the False Claims Act amounted to nearly \$900 million. An example of a False Claim violation is shown in Case 5.

GAINSHARING

Gainsharing originated with manufacturing firms, and many large companies allow workers to share financially in productivity improvements as a result of workers' contributions. In health care, gainsharing is an arrangement whereby a physician or group of physicians develops cost-saving measures in certain treatment protocols, which would result in financial savings. In this type of arrangement, the hospital and the physician or physicians would share the profits gained from this endeavor.

Although in some cases such streamlined programs might be beneficial, the OIG has usually indicated that these associations violate the Civil Monetary Penalties section of the Social Security Act. This prohibits hospitals and physicians from conspiring to reduce benefits to Medicare beneficiaries. Fines of up to \$2,000 may be imposed for each affected patient.

There have been cases where the OIG has sanctioned some gainsharing arrangements. This occurred at an Atlanta hospital in reference to a cardiac surgical program. Subsequent to this, however, a federal court ruled that another gainsharing arrangement at the Robert Wood Johnson Hospital in New Jersey was in violation of the law and ordered the program terminated. Because of the potential benefit of gainsharing programs for patient efficiency and safety, the OIG is allowing six new programs to function on a trial basis starting in 2007.

FEDERAL REGULATIONS

In addition to the previously mentioned laws, there are additional areas in which physicians may face federal regulations. Five of them are listed in the following paragraphs.

Concierge Medicine

Physicians have had to expand their patient base in order to maintain the financial integrity of their practice. Many providers believe this results in a decrease in the quality of care. In order to provide quality care to a smaller number of individuals, some practices utilize concierge medicine.

In this instance, the patient pays a fee to the practice for preferred treatment, which may include longer office visits, physician accompaniment to a visit with a specialist, and 24/7 access to the physician or the practice. This fee is paid in addition to the health care premiums

charged by third-party providers. Problems may arise with CMS if they believe any of the added services are covered by their Medicare benefits.

Medical Directorships

In the past, medical directorships were used by hospitals as a means of conveying money to a physician or group of physicians who served as directors of various programs in the hospital. In many instances, the duties of the medical director were not specified, and the amount of compensation was excessive. Theoretically, hospitals could use this mechanism to maintain the loyalty of physicians on its staff and ensure the flow of patients to the institution for diagnostic and therapeutic procedures.

In many cases, medical directors serve a valuable function, although it is probably best to refer to these as *medical consultation agreements*. The hospital should specify the duties that will be performed by the medical director and the time that will be spent in these efforts. The compensation should be at fair market value.

Industry-Physician Relationships

There is increasing concern by the government, the public, and the medical community about actions of the pharmaceutical and device industries when attempting to get their product to the marketplace. Several large firms have been indicted for their actions in this regard.

In addition, there is growing concern about the influence that gifts and payments from the pharmaceutical and device manufacturing industry have on various treatment recommendations by physicians. The pharmaceutical industry has developed a code of ethics relative to physician relationships, and device manufacturers have done the same. Their latter code of ethics (AdvaMed) is a voluntary commitment to facilitate ethical interactions with healthcare providers and those responsible for purchasing medical equipment.⁶

ASCs

ASCs have some special considerations with regard to legal statutes. Most of these entities are established as limited liability companies and may be owned by physician groups or in conjunction with a hospital. They are subject to accreditation by various national organizations, including a Medicare certification if they accept CMS patients. In some states, a Certificate of Need is required.

Generally, the Stark Law does not apply in these arrangements because global payments for the facility include routine testing as a part of the surgical procedure. The professional fee is billed by the physician's office. With regard to the Anti-Kickback Act, certain safe harbors apply to the ASC. Their purpose is to ensure that physi-

cians and surgeons use the ASC to perform procedures related to their practice and not solely for economic gain.

Advanced Beneficiary Notice

In the case of noncovered services, the beneficiary of such services is expected to pay unless he or she had no way of knowing that the services were not covered. In these cases, the physician may ask the patient to sign a form indicating that there was prior knowledge that the service would not be covered. This form must be signed if the physician wants to bill the patient.

In an emergency situation when the patient is incapable of signing, the physician cannot seek payment from the patient. If the patient needs treatment and refuses to sign such a form, the physician can choose either not to provide the service or to provide the service realizing that he/she may not receive payment.

CONCLUSION

Economic realities in today's health care environment have placed a significant strain on medical practices. Physicians have increased their clinical volume in an effort to maintain the financial viability of their practices. A point has been reached, however, where increasing patient load will have a detrimental effect on the quality of care. For this reason, many practices have looked for alternative sources of funding. As ancillary services are added, providers face a number of federal and state regulations, many of which were described in this article. The statements and descriptions in this article were not meant to provide legal advice. Rather, it serves as a means of familiarizing physicians with the problems they will face and the areas in which they will most likely need legal counsel. ■

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