Health care reform, rising costs, and an increased number of health management organizations have led health care providers to seek new and more profitable business relationships. These new business relations include, among others, physician mergers, physician networks, hospital–physician joint ventures, and other types of hospital affiliated physician networks. These types of arrangements often raise legal concerns surrounding possible kickbacks, self-referrals, false claims, and even antitrust violations. It is important that all these legal issues be understood and that potential business relations be analyzed not only from a financial prospective, but also from a legal and regulatory prospective. Taking such matters into account during the planning stage will help businesses and individuals alike structure organizations so as to avoid the potential civil and criminal consequences of violating the law.

Historically, the legal structure of the health care delivery system in the United States consisted almost exclusively of personal interactions between patients and physicians. Whenever an individual was in the need of medical care he or she could call their physician personally to arrange for an appointment. Those days are all but over. Today, the health care delivery system is dominated by corporate entities with investors focused on profitability or large nonprofit organizations. As a result, the industry has evolved from one made up mostly of individual physicians to an industry dominated by medical groups including from physician-owned entities, independent practice associations (IPA), hospitals, and ancillary providers.

**Physician-Owned Entities**

Physician-owned entities that provide medical care range in nature from those entities that are owned solely by physicians, to those owned partly, or solely, by non-physicians. Generally, these entities are formed as professional corporations, limited liability companies, or
business corporations. When deciding upon a legal structure for a given medical practice, it is important to keep in mind what is referred to as the Corporate Practice of Medicine Doctrine (CPMD).

In general terms, the CPMD prohibits unlicensed individuals or entities from “practicing medicine.” The term *practicing medicine* can mean employing health care professionals, owning professional practices, providing medical diagnoses, and treating patients. As a result, the doctrine prohibits the ownership of diagnostic testing facilities by someone other than a licensed physician.

Historically, the CPMD arose from physicians’ fear that corporations might unduly influence their decisions regarding level of care and amount of treatment, all in an effort to increase corporate profits. Consequently, some jurisdictions prohibit physicians from splitting professional fees with unlicensed entities or individuals.

State corporate practice of medicine laws can potentially affect the ability of a risk-sharing organization to offer both facility and professional services, or to create a single-provider risk-sharing organization. The scope and effects of the CPMD vary from state to state and must be analyzed on an individual state level. In certain states, such as Florida, any person or entity can employ or contract with a physician. Other states have created narrow exceptions dealing with specific types of organizations, such as not-for-profit corporations or hospitals. Still others will allow certain entities to contract with physicians, but only under an independent contractor arrangement. Finally, some states allow only licensed entities comprised of physicians to employ or even contract with other physicians. Any exceptions to the CPMD, and whether a CPMD exists in a particular state, are state-specific issues and require individualized analysis.

**Independent Practice Associations**

In the late 1980s and early 1990s, managed care contracts became very complex. It was no longer a process of physicians simply offering discounts to particular insurance carriers. In an effort to better control costs and help increase profits, insurance carriers proceeded to take a greater role in the supervision of patient treatment. Soon, insurance carriers became so involved in the supervision of patient care that physicians began to feel that their physician–patient relationships were being adversely affected. Consequently, physicians approached insurance carriers in an attempt to find a way to regain the authority to independently manage their patients’ care. The effect was the creation of what is known as an IPA.

IPAs are a form of business organization (generally formed as a limited liability company, professional corporation, business corporation, or partnership), that provides a very limited degree of integration between medical practices. They were created by physicians to obtain capitated or other risk-sharing payer contracts. All medical practices contained within a particular IPA continue to operate as their own independent business enterprise. In fact, many physicians within an IPA continue to compete even among themselves. Thus, an IPA is simply a means of supplementing a physician’s existing private patient base, not a vehicle to completely integrate their practices. Nevertheless, every IPA is different and can choose to implement its own desired level of operational integration. Consequently, there exist many “types” of IPAs depending on the individual level of integration. Interestingly enough, IPAs do not actually provide medical care to patients. IPAs simply arrange for health care services to be provided by independent physicians or small group practices.

Generally, ownership interests in an IPA are sold to physicians in exchange for start-up working capital. The IPA then enters into payer contracts and collects fees related to professional services. Thereafter, the IPA enters into professional service agreements with its owners (physicians) who in return end up personally employing the majority of personnel that the physician needs in order to operate his or her private practice. To the extent that an IPA takes over individual physicians’ billing and collection activities, the IPA moves closer to becoming an integrated group practice.

The utilization of an IPA has both advantages and disadvantages. Physicians prefer the IPA because there is no need to transfer their existing practice to a new organization, not to mention that it allows them to retain a significant amount of control over their practice. Unfortunately, many IPAs have been proven failures or at least disappointments in many markets. Reasons for this include undercapitalization, absence of management or administrative experience, an overemphasis on specialists in markets that need more primary care doctors, lack of effective cost controls, and the inability of physicians to agree on a compensation plan that is acceptable to them and, at the same time, consistent with the goals and well-being of the IPA itself.

The main problem with IPAs is that they represent a group of physicians who are neither truly integrated nor completely independent. In fact, the competition even among owners remains high. The result is a group of individual practitioners with competing interests and a lack of motivation to completely integrate their practices. With integration would come greater economies of scale, which would mean greater profits for the owners. Without greater integration the IPA owner will continue to work for the
best interests of his or her independent practice rather than the best interests of the IPA as a whole.

**Hospitals**

With the rapidly growing health care industry, hospitals have begun developing new strategies for remaining competitive. This multifaceted strategy has resulted in hospitals utilizing a variety of legal and business structures. These structures include for-profit hospitals, not-for-profit hospitals, the acquisition and/or management of medical practices and greater emphasis on freestanding outpatient facilities, even in competition with the medical community.

A for-profit hospital is a hospital that is incorporated and run like any other for-profit organization. It has shareholders who demand a return on their investment, and is thus profit oriented. A portion of those profits eventually make their way down to shareholders in the form of dividends. A for-profit hospital must also pay taxes on its profits and dividend payouts.

The most significant distinction between a for-profit and a not-for-profit hospital is the not-for-profit hospital's tax-exempt status. Typically, health care organizations (e.g., hospitals) organize themselves and operate for “charitable” purposes in order to qualify for tax-exempt status. According to the Internal Revenue Service (IRS), a “charitable” purpose includes the provision of health care services, even if the class of beneficiaries receiving benefits from the hospital does not include the entire community, provided that the class of individuals is not so small as to be determined not to be of benefit to the community in which it operates. Generally, the IRS requires something more than simply the provision of health care services in order to qualify for tax-exempt status. As it concerns hospitals, the IRS used to require that hospitals provide charity health care in order to qualify for tax-exempt status.

Since the late 1960s and early 1970s, the IRS has granted exempt status to hospitals that meet the “community benefit” or “public benefit” standard. According to this standard, a hospital must show that it provides an overall benefit to the community in which it operates. This standard requires a facts and circumstances examination of, among other things, whether the hospital: has a board of directors that is representative of the community; refrains from engaging in the practice of patient dumping; has an inclusive medical staff; provides community education programs; and provides health services to a broad class of individuals, regardless of ability to pay.

Apart from being required to provide a charitable or public purpose, in order to qualify for tax-exempt status a hospital is prohibited from providing a private benefit to those who operate it. In other words, no part of the net profits of a tax-exempt organization may inure to the benefit of a private individual. If any tax-exempt organization (including tax-exempt hospitals) violates the prohibition on private benefit or private inurement, then that organization will be at risk of losing its status as a tax-exempt organization.

It is important to note that in 1991, the IRS released a general counsel memorandum in which it addressed issues related to fraud and kickback schemes in the context of tax-exempt organizations. It stated that tax-exempt organizations taking part in fraud and abuse or kickback schemes are at risk of losing their tax-exempt status as they may also be violating the IRS prohibition on private inurement and private benefit within tax-exempt organizations. Therefore, it is very important that tax-exempt hospitals keep in mind fraud and abuse and kickback regulations when evaluating their relationships with health care providers.

Yet another way for hospitals to become involved in the delivery of health care is through the use of hospital-owned or hospital-controlled medical practices. These structures are the two most effective ways of creating a fully integrated health care delivery system. It allows a hospital and medical group to essentially be combined within a single organization.

The hospital or its corporate parent directly employs the physicians or an entirely new entity can be created by the hospital to serve as the hospital’s medical services component. There are a number of business entities that could be used to achieve such goals, including limited liability companies, limited partnerships, standard business corporations, professional associations, professional corporations, nonprofit corporations, trusts, foundations, and standard business corporations. Generally, the most determinative factor in choosing an appropriate entity is the applicable state law concerning an entity’s ability to employ physicians. As discussed above, prohibitions against corporate practice of medicine may eliminate the ability to use separate entities, prohibit the direct employment of physicians by hospitals, or even limit the types of entities from which to choose. Because the corporate practice of medicine is a state law issue, it is important that individuals contemplating this option first research the law of their particular state. It is important to note that teaching hospitals often are exempt from CPMD restrictions as they relate to faculty practice plans. If state law does in fact prohibit a hospital from owning a medical practice, a hospital may be able to circumvent the prohibition by utilizing a management services organization (MSO), although the use of MSOs has declined.
in recent years as hospital organizations proved to be poor managers of physician practices.

An MSO is an entity set up to provide assets and services to a medical practice. In most cases, the MSO purchases all the tangible assets of a medical practice and thereafter leases them back to a medical practice as part of a management services agreement. Other times, an MSO purchases new equipment and leases it to the practice. There are a variety of types of MSOs, but the overall concept remains the same. The distinction between the various types of MSOs is based upon its specific combination of purpose (e.g., whom will it serve, financial goals), function (e.g., degree of services offered), and ownership structure (e.g., subsidiary, joint venture).

Whenever hospitals have an ownership interest in medical practices, it is important to stay alert to possible kickback and self-referral implications (both antikickback and self-referral laws are discussed later in this chapter). If a hospital (or any other entity that receives patient referrals) subsidizes an MSO (and by implication the medical group) and the medical group thereafter refers patients to the hospital, then arguably the MSO arrangement could be an indirect payment by the hospital to the MSO in an effort to obtain patient referrals, resulting in a possible violation of the antikickback statute.

Alternatively, if the MSO is owned by the hospital, then the MSO’s physicians’ referral of patients for designated health services to the hospital could raise possible Stark Law violations. Even if the MSO is established as a separate and distinct entity from the hospital, the activities of the MSO may be attributed to the hospital for purposes of analyzing antikickback and self-referral laws if it is capitalized or controlled by the hospital. These are very difficult and often complicated issues that need to be addressed prior to forming an MSO. Most importantly, attorneys should be strict in cautioning their clients with respect to MSO arrangements, especially if the MSO operates at a financial loss.

To minimize the risks of violating these federal laws, it is important to be aware of, and comply with, all “safe harbors” applicable to each component of the MSO arrangement. These “safe harbors” are discussed in more detail later in this chapter.

Ancillary Providers
Spurred by reimbursement incentives during the 1980s and a rapidly growing level of technological innovation, health care is being transformed from a hospital-based system to a less expensive outpatient-based system, for such services as surgery, imaging, cardiac catheterization, radiation, therapy, etc. This trend has been encouraging to health management organizations, corporations, and even the federal government, which have been working hard to find new ways of controlling the rising cost of health care in this country. This development has resulted in exponential growth in the number of ancillary health care providers, which may be owned by physicians, hospitals, joint ventures between physicians and hospitals, and outside business entities.

Because of the ownership structure of these ancillary systems, fraud and abuse and self-referral issues are commonplace. It is important to fully analyze all payments to be sure that none run afoul with the antikickback statute or the patient self-referral statute. These issues are discussed in more detail later in this chapter. It is also helpful to seek guidance from previously released advisory opinions issued by the Health and Human Services Office of Inspector General (OIG). Even though OIG advisory opinions specifically state that they may not be relied upon by anyone other than the requester, it is nonetheless a way to get a good sense of how the OIG would view certain types of business arrangements.

Legal Entities

Physicians and medical groups forming and operating under legal entities must be aware of the tax and personal liability consequences that the various entity structures entail. Generally, the two broad categories of entity structures available, incorporated and unincorporated entities, will afford the physician different levels of protections in those crucial areas. Although no business structure will protect or afford the physician immunity from liability stemming from his own professional actions, some entities provide better personal protection than others in the event the actions of a partner or colleague of the physician were the cause of the suit. A closer examination of the advantages and drawbacks of each entity is required to provide physicians and medical groups with a better idea of how to structure their business. However, one should not solely rely on the following brief overview regarding the choice of optimal physician entity. Laws and tax regulations concerning the various entities can vary from state to state and it is therefore crucial that a physician consult a legal expert from his or her own state before making the ultimate decision under which entity to operate.

Unincorporated Entities
These forms of practices have the distinct advantage that they are easily structured and cheap to create. The main drawback of unincorporated practices is that they do not
serve to limit a physician's personal liability in the event of a lawsuit.

**Sole Proprietorship**
For physicians who do not plan to work in a group or form a practice entity with other physicians, the sole proprietorship presents itself as a convenient choice of entity. Setting up a sole proprietorship involves minimal effort and expenses, and provides the advantage that entity and physician are treated as one and the same for tax purposes. However, the sole proprietorship has the considerable drawback that it offers no form of personal liability protection whatsoever, and a physician's personal assets are subject to exposure to satisfy judgments against the business.

**General Partnership (GP)**
Physicians who plan on working together and forming small medical groups may be tempted to form a general partnership since they are uncomplicated and inexpensive to create and are not subject to federal income taxation. However, the general partnership presents the same considerable drawback of the sole proprietorship: Personal assets are subject to company judgments. In addition to that downside, each physician is also personally liable for claims rendered against his or her partner. Due to the negative liability characteristics of a general partnership, they are becoming increasingly unpopular as a choice of entity.

**Limited Liability Partnership (LLP)**
Like other forms of unincorporated entities, the limited liability partnership has the distinct advantage of not being subject to federal taxation, that is, all income flows through the entity directly to the partners and must only be reported by them as income. The limited liability partnership is unique, however, in the respect that it is the sole unincorporated entity that will shield the physician's assets from liability caused by partner's malpractice. Nevertheless, a physician partner must be aware that his investment in the company could still be lost to an unfavorable judgment, if such judgment exceeds the amount guaranteed by the insurance policy. Limited liability partnerships also offer the advantage of flexible structuring, by limiting or expanding a partner's decision making rights regardless of his or her individual income or status within the partnership.

**Incorporated Entities**
Despite the increased cost and the more formal structure of incorporated entities, to most physicians they represent favorable alternatives to unincorporated entities for the simple reason that a physician's personal assets are secure and will not be subject to any judgments against the business resulting from a colleague's malpractice. The most a physician could lose is his investment in the business. However, a physician must be aware that his or her own personal assets are not secure if judgment has been rendered against the practice as a result of the physician's own negligence.

**C-Corporation**
The C-corporation is a fairly flexible entity structure that may issue two types of stock: common and preferred. Different voting and distribution rights are assigned through the type of stock ownership, allowing greater consideration for shareholder seniority. Since stock ownership represents one's interest in the entity, physicians may easily buy in or buy out of the entity by acquiring or selling stock. The C-corporation is often a choice entity for large medical groups since the law imposes no limitation on the amount and the nature of the corporation's shareholders. The major drawback of C-corporations concerns their tax liability. Any income the corporation receives is taxed twice, first to the corporation and then to the shareholders receiving dividends on their shares. C-corporations may seek to avoid the taxation to shareholders by distributing the profits received as “bonuses,” however, if such bonus is disproportionately large to regular income, the physician receiving the bonus may come under IRS scrutiny.

**S-Corporation**
The S-corporation has become a favorable alternative to the C-corporation since it limits personal liability to the corporate investment and all profits flow through the corporation directly to the shareholders and as such are only subject to one layer of taxation. Election of an S-corporation physician entity or group practice is often limited to smaller local physician entities as the corporation may not have more than 75 shareholders or have any non-resident aliens as its shareholders. Ownership is further restricted to natural persons, which prohibits another corporation or other entity holding shares in the S-corporation as well. Another drawback concerns the limitation that an S-corporation may only issue one class of stock, which inhibits the flexibility of voting and distribution rights. However, the S-corporation has the advantage that any losses incurred during the start-up of the entity are passed directly to the shareholder and therefore can be set off from taxable income derived from other sources. In a C-corporation, such losses remain within the corporation and cannot be used to the benefit of its shareholders.

**Limited Liability Companies (LLC)**
Limited liability companies are a relatively new form of incorporated entity that did not emerge until the 1990s.
its attributes resemble a hybrid of a partnership and corporation, offering limited liability to its members, flow-through taxation on profits and losses, and, like the C-corporation, flexibility on the amount and nature of its owners. Additionally, profits distributions are not as rigid as with an S-corporation since they may be distributed disproportionately to membership in the entity. Likewise, the limited liability company does not require the observation of corporate formalities like minutes or annual shareholder meetings. Due to the novelty of the limited liability company, its liability protection has not faced the extensive court challenges and scrutiny that corporations have, and therefore its protection is not as judicially recognized. Unlike the established corporate structure, some states might also not recognize all rights and privileges afforded to the LLC by other states. There is also a perceived conception that upon receipt of considerable revenue, the risk of an IRS audit is higher with a company than it would be with a corporation. Moreover, if the members wish to maintain earnings within the company rather than distributing them, a corporation might be a more suitable choice of entity to retain savings since, depending on the amount of income, the corporate tax rates could be lower than the individual income tax rates incurred upon distribution.

Federal Antikickback Statute

The federal antikickback statute states in pertinent part: (1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a federal health care program, or (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a federal health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.3

Additionally, if the person submitted claims to the Medicare program as a result of an illegal kickback arrangement, he or she may be found to have violated the federal civil False Claims Act4 and/or may be subject to Civil Monetary Penalties for each item or service for which a fraudulent claim was submitted, and/or may be excluded from participating in federal health care programs.

The antikickback statute also sets forth certain statutory exemptions (e.g., discounts, payments to employees, payments to group purchasing organizations) and authorizes the Secretary of the Department of Health and Human Services to exempt specified transactions by safe harbor regulations.5 It is very important to note that the antikickback safe harbors are extremely narrow in scope. Transactions that do not fit squarely within the regulatory safe harbors are not per se illegal, but must be analyzed according to the particular facts and circumstances of each transaction.6

The 1996 amendments under the Health Insurance Portability and Accountability Act (HIPAA) extended the antikickback statute to all “federal health care programs,” added a statutory exception for certain risk-sharing arrangements and established several methods designed to increase the flow of information between the OIG and the public about the application of the statute to various transactions. Included among these methods was the requirement that the OIG establish a procedure whereby providers could apply for advisory opinions pertaining to the applicability of the antikickback statute or a particular safe harbor to a particular transaction.7 Such a procedure has been established and a number of advisory opinions have been issued.8

All requests for OIG advisory opinions must be submitted in writing, the requestor must be a party to the existing or proposed arrangement, and an initial filing fee must be enclosed.9 It is important to point out that no individual other than the requestor(s) may rely on any advisory opinion issued by the OIG.10 The OIG has developed a list of subject matters appropriate for advisory opinions and those that are not. The OIG will issue advisory opinions regarding what constitutes prohibited remuneration; whether an existing or proposed arrangement satisfies the criteria under the safe harbor regulations as an activity that does not result in prohibited remuneration; what constitutes inducement to reduce or limit services to

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Also intended to compensate for professional services.14 Services, as well as for explaining the test results to patients. However, the amount paid to the referring physician was more than Medicare allowed for such services. The court stressed that the antikickback statute “is aimed at the inducement factor” and held that “if one purpose of the payment was to induce the physician to use [the laboratory’s] services, the statute was violated, even if the payments were also intended to compensate for professional services.”14

The OIG has since adopted the Greber “one purpose” standard as the test in its advisory opinions.15 If any purpose of the transaction is to induce Medicare or Medicaid referrals, the position of the OIG is that the antikickback statute is violated.16 Similarly, in its General Comments to the 1999 Final Safe Harbor Regulations, the OIG states:

Payment practices that do not fully comply with a safe harbor may still be lawful if no purpose of the payment practice is to induce referrals of federal health care program business.”17

The Greber one purpose test also has been adopted by the Ninth Circuit in United States v. Kats and by the Fifth Circuit in United States v. Davis.18 In United States v. Kats, the court concluded that when a payment is not incidental to the delivery of health care services or goods, the antikickback statute is violated.19 In that case, the owner of a diagnostic laboratory “agreed to ‘kick back’ 50 percent of Medicare payments received by the laboratory as a result of referrals” from a medical services company. The appellate court held that the trial court’s instruction that the “jury could convict [the defendant] unless it found the payment ‘wholly, and not incidentally attributable to the delivery of goods or services’ accurately stated the law.”20 The court quoted with favor the Greber one purpose test, opining that the Greber interpretation “is consistent with the legislative history.”21

In United States v. Anderson,22 the US District Court in Kansas also adopted Greber. In a companion case, United States v. McClatchey23 the Tenth Circuit officially adopted Greber, but with a caveat. A jury instruction in McClatchey provided that the defendant “cannot be convicted merely because [he] hoped or expected, or believed that referrals may ensue from remuneration that was designed wholly for other purposes.”24 In a somewhat analogous holding, the US District Court for the Middle District of Florida, in United States v. Siegel, held that if “one material purpose” of the payment were for purposes of illegal remuneration the antikickback statute was violated.25

The Primary Purpose Test

The case of United States v. Bay State Ambulance and Hosp. Rental Serv., Inc. looked at the primary purpose, rather than any or one purpose, of a payment to determine its illegality.26 Bay State contained a complicated set of facts, which involved a series of gifts and payments made by an ambulance company to a well-placed employee of a city hospital. The apparent purpose of the gifts was to influence the hospital’s decision concerning its choice of ambulance services. One issue under consideration concerned the correctness of the following jury instructions given by the trial court judge:

[T]he government has to prove that the payments were made with a corrupt intent, that they were made for an improper purpose. If you find that payments were made for two or more purposes, then the government has to prove that the improper purpose is the primary purpose or was the primary purpose in making and receiving the payments. It need not be the only purpose, but it must be the primary purpose for making the payments and for receiving them. You cannot convict if you find that the improper purpose was an incidental or minor one in making the payments.27

Tests and Requirements Under the Federal Antikickback Statute

The One Purpose Test

As demonstrated by its plain language, the antikickback statute is extremely broad. In United States v. Greber,13 the United States Court of Appeals for the Third Circuit announced the “one purpose test.” The court addressed whether payments made to a physician for professional services related to tests performed by a laboratory could be the basis for Medicare fraud. A laboratory providing physicians with diagnostic services billed the Medicare program for the services. When the laboratory received payment, the laboratory forwarded a portion of the payment to the referring physician. The defendant (an osteopathic physician who owned the diagnostic laboratory) contended that the laboratory was merely paying the referring physicians “interpretation fees” for their initial consultation services, as well as for explaining the test results to patients. However, the amount paid to the referring physician was more than Medicare allowed for such services. The court stressed that the antikickback statute “is aimed at the inducement factor” and held that “if one purpose of the payment was to induce the physician to use [the laboratory’s] services, the statute was violated, even if the payments were also intended to compensate for professional services.”14

The OIG has since adopted the Greber “one purpose” standard as the test in its advisory opinions.15 If any purpose of the transaction is to induce Medicare or Medicaid referrals, the position of the OIG is that the antikickback statute is violated.16 Similarly, in its General Comments to the 1999 Final Safe Harbor Regulations, the OIG states:

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The Greber one purpose test also has been adopted by the Ninth Circuit in United States v. Kats and by the Fifth

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The appellate court agreed that the defendant's payments were made primarily for inducing referrals; therefore, it upheld the trial court's jury instructions, recognizing that the test applied by the trial court was less expansive than the Greber one purpose rule. The Bay State appellate court, citing Greber with favor, stated “the gravamen of Medicare fraud is inducement,” and that the “key to a Medicare fraud case is the reason for the payment—was the purpose of the payments primarily for inducement.” However, the court chose not to adopt the Greber test.

**Scienter Requirement**

The antikickback statute also requires that the government establish scienter, i.e., criminal intent, under a “knowingly and willfully” standard. The courts are split as to the proper interpretation of these words. In Hanlester Network v. Shalala, a clinical laboratory established joint ventures with physician partners who made nominal investments. Substantially all of the financial risk was borne by SmithKline Beecham Clinical Laboratories, the organizer and manager of the joint ventures. The joint venture agreements required the physicians to resell their interests at nominal prices if they moved out of the trade area, retired, or lost their licenses. As the joint venture manager, SmithKline took a management fee equal to 76 percent of revenues. The joint venture had no employees, and the laboratory work was done at SmithKline. The OIG alleged that the physicians were paid a disproportionate return (more than 50 percent annually) for their investment, which was financed by the manager, and that the physician investors were selected from among physicians expected to make referrals to the laboratories. There was, however, no requirement that physician investors make referrals to the labs.

The fundamental issue before the court was whether the “inducement” prohibition of the antikickback statute was met on the basis that the structure and operations of the joint venture laboratories “merely encouraged” the physician partners to refer patients to the laboratory, which may not violate the law (as opposed to “induced” the referral of business, which clearly would violate the statute). The Ninth Circuit Court of Appeals held that, in order for an individual to violate the antikickback statute, there must be a “knowing and willful” intention to violate a law. In this case, the court found proof lacking that the defendant physicians knew that it was illegal to be paid for referrals or that they engaged in conduct with the specific intent to violate the law.

All courts that subsequently considered the issue have rejected the Hanlester Network holding. These courts have held that the defendant need not have intended to violate or known that he or she was violating the antikickback statute in particular. Rather he or she needs only to have intended to engage in conduct that was unlawful.

In a typical case, the Florida Fourth District Court of Appeal easily set aside Hanlester when determining that a percentage commission paid to a marketing company by a durable medical equipment supplier was an illegal kickback:

The antikickback statute is directed at punishment of those who perform specific acts and does not require that one engage in the prohibited conduct with the specific intent to violate the statute. We therefore decline to follow the Hanlester interpretation of the antikickback statute.

Also in contrast to Hanlester, the court in United States v. Jain, supported the position that the government must only prove that the defendant knew his conduct was wrong. However, the court noted that the defendant's good faith belief that he was being paid for services rather than patient promotion would be a defense.

In United States v. Starks, the Eleventh Circuit confirmed that payments of $250 for each referral from Future Steps to Project Support employees violated the antikickback statute. Two Project Support employees were paid for referrals that cost the Medicaid program $323,000. The Eleventh Circuit rejected the argument that the antikickback statute was technically complex and ruled that the defendant's specific knowledge of the statute did not have to be proved, especially in view of the fact that the payments for the referral were made to the employees in a clandestine fashion (cash under the table).

In United States v. Anderson, hospital officials and doctors were convicted under the antikickback statute for fees paid by a hospital under consulting agreements to physicians. The fees were excessive for the services rendered and the court therefore concluded that the consulting agreements were shams to disguise payments for patient referrals. The court found that although the antikickback statute was not a simple statute it was not highly technical. It therefore adopted the general knowledge standard.

Although the Supreme Court has not interpreted the words knowingly and willfully in the context of the antikickback statute, it has done so in connection with another criminal statute using the same intent standard. In the case of Bryan v. United States, the Supreme Court concluded that an individual acts willfully when he or she acts with knowledge that his or her conduct is unlawful.
The question raised in the Bryan case was whether the defendant had to know that he was violating a specific statute prohibiting the unlicensed sale of firearms. The Court distinguished complex statutes that are highly technical and capable of entrapping people engaged in conduct they believed to be innocent from other statutes. When the law is complex and capable of trapping people, the Court stated that a defendant had to have specific knowledge of the law being violated. The Court concluded that when it came to the statute before it, the government had only to prove that the defendant acted with the knowledge that his conduct was unlawful. The Court held that as “a general matter, when used in the criminal context, a ‘willful’ act is one undertaken for a ‘bad purpose’.” The Bryan case lends support to the majority view that specific intent to violate the antikickback statute is not necessary for conviction.

Penalties for Violation of Antikickback Statute

The stakes in running afoul of the antikickback statute are high. Section 4304(b) of the Balanced Budget Act of 1997 (BBA) granted HHS the authority to impose civil money penalties of: (i) up to $50,000 and (ii) three times the amount of remuneration in question, for each violation of the statute. In addition to the criminal and civil penalties under the antikickback statute, violations of the statute can lead to exclusion from participation in federal health care programs. In 1998, the OIG issued a final rule extending its exclusion authority to “indirect providers” such as drug and device manufacturers. The effect of such exclusion would be to eliminate coverage for any products of the excluded manufacturer. However, significant questions remain regarding the OIG’s legal and practical authority to exclude manufacturers involved in the distribution of, or billing for, covered drugs.

Enforcement Action

An increase in criminal enforcement of the health care fraud and abuse laws has, not surprisingly, resulted in a greater number of successful enforcement actions under the antikickback statute. However, the increasing number of successful prosecutions is due not only to the greater number of enforcement actions initiated by the OIG and US attorneys, but also the government’s increasingly creative application of the broadly worded statute. The antikickback statute establishes criminal penalties for anyone offering, soliciting, receiving, or paying remuneration, directly or indirectly, in cash or in kind, in return for the referral of a patient, for whom health care services are paid by a federal health care program. Since its inception, many legal practitioners predicted that this statute could be applied in a manner unforeseen by its original authors. This is because the statute’s broad language allows it to be interpreted to prohibit not only egregious kickback schemes, but also seemingly innocuous transactions.

Joint venture transactions and compensation arrangements that implicate the antikickback statute may be viewed on a continuum ranging from blatant violations of the law to financial arrangements that implicate the law in less obvious ways. The recent enforcement efforts by the US attorneys and the OIG throughout the country evidence a trend to apply the antikickback statute not only to the most egregious forms of abuse, but also to those instances where its application may not be directly supported by prior case law and do not involve an obvious threat to patient and program abuse. Furthermore, perhaps due to the significant criminal and civil money penalties available to the federal agencies, enforcement actions have been aimed at small and large as well as simple and sophisticated transactions. In short, the recent enforcement actions of the US attorney and the OIG signify an expansion of the applicability of the antikickback statute in as broad a fashion as its language permits and in a manner probably unforeseen by the original authors of the law.

Perhaps the most aggressive enforcement actions involving the antikickback statute have been undertaken in the Middle District of Florida focusing on the mental health and substance abuse sector of the health care industry and more recently including payments for referrals between physicians and ancillary service providers such as clinical laboratory and durable medical equipment and mobile diagnostic providers. These cases all involve alleged violations of the federal antikickback statute involving payment for remuneration in various forms in return for the referral of patients under the Medicare and Medicaid programs. The following are the alleged types of illegal payment for referrals that have been reflected in the indictments and plea agreements in these cases:

1. The solicitation and receipt of payment from hospitals providing inpatient care to psychiatric and substance abuse patients in return for the referral of those patients to the hospitals.

2. These payments were allegedly made by disguising their illegal nature in the form of fraudulent contracts and agreements falsely characterizing the payments made for the referral of patients as payment for management services, marketing services,
initial psychiatric clinical assessments, aftercare treatment and other purported services.

3. The hospitals which were paying remuneration in return for the referral of psychiatric and substance abuse patients would also request fraudulent claims for reimbursement on their cost reports for the salaries of persons who had entered into fictitious employment contracts with the hospitals.

4. There were also alleged payments for referrals in the form of the routine waiver of co-payments for patients and payments for their transportation, often involving air travel, from their cities of residence (which were often in the northern part of the United States) to the facilities (which were in Florida).

5. The payments for referrals of patients for clinical lab and other ancillary services were often purported to be for equipment and space rentals, phlebotomists and other employee salaries and compensation for professional services, such as doctors acting as “testing review officers” or “medical review officers” for clinical lab work.

These cases represent the enforcement of the anti-kickback statute against arrangements that may appear on their face to be arrangements for legitimate services or for equipment or space and may also appear to fit into federal “safe harbors” under the antikickback statute. Nevertheless, these arrangements have formed the basis for indictments and successful prosecutions involving plea agreements based on the theory that they were “sham” arrangements that were merely designed to mask the intent to make payment for referrals. These enforcement actions underscore that apparent compliance with safe harbor criteria, such as personal services arrangements, equipment and space leases and even employment agreements, must be necessary, commercially reasonable and bona fide in all respects, otherwise they could be as vulnerable to attack as if payments were made in cash for the referral of patients.

Perhaps the most dramatic example of the use of criminal sanctions under the federal antikickback statute was the criminal plea agreements in United States v. Kimberly Home Health Care, Inc. d/b/a/ Olsten Kimberly Quality Care, a wholly owned subsidiary of The Olsten Corp. (Olsten) (Southern District of Florida and Middle District of Florida 1999). In Olsten, the company agreed to the sale of home health agencies to a large unnamed hospital company in return for a management agreement to manage those same home health agencies and others, which the hospital would purchase in the future. The government alleged that the transaction violated the federal antikickback statute because the sale of the home health agencies was for a price below fair market value in return for an agreement to enter into a lucrative management contract under which Olsten would be paid on a per visit basis for serving the patients of the hospital-owned home health agencies. The cost of acquisition of the home health agencies is not reimbursable by the Medicare program, but the costs of management services are reimbursable by Medicare. In plea agreements executed to resolve two separate proceedings in the Middle District of Florida and the Southern District of Florida, Olsten pled guilty to mail fraud and several violations of the antikickback statute. Olsten agreed to pay $61 million in criminal restitution and fines and civil penalties. Olsten further agreed to implement a corporate integrity agreement that was separately negotiated with the OIG.

These enforcement actions represent an effort by government agencies to expand the reach of the antikickback statute as broadly as its language permits. The government's increasingly aggressive use of criminal penalties demonstrates the government's willingness to use all tools at its disposal to eliminate health care fraud. Because seemingly small or simple transactions may later become the subject of a government investigation, it is imperative that health care providers have qualified counsel review all of their proposed transactions for compliance with applicable federal and state fraud and abuse laws.

**Physician Self-Referral——Stark Law**

The Stark law generally prohibits a physician’s referral of Medicare patients to an entity for the furnishing of designated health services (DHS) if there is a financial relationship between the referring physician or an immediate family member and the entity, unless an enumerated exception applies."44 Unlike other statutes and regulations that are applicable to the health care industry as a whole, the Stark law applies only to physicians (which also include dentists, podiatrists, and chiropractors).45 The underlying reason behind the Stark law was to deter physicians from referring patients only to facilities in which they had an ownership interest, rather than to a facility that could provide the patient with the best medical care. It was also believed that self-referrals could, and would, lead to physicians ordering unnecessary services or procedures based merely upon the physician’s financial interest in a given facility. By establishing the Stark law, Congress was attempting to create a “bright line” rule whereby physicians would know, in advance, which types of business arrangements were illegal.
On January 4, 2001, the Centers for Medicare & Medicaid Services (CMS, formerly the Health Care Financing Administration) issued Phase I of the final Stark II regulations as a final rule with a 90-day comment period (Final Rule). The Final Rule, which became effective March 4, 2002, relates to the Ethics in Patient Referral Act of 1989 (Stark I) as amended by the Omnibus Budget and Reconciliation Act of 1993 (Stark II) (collectively Stark law). Phase I of the Final Rule concerns the Stark law’s prohibition and exceptions to the ownership/investment interests, compensation arrangements and statutory definitions. Phase II of the Final Rule is to address additional ownership interest exceptions, reporting requirements, sanctions and Stark law’s application to Medicaid. CMS clarifies and modifies the definition of several statutory terms in the Final Rule and creates a new exception for entities that submit claims for DHS where the entities could not have been aware of the physician who made the referral. This chapter does not discuss Phase II of the final Stark II Rule which was passed in the beginning of 2004 and took effect on July 26, 2004.

Sanctions for violating the Stark law include the denial of payment, requiring refunds of claims that were billed in violation of the statute, civil monetary penalties of not more than $15,000 for each service billed pursuant to a prohibited patient referral, and civil monetary penalties of not more than $100,000 for each unlawful arrangement or scheme which the physician or entity knows or should know has a principal purpose of assuring referrals by the physician to a particular entity which, if the physician directly made referrals to such entity, would be a violation of the Stark law. Additionally, any person who fails to meet the reporting requirements under the act may be assessed a civil money penalty in the amount of not more than $10,000 for each day for which reporting is required to have been made.

Definitions
Statutes and regulations define DHS to include clinical laboratory services, physical therapy, occupational therapy, and speech-language pathology services, radiology and certain other imaging services, 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, and inpatient and outpatient hospital services.

The Final Rule modifies the definition of referral to no longer include services performed personally by the referring physician. This modification allows a physician to initiate and personally perform services without these services being deemed “referrals to an entity.” However, all other Medicare-covered DHS performed at the request of a physician are still considered physician referrals. For example, services performed by a physician’s employees and “incident to” services are still considered performed as a result of the physician’s referrals. CMS has taken the position that a referral is imputed to a physician if the physician directs or controls the referral. The Final Rule contains an exception to the referral definition for pathologists, radiologists and radiation oncologists. The Final Rule permits the request for consultation to be made to a party with which the specialist is affiliated.

The Final Rule’s definition of entity does not include referring physicians, but does include their medical practices. The Final Rule defines entity to include any person or entity receiving payment for DHS. Specifically, the Final Rule reasons that the payee is the entity for purposes of determining to whom the beneficiary was referred. Additionally, the entity to which patient has reassigned his or her Medicare benefits will be considered the entity furnishing the DHS service. Managed care organizations (MCO), health plans and IPAs are deemed entities if they employ a supplier or operate a facility that could accept reassignment from a physician or supplier.

The Stark law only addresses situations in which the referring physician has a financial relationship with the DHS entity. The two types of financial arrangements that the statute focuses on are (a) compensation arrangements, and (b) an ownership or investment interest in the entity. The Final Rule also expands the definition of “financial relationship,” and makes a distinction between “direct” and “indirect” financial relationship. Direct ownership or investment interest includes ownership or investment through equity, debt or other means, including ownership in an entity that holds an ownership interest in another entity that provides DHS. However, ownership in a subsidiary entity does not constitute ownership in a parent entity unless the subsidiary owns an interest in the parent.

An ownership or investment interest is defined to include: stock, partnership shares, limited liability company memberships, loans, bonds or other instruments secured by an entity’s property or revenues. An unsecured loan, however, is not an ownership interest under the Final Rule. Accordingly, if a physician provides secured financing to an entity, the physician possesses an ownership interest in the entity, and not a compensation arrangement. Further, the Final Rule specifies that interest in a retirement plan, stock options and convertible securities (until exercised), unsecured loans and “under
arrangements” between a hospital and an entity owned by a physician or physician group are not ownership or investment interests. The statute broadly defines compensation arrangements to include any arrangement involving remuneration, directly or indirectly, overtly or covertly, in cash or in kind, between a physician and an entity. Remuneration can consist of (a) the forgiveness of amounts owed for inaccurate tests or procedures, mistakenly performed tests or procedures, or the correction of minor billing errors; (b) the provision of items or supplies used to collect or transport specimens for the entity, or orders to communicate the result of tests and procedures to the entity; and (c) a payment made by an insurer to a physician to satisfy a claim, submitted on a fee for service basis, for the furnishing of health services by that physician to an individual who is covered by a policy with the insurer if, (i) the health services and the payment therefore are not furnished pursuant to a contract or arrangement, and (ii) the payment which otherwise would be made to the individual was made to the physician on his behalf, and (iii) the payment amount was set in advance and did not exceed fair market value. The Stark law, however, also provides for various compensation arrangement exceptions which require that the arrangements set compensation in advance and not take into account the volume or value of referrals, other business generated between the parties or condition compensation on referrals to a particular provider.

The Final Rule added a new exception that allows an entity lacking the requisite culpable mental state to submit a claim for DHS even when the services originate from an impermissible referral. The exception provides:

Payment may be made to an entity that submits a claim for designated health services if: (1) the entity did not have actual knowledge of, and did not act in reckless disregard or deliberate ignorance of, the identity of the physician who made the referral of the designated health service to the entity; and (2) the claim otherwise complies with all applicable federal laws, rules and regulations.

This rule protects a DHS provider who is unaware or does not have reason to know that an oral or indirect referral originated from a party with a financial relationship with the DHS provider. CMS has stated that the new “knowledge exception” applies to indirect and oral referral where there is no written documentation of the referral. The Final Rule’s language, however, does not specifically limit the new knowledge exception to oral and indirect referrals. The DHS provider is not under an affirmative duty to investigate the origination of a referral unless the DHS provider has reason to suspect that such a financial relationship exists with the referring physician. It must be noted that while this exception allows the DHS provider to bill for the services, arguably, the physician remains liable for his prohibited referral.

The Final Rule establishes a knowledge requirement before a DHS provider is held liable for receiving a tainted referral. The Final Rule provides that an indirect ownership or investment interest exists if: (1) between the referring physician and the entity furnishing DHS there exists an unbroken chain of persons having an ownership or investment interests between them, and (2) the entity furnishing the DHS has actual knowledge of, or acts in reckless disregard or deliberate ignore of, the fact that the referring physician has some investment or ownership interest in the DHS entity. The main modification to this principle is the addition of the knowledge element. A DHS provider without “knowledge” will not be liable for providing services originated by an impermissible referral.

The Final Rule sets forth three elements in defining indirect compensation. The elements are: (1) the unbroken chain test; (2) the volume or value test, and (3) knowledge requirement. The unbroken chain test requires “an unbroken chain of any number (but not fewer than one) of persons or entities that have financial relationships between them.” The second element of the test requires that:

The referring physician…receive aggregate compensation from the person or entity in the chain with which the physician has a direct financial relationship that varies with, or otherwise reflects the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS.

If total payments to the physician rise or fall based upon the volume or value of referrals, it is an “indirect compensation arrangement” that triggers the referral prohibition unless it complies with an exception. This element examines the entity’s direct financial relationship with the referring physician. Once a direct financial relationship is found, it must be determined whether the compensation arrangement varies with the volume or value of referrals or “business otherwise generated.” If the arrangement varies in the aforementioned manner, then an indirect compensation agreement exists. Almost all contracts between physician groups, in which the physicians have an ownership interest, and hospitals will be subject to the volume or value test. However, if the physicians do not have an ownership interest, the volume or value test will be applied to the compensation physicians
receive to determine whether their compensation is based upon the physicians’ referrals to the hospital.

The Final Rule also provides that for an indirect compensation arrangement to exist, the DHS provider must have “knowledge” that the referring physician’s compensation is based upon the physicians’ volume or value referrals or “other business generated by the referring physician” to the DHS provider.70

Where an indirect compensation arrangement exists, DHS referrals are prohibited unless the arrangement fits within the indirect compensation exception. The indirect compensation exception requires that: (1) The compensation received by the referring physician (or immediate family member) is fair market value for services and items actually provided not taking into account the value or volume of referrals or other business generated by the referring physician for the entity furnishing DHS; (2) The compensation arrangement is set out in writing, signed by the parties, and specifies the services covered by the arrangement, except in the case of a bona fide employment relationship between an employer and an employee, in which case the arrangement need not be set out in a written contract, but must be for identifiable services and be commercially reasonable even if no referrals are made to the employer; and (3) The compensation arrangement does not violate the anti-kickback statute or any laws or regulations governing billing or claims submission.71

Exceptions72

The Stark law provides for various enumerated exceptions to the general prohibition on financial relationships between the referring physician and DHS entity. General exceptions to both ownership interest and compensation arrangements apply to physician services, in which the services are provided by a physician in the same group practice as the referring physician.73 A group practice is a group of two or more physicians legally organized as a partnership, professional corporation, foundation, not-for-profit corporation, faculty practice plan, or similar association.74 A physician’s referrals are excepted from the Stark law’s referral prohibition as long as the service is performed in the same building in which the nondesignated health services are performed, or in the case of a group practice, in a building used by the group exclusively for the provision of the group’s designated health services. The services must be billed by the physician performing or supervising the services, the practice group, or the entity that is owned by the physician or the physician practice group.75 The final overall exception concerns prepaid plans. Referrals for DHS services made by

certain managed care organizations (Health Maintenance Organization, Medicare + Choice Organization) to individuals enrolled within the organization will not constitute a financial relationship under the Stark law.76

The law further provides that the referring physician’s ownership of publicly traded investment securities and mutual funds will not constitute ownership or investment interest if the securities are traded on a public market and the corporation that issued the securities has stockholder equity exceeding $75 million for the past three years.77 Shares issued by a regulated investment company are also excluded if the company has total assets exceeding $75 million for the past year, or on average during the previous three years.78 Ownership or investment interest in hospitals will not constitute ownership interest under the Stark law if the referring physician is authorized to perform services at the hospital and the interest the physician owns is interest in the hospital itself, and not in a hospital subdivision.79 Furthermore, if any referrals for designated health services are made to hospitals in Puerto Rico or to rural providers, any investment of ownership interest the referring physician may have in such entities will not constitute a violation of the Stark law.80

The Stark law also lists various types of compensation arrangements exceptions that are permitted. Compensation arrangements between the referring physician and the entity providing the designated health services are allowed if the compensation is for the rental of office space or the rental of equipment.81 Both rentals require that they be in writing, that space and equipment rented does not exceed that which is necessary for legitimate business purposes, and that the duration of the lease is at least one year.82 Compensation arrangements involving bona fide employment arrangements and personal service arrangements are also permitted. Amounts paid by an employer to a physician under a bona fide employment relationship do not constitute compensation arrangements under the statute as long as the amount of remuneration is consistent with the fair market value and is provided pursuant to an agreement.83 Amounts compensated under a personal service arrangement qualify as an exception if the arrangement is in writing, covers the services provided by the physician, the duration of the arrangement is at least one year, the compensation received does not exceed fair market value, and the services performed under the arrangement do not involve counseling of a business arrangement or other illegal activity.84

Additional remuneration that does not qualify as compensation is remuneration received that is unrelated to
the provision of designated health services, remuneration provided for physician recruitment by a hospital as long as the recruited physician is not required to provide the hospital with referrals, and isolated transactions between a hospital and physician, such as a one-time sale of practice if the remuneration is consistent with fair market value and is provided pursuant to an agreement. The statute further provides that compensation received in certain practice arrangements between a group performing designated health services and a hospital billing for them is exempt if such an arrangement had been entered into and has been uninterrupted since December 19, 1989. For such an arrangement to meet the exception, the arrangement has to be in writing, the group must substantially furnish all designated health services covered by the arrangement, and the amount of compensation is consistent with fair market value. Finally, any payments made by a physician to a laboratory in exchange for the provision of clinical laboratory services or payments made to an entity as compensation for other services or items furnished at a price consistent with the fair market value is exempted from a compensation arrangement.

It is important to note that any remuneration received for the rental of office space exception, the rental of equipment exception, the bona fide employment relationship exception, the personal service arrangement exception, the exception concerning physician recruitment, and the certain practice arrangement with hospital exception may not take into account the volume or value of referrals or other items furnished at a price consistent with the fair market value. An exception exists however for personal service arrangements that are physician incentive plans. There, the compensation between physician and entity may consider the volume and value of the referrals in establishing the amount of remuneration, however, no specific payment may be made that serves as an inducement to reduce or limit the medically necessary services provided by the physician enrolled in the entity.

In addition to the above mentioned exceptions that do not violate the Stark law's general prohibition regarding financial relationships, Congress included in the Stark law a provision giving the Secretary authority to issue regulations creating additional exceptions to the general prohibition against physician referrals to entities with which the physician has a financial relationship, if the Secretary determines that the financial relationship “does not pose a risk of program or patient abuse.” Accordingly, the Final Rule contains several new exceptions.

Under the Stark law, physicians practicing in the academic medical centers would have to conform to the personal service arrangement or employment exceptions, or the group practice definition. The Final Rule has recognized that these exceptions and definitions do not fit the multiple relationships and monetary transfers inherent in most academic medical centers and has issued a new exception protecting those relationships, if certain conditions are met. An academic medical center, for these purposes, consists of an accredited medical school, an affiliated tax-exempt faculty practice plan, and one or more affiliated hospitals in which the majority of medical staff members are faculty members and in which a majority of admissions are made by faculty members.

The Final Rule includes a fair market value exception, which requires: (1) The agreement must be in writing, signed by the parties, and must cover only identifiable items and services, all of which are specified in the agreement; (2) The agreement must specify the time frame, which can be for any period of time and which may include a termination provision, but the parties may enter into only one arrangement for the same items or services during the course of a year. If the term is for less than one year, the parties may renew it any number of times, if the terms and compensation do not change; (3) The agreement must specify the compensation, which 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 any referrals or any other business generated by the referring physician; (4) The arrangement must be commercially reasonable, taking into account the nature and scope of the transaction, and must further the legitimate business purposes of the parties; (5) The arrangement must meet an antikickback safe harbor, or must not otherwise violate the antikickback statute, or the parties must have received a favorable advisory opinion (note that only the parties requesting an advisory opinion may rely on it for these purposes); and (6) The services must not involve the counseling or promotion of a business arrangement or other activity that violates a state or federal law.

Yet another exception to the Stark law pertains to nonmonetary compensation up to $300. This new exception protects compensation from an entity in the form of items or services (not cash or cash equivalents), that does not exceed $300 per year, if certain conditions are met. In other words, the $50 limit has been dropped, and a physician may receive a single gift valued at $300, or several gifts totaling no more than $300, in a single year. The other conditions of this exception are: (1) The compensation may not be determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician; (2) the compensation may not be solicited by the physician or
the physician’s practice; and (3) the compensation arrangement must not violate the antikickback statute.\(^{92}\)

This exception applies only to gifts to individual physicians, not to group practices. All physicians in a group practice could receive gifts up to the $300 per year maximum, so long as the group did not solicit the gifts (i.e., make them a condition of the group doing business with the entity) and so long as they did not violate the antikickback statute.

The Final Rule recognizes that it is common in the industry for hospitals to provide certain benefits to its medical staff members, and that such benefits largely serve to benefit the patients and the hospital. Examples are free parking spaces for medical staff members while they are seeing patients in the hospital, free computer and Internet access on the hospital campus to enhance recordkeeping, and occasional meals for medical staff members while on hospital or patient business. The Final Rule creates an exception for such benefits, if all of the following conditions are met: (1) The compensation is offered to all members of the medical staff without regard to the volume or value of referrals or other business generated between the parties; (2) the compensation is offered only during periods when the medical staff members are making rounds or performing other duties that benefit the hospital or its patients; (3) the compensation is provided by the hospital and used by the medical staff members only on the hospital’s campus; (4) the compensation is reasonably related to the provision of, or designed to facilitate directly or indirectly the delivery of, medical services at the hospital; (5) the compensation is consistent with the types of benefits offered to medical staff members by other hospitals within the same local region, or by comparable hospitals in comparable regions; (6) the compensation is of low value—less than $25—with respect to each occurrence of the benefit (i.e., each meal given to a physician while he or she is serving hospital patients); (7) the compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated between the parties; and (8) the compensation arrangement does not violate the antikickback statute.\(^{93}\)

This exception will protect many medical staff benefits that could not be covered under the fair market value exception, since there is often no written agreement, and which may, in the aggregate, constitute a value greater than $300 per year, taking it out of the De Minimus exception. Note, however, that Comments to the Final Rule explicitly state that medical transcription services are \textit{not} considered to be of incidental benefit of nominal value and would not be covered under this exception.

Comments to the Final Rule recognize that many hospitals are offering compliance training to their medical staffs. The Secretary believes that such training programs are beneficial and pose no risk of fraud or abuse. Therefore, the Final Rule contains a new exception for compliance training provided by a hospital to a physician that practices in the hospital’s local community or service area, provided the training is held in the local area or service area. Compliance training is defined as training regarding the basic elements of a compliance program (not setting up a compliance program for the physician), or specific training regarding Medicare or Medicaid requirements (such as billing or coding).\(^{94}\)

### Comparison of the Federal Antikickback Statute to the Physician Self-Referral Act

The Antikickback Statute and the Physician Self-Referral Act (“Stark Law”) are two different statutes passed by Congress at different times that, nevertheless, target the same problem in our health care delivery system. The goal of each statute is to eliminate the prospect of financial inducements as a factor in the referral of patients and the ordering of goods or services paid for, in whole or in part, by federal health programs. An ancillary purpose behind both laws is to eliminate financial considerations in the making of clinical and medical judgments involving patient care, which Congress has concluded lead to overutilization of services and potential overcharges, in addition to undermining the quality of care, all of which increase the costs to federal health programs. The goal of both statutes is to eliminate the financial inducement factor from clinical decision making in the care and treatment of patients so there is a positive effect on the escalating costs to federal health care programs. This section will examine these two statutes in detail in an attempt to highlight their similarities—even more importantly, their differences—in attempting to address the similar problems under federal health care programs. The antikickback statute prohibits the following:

- Soliciting or receiving remuneration for referrals of Medicare or Medicaid patients or for referrals for services or items which are paid for, in whole or in part, by Medicare or Medicaid.\(^{95}\)
- Soliciting or receiving remuneration in return for purchasing, leasing, ordering or arranging for, or recommending purchasing, leasing, or ordering any goods, facility, service or item for which payment
may be made, in whole or in part, by Medicare or Medicaid.\textsuperscript{96}

- Offering or paying remuneration for referrals of Medicare or Medicaid patients or for referrals for services or items which are paid for, in whole or in part, by Medicare or Medicaid.\textsuperscript{97} and

- Offering or paying remuneration in return for purchasing, leasing, ordering, arranging for, or recommending purchasing, leasing, or ordering any goods, facility, service or item for which payment may be made, in whole or in part, by Medicare or Medicaid.\textsuperscript{98}

The basic prohibition under the antikickback statute is against remuneration in return for the referral of patients or the ordering of goods or services paid for, in whole or in part, by federal health programs, whether it be direct or indirect, overt or covert, or cash or in-kind.\textsuperscript{99}

In comparison, the Stark law prohibits a physician or his immediate family member from having a financial relationship with an entity to which he or she may refer Medicare and Medicaid patients to receive any one of the statutorily defined designated health services.\textsuperscript{100} A financial relationship can exist as an ownership or investment interest or a compensation arrangement with such an entity.\textsuperscript{101} An entity may not present a claim for payment for services provided to a patient as a result of a prohibited referral under the law.\textsuperscript{102}

The antikickback statute is first and foremost a criminal statute which, upon conviction, may result in a penalty of up to $25,000, imprisonment of up to five years, or both.\textsuperscript{103} The antikickback statute also has civil remedies, including the imposition of civil money penalties of up to three times the amount of remuneration paid for referrals, plus up to a $50,000 penalty for each kickback payment.\textsuperscript{104} Additionally, the antikickback statute also allows for discretionary exclusion from federal health care programs.\textsuperscript{105} A conviction under the antikickback statute could, conceivably, include a felony with fine and imprisonment, a civil money penalty amount, and exclusion from federal health care programs, all for the same underlying offense.

In contrast, the Stark law is a civil statute only, which carries with it a civil money penalty of a maximum of $15,000 for each service billed or furnished as a result of a prohibited referral.\textsuperscript{106} Additionally, because the Stark law’s terms explicitly preclude an entity from presenting a claim for payment for services provided to a prohibited referral, it raises the specter of liability under the United States Civil False Claims Act and the Civil Money Penalty law for submission of an improper claim.

The antikickback statute is a broad-based statute which, potentially, could encompass conduct involving anyone offering or receiving remuneration or arranging for, offering or receiving remuneration in return for referrals.\textsuperscript{107} Since the antikickback statute is primarily a criminal statute with criminal penalties, it is necessary for the government to prove that a party intended to violate the antikickback statute’s prohibition with evidence beyond a reasonable doubt (the “intent standard”). This standard of proof would require proof beyond a reasonable doubt in a criminal prosecution, although in an action to impose civil money penalties or an exclusion from federal health care programs, the intent to pay remuneration in return for referrals may only be required to be established by a preponderance of the evidence.\textsuperscript{108}

The Stark law, on the other hand, is a “strict liability” statute, which does not require proof of intent to offer or receive remuneration in return for a referral.\textsuperscript{109} The law merely requires proof that a physician referred a federal health care program patient to an entity that provides any one of a number of designated health services.\textsuperscript{110} If the physician or an immediate family member has a financial relationship with this entity, then the law is violated, unless an exception in the Stark law would apply. This is an important distinction between the antikickback statute and the Stark law, which fundamentally affects the scope of either law’s application and the ability of the government to impose liability through either of these statutes.

Finally, the antikickback statute prohibits certain activity and relationships between two or more parties, while the Stark law, in addition to addressing relationships between physicians and another party, also has a focus on what is commonly referred to as “physician self-referral” in that it addresses referrals for designated health services within a physician’s own practice.\textsuperscript{111} The Stark law prohibits physicians from being compensated for services in their own practice, or as a member of a group practice, where such compensation is related, directly or indirectly, to the volume or value of referrals for designated health services, even if those ancillary services are performed within the medical practice.\textsuperscript{112}

The following grid sets out the antikickback statute’s safe harbor regulations and the Stark law’s exceptions, which address similar financial relationships, highlighting the similarities and differences between the two (Table 18-1).

There are several safe harbors to the antikickback statute that do not have corresponding exceptions to the Stark law. These exceptions are as follows:

- Referral Services.\textsuperscript{131} Referral services are not prohibited if participants qualifying for participation
### Table 18-1  Comparison of antikickback safe harbors and Stark Law exceptions

<table>
<thead>
<tr>
<th>Antikickback Safe Harbors</th>
<th>Stark Law Exceptions</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Investment Interests</strong></td>
<td><strong>Ownership or Investment Interests</strong></td>
<td>Note that the Stark law exception does not have an equivalent to what is commonly called the “small entity” safe harbor which allows investment in unlisted investments. This difference leads to a prohibition against joint ventures under the Stark law.</td>
</tr>
<tr>
<td>1. For entities that possess more than $50 million in undepreciable net tangible assets, this safe harbor requires that:</td>
<td>Ownership of the following is not a prohibited ownership or investment interest:</td>
<td></td>
</tr>
<tr>
<td>a. The entity must be registered with the SEC;</td>
<td>Ownership of investment securities (including shares or bonds, debentures, notes, or other debt instruments) which may be purchased on terms generally available to the public and which are:</td>
<td></td>
</tr>
<tr>
<td>b. The investment interest must be obtained on terms equally available to the public through trading on a registered national securities exchange;</td>
<td>a. (1) Securities listed on the New York Stock Exchange, the American Stock Exchange, or any regional exchange in which quotations are published on a daily basis, or foreign securities listed on a recognized foreign, national, or regional exchange in which quotations are published on a daily basis, or</td>
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<tr>
<td>c. The entity’s services or items must be furnished or marketed the same to passive investors as noninvestors;</td>
<td>a. (2) Traded under an automated interdealer quotation system operated by the National Association of Securities Dealers, and</td>
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<td>d. The entity must not loan or guarantee funds to an investor in a position to make referrals if used to obtain the investment interest; and</td>
<td>b. In a corporation that had, at the end of the corporation’s most recent fiscal year, or on average during the previous 3 fiscal years, stockholder equity exceeding $75 million.</td>
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<td>e. The amount of return to the investor must be directly proportional to amount of capital investment.</td>
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<td>2. For entities that possess interests held by passive or active investors, this safe harbor requires that:</td>
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<tr>
<td>a. No more than 40% of the value of the investment interests of each class of investors may be held by investors in a position to make referrals;</td>
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<tr>
<td>(1) The OIG has stated that those investors who promise in writing not to make referrals to the entity will not be considered as being in a position to make referrals.</td>
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<tr>
<td>b. The terms of an investment interest offered to a passive investor in a position to make referrals must be no different than those offered to other passive investors;</td>
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<tr>
<td>c. The terms of an investment interest offered to an investor in a position to make referrals or generate business must not be based on the volume or value generated from the investor to the entity;</td>
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<tr>
<td>d. There is no requirement that a passive investor make referrals or generate business for the entity as a condition to remaining as an investor;</td>
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<tr>
<td>e. The entity’s services or items must not be marketed to passive investors differently than noninvestors;</td>
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<tr>
<td>f. No more than 40% of the entity’s gross revenue may come from referrals or business generated by an investor;</td>
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<td>g. The entity must not loan or guarantee funds to an investor in a position to make referrals if used to obtain the investment interest; and</td>
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<tr>
<td>h. The amount to the investor must be directly proportional to amount of capital investment.</td>
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(continues)
### Table 18-1  Comparison of antikickback safe harbors and Stark Law exceptions (continued)

<table>
<thead>
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<th>Antikickback Safe Harbors</th>
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<tbody>
<tr>
<td><strong>Space or Equipment Rental</strong>&lt;sup&gt;115&lt;/sup&gt;</td>
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<tr>
<td>Requires:</td>
<td>Payments made by a lessee to a lessor for the use of space or equipment are excluded if:</td>
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</tr>
<tr>
<td>1. Lease is in writing;</td>
<td>1. The lease is set out in writing, signed by the parties, and specifies the space/equipment covered by the lease;</td>
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<tr>
<td>2. Lease specifies premises covered;</td>
<td>2. The space/equipment rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease or rental and is used exclusively by the lessee when being used by the lessee;</td>
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<tr>
<td>3. If lease allows access/use for only periodic intervals rather than on a full-time basis, it must specify the schedule with the precise length and rent for such intervals;</td>
<td>a. Except that for the rental or lease of space the lessee may make payments for the use of space consisting of common areas if such payments do not exceed the lessee's pro rata share of expenses for such space based upon the ratio of the space used exclusively by the lessee to the total amount of space (other than common areas) occupied by all persons using such common areas.</td>
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<tr>
<td>4. Term of lease is for at least 1 year; and</td>
<td>3. The lease provides for a term of rental or lease for at least 1 year;</td>
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<tr>
<td>5. Aggregate rent is set in advance, consistent with the fair market value, and is not based on volume or value of referrals or business generated between the parties.</td>
<td>4. 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; the lease would be commercially reasonable even if no referrals were made between the parties, and the lease meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.</td>
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| **Personal Services and Management Contracts**<sup>117</sup>  |
| Requires: | Remuneration from an entity under an arrangement (including remuneration for specific physicians' services furnished to a nonprofit blood center) is excluded if: |
| 1. Agreement in writing and signed by the parties; | 1. The arrangement is set out in writing, signed by the parties, and specifies the services covered by the arrangement; |
| 2. Agreement specifies the services to be provided; | 2. The arrangement covers all of the services to be provided by the physician (or an immediate family member of such physician) to the entity; |
| 3. If the agreement for services is for only periodic or part-time intervals rather than on a full-time basis, it must specify the schedule with the precise length and charge for such intervals; | 3. The aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement; |
| 4. Term of agreement must not be less than 1 year; and | The key difference is that the safe harbor protects not only personal services (i.e., those provided pursuant to a contract with an individual) but also management services which could be provided by an entity. The Stark law exception only protects |
| 5. The aggregate compensation paid to the agent is set in advance, consistent with fair market value, and does not take into account referrals or business generated between the parties; | personal services but not management services. The Stark law exception is designed to protect the physician's business interests, while the safe harbor is more focused on maintaining fairness in the distribution of payments. |

One of the key differences is that under the safe harbor, the aggregate payment for the term of the lease must be set in advance. The Stark law exception does not require this. In fact, per-use payments are permitted under Phase I of the Final Stark II regulations.
6. The services under the agreement do not involve the counseling or promotion of a business arrangement or activity that violates federal or state law.

4. The term of the arrangement is for at least 1 year;
5. The compensation to be paid over the term of the arrangement is set in advance, does not exceed fair market value, and except in the case of a physician incentive plan described in subparagraph (B) (see Physician Incentive Plan below), is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties;
6. The services to be performed under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates any state or federal law; and
7. The arrangement meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.

Sale of Practice

This safe harbor allows a hospital or other entity to buy the practice of a practitioner so long as the following four standards are met:
1. The sale is completed within not more than three years;
2. The selling practitioner will not be in a professional position to make referrals to, or otherwise generate business for, the purchasing hospital or entity;
3. The practice being acquired is in a HPSA for the practitioner’s specialty;
4. Commencing at the time of the first agreement pertaining to the sale, the hospital or entity must diligently and in good faith begin commercially reasonable recruitment efforts to obtain a new practitioner to take over the acquired practice within one year, pursuant to a recruitment arrangement that meets the recruitment safe harbor.

Sale of Practice or Property

An isolated financial transaction, such as a one-time sale of property or practice, is excluded if:
1. The requirements described in subparagraphs (B) and (C) of paragraph (2) are met with respect to the entity in the same manner as they apply to an employer (see 2 and 3 of Bona Fide Employment Relationships below); and
2. The transaction meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.

The safe harbor is much narrower, only applying to a hospital’s acquisition of a practice. The Stark law exception is not limited in this manner. Another key difference is that the safe harbor requires that the practice must be in a health professional shortage area and does not apply to any property other than the physician’s practice.
**Table 18-1**  Comparison of antikickback safe harbors and Stark Law exceptions (continued)

<table>
<thead>
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| **Bona Fide Employment Relationships**<sup>121</sup>  
This safe harbor applies to employer payments to employees for covered services rendered in a bona fide employment relationship. | **Bona Fide Employment Relationships**<sup>122</sup>  
Any amount paid by an employer to a physician (or an immediate family member of such physician) who has a bona fide employment relationship with the employer for the provision of services is excluded if:  
1. The employment is for identifiable services;  
2. The amount of the remuneration under the employment;  
   a. is consistent with the fair market value of the services; and  
   b. is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician;  
3. The remuneration is provided pursuant to an agreement which would be commercially reasonable even if no referrals were made to the employer; and  
4. The employment meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.  
Subparagraph b shall not prohibit the payment of remuneration in the form of a productivity bonus based on services performed personally by the physician (or an immediate family member of the physician). | The safe harbor is far less restrictive than the Stark law exception. Note, however, that the safe harbor only applies to payments related to “covered services.” |

| **Underserved Areas**<sup>123</sup>  
Investment interests in entities in underserved areas requires that the entity be located in an underserved area (rural or urban) and that the following eight standards be met:  
1. No more than 50% of the investment interests of each class of investors may be held in the past fiscal year or 12-month period by “interested” investors (i.e., investors who are in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for, the entity). In determining whether this requirement is met, equivalent classes of equity investments may be combined and equivalent classes of debt instruments may be combined. | | |

| **Rural Provider**<sup>124</sup>  
Designated health services furnished in a rural area (an area outside a Metropolitan Statistical Area as defined by the Office of Management and Budget) by an entity are not a prohibited ownership or investment interest, if substantially all of the designated health services furnished by such entity are furnished to individuals residing in such a rural area. | | The Stark law exception is far broader than the safe harbor, potentially applying to any area outside the Metropolitan Statistical Area, whether underserved or not, with very few specific requirements. |
2. The terms on which a passive investment interest is offered to an “interested” investor must be no different than the terms on which passive investment interests are offered to other investors.

3. The terms on which an investment interest is offered to an “interested” investor cannot be related to the volume or value of past or expected referrals, services, or business generated by the investor to the entity.

4. Passive investors cannot be required to make referrals to, or be in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for, the entity as a condition for remaining an investor.

5. The entity or any investor must not market or furnish the entity’s items or services (or those of another entity as part of a cross-referral agreement) to passive investors differently than to noninvestors.

6. At least 75% of the dollar volume of the entity’s business in the past fiscal year or 12-month period must come from providing services to patients residing in a Medically Underserved Area (MUA) or who are members of a Medically Underserved Population (MUP).

7. The entity or any other investor (or anyone acting on behalf of the entity or other investor) must not loan funds to or guarantee a loan for an investor if the investor uses any part of such loan to obtain the investment interest.

8. The amount of return on the investment must be directly proportional to the amount of capital investment by the investor.
Table 18-1  Comparison of antikickback safe harbors and Stark Law exceptions (continued)

<table>
<thead>
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<tbody>
<tr>
<td><strong>Physician Recruitment</strong></td>
<td><strong>Physician Recruitment</strong></td>
<td>The Stark law exception is broader than the safe harbor in that it does not apply only to underserved areas, although its use is limited to hospitals.</td>
</tr>
</tbody>
</table>
| Practitioners recruited in underserved (rural or urban) areas must either have been practicing in their specialty for less than one year, or be relocating their primary place of practice to the underserved areas and the arrangement must comply with all of the following nine standards:  
1. The arrangement is in writing signed by the parties and specifies the benefits provided by the recruiting party, the terms under which the benefits are provided, and the obligations of each party;  
2. If the practitioner is leaving an established practice, at least 75% of the practitioner's revenues must come from treating new patients not previously seen by the practitioner at the previous practice;  
3. The benefits cannot be provided for more than three years, and during this period the terms cannot be renegotiated in any substantial respect;  
4. The practitioner is not required to refer, be in a position to refer or to influence referrals, or otherwise generate business for the recruiting entity, except that the entity may require the practitioner to maintain staff privileges;  
5. The practitioner is not restricted from establishing staff privileges or referring patients to other entities;  
6. The benefits may not vary based on the volume or value of referrals or other business generated by the practitioner that may be covered by Medicare or state health care programs;  
7. The practitioner must agree to treat patients covered by any federal health care program in a nondiscriminatory manner;  
8. At least 75% of the revenues of the practice come from treating patients residing in a Health Professional Shortage Area (HPSA) or MUA;  
9. The payments may not directly or indirectly benefit any person or entity, other than the recruited practitioner, who is in a position to make or influence referrals covered by a federal health care program. | Remuneration which is provided by a hospital to a physician to induce the physician to relocate to the geographic area served by the hospital in order to be a member of the medical staff of the hospital is excluded if:  
1. The physician is not required to refer patients to the hospital;  
2. The amount of the remuneration under the arrangement is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician; and  
3. The arrangement meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse. |
**Group Practice**

Protects ownership interests in the group itself and a physician may receive payment from investing in his/her own group practice as long as the following four standards are met:

1. The equity interests in the group practice are all held by licensed health care professionals who practice in the practice or group;  
2. The equity interests must be in the practice or group itself, and not in some subdivision of the practice or group;  
3. In the case of a group practice, the practice must meet the definition of group practice in the Stark law, and must be a unified business with centralized decision-making, pooling of expenses and revenues, and a compensation distribution system that is not based on satellite offices operating substantially as if they were separate enterprises or profit centers;  
4. Revenues from ancillary services, if any, must be derived from "in-office ancillary services" that meet the definition in the Stark law and implementing regulations.

**In-Office Ancillary Services**

Physician referrals are not prohibited for services that are furnished:

1. Personally by the referring physician, personally by a physician who is a member of the same group practice as the referring physician, or personally by individuals who are directly supervised by the physician or by another physician in the group practice, and  
   a. (1) In a building in which the referring physician (or another physician who is a member of the same group practice) furnishes physician's services unrelated to the furnishing of designated health services; or  
   a. (2) In the case of a referring physician who is a member of a group practice in another building which is used by the group:  
      i. for the provision of some or all of the group's clinical laboratory services; or  
      ii. for the centralized provision of the group's designated health services (other than clinical laboratory services).

**Price Reductions Offered by Contractors with Substantial Financial Risk to Managed Care Organizations**

Remuneration does not include any payment made between a qualified managed care plan (MCP) and a first tier contractor for providing or arranging for items or services where the following are met:

1. The agreement between the qualified MCP and the first tier contractor must:  
   a. Be in writing and signed by the parties;  
   b. Specify the items and services covered by the agreement;  
   c. Be for a period of at least one year;  
   d. Require participation in a quality assurance program;  
   e. Specify a methodology for determining payment that is commercially reasonable and consistent with fair market value and includes the intervals at which payment will be made.  
2. If a first tier contractor has an investment interest in a qualified MCP, the investment interest must meet the criteria of "Investment Interests" above.  
3. The first tier contractor must have substantial financial risk for the cost or utilization of services it is obligated to provide through one of the following payment methodologies:

**Physician Incentive Plans and Risk Sharing Arrangements**

In the case of a physician incentive plan that takes into account directly or indirectly the volume or value of any referrals or other business generated between the parties, the plan must meet the following requirements:

1. No specific payment is made directly or indirectly under the plan to a physician or a physician group as an inducement to reduce or limit medically necessary services provided with respect to a specific individual enrolled with the entity;  
2. In the case of a plan that places a physician or a physician group at substantial financial risk as determined by the Secretary pursuant to § 1876(i)(8)(A)(ii), the plan complies with any requirements the Secretary may impose pursuant to such section;  
3. Upon request by the Secretary, the entity provides the Secretary with access to descriptive information regarding the plan, in order to permit the Secretary to determine whether the plan is in compliance with the requirements of this clause.

Compensation pursuant to a risk-sharing arrangement between a managed care organization or an independent physician association...

Note that the safe harbor provision requires compliance with the Stark law exception in terms of the definition of a "group practice" and in how ancillary revenues are distributed.

The Stark law exception is again broader and less restrictive, but specifically requires compliance with the antikickback statute.

(continues)
Table 18-1  **Comparison of antikickback safe harbors and Stark Law exceptions (continued)**

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<tbody>
<tr>
<td>a. A periodic fixed payment per patient that does not take into account the date, frequency, extent, or kind of service provided;</td>
<td>and a physician (either directly or indirectly through a subcontractor) for services provided to enrollees of a health plan, provided that the arrangement does not violate the federal antikickback statute, § 1128B(b) of the act, or any law or regulation governing billing or claims submission.</td>
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<td>b. Percentage of premium;</td>
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<td>c. Inpatient federal health care program diagnosis-related groups (DRGs);</td>
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<tr>
<td>d. Bonus and withhold arrangements (see regulation for conditions).</td>
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4. Payments for items and services reimbursable by a federal health care program must comply with the following standards:
   a. The qualified MCP must submit the claims directly to the federal health care program in accordance with a valid reassignment agreement for items or services reimbursed by the federal health care program;
   b. Payments to first tier contractors and any downstream contractors for providing or arranging for items or services reimbursed by a federal health care program must be identical to payment arrangements to or between the parties for the same items or services provided to other beneficiaries with similar health status, provided that such payments may be adjusted where the adjustments are related to utilization patterns or costs of providing items or services to the relevant population.

5. In establishing the terms of an arrangement:
   a. Neither party gives or receives remuneration in return for or to induce the provision or acceptance of business (other than business covered by the arrangement) for which payment may be made in whole or in part by a federal health care program on a fee-for-service basis; and
   b. Neither party to the arrangement shifts the financial burden of such arrangement to the extent that increased payments are claimed from a federal health care program.

Remuneration does not include any payment made between a first tier contractor or between downstream contractors to provide or arrange for items or services, as long as the three standards listed above in 3, 4, and 5 are met.
are not excluded, payments to the service are assessed equally against all participants, there are no requirements on the manner in which the participant provides services to the referral, and the service makes the required disclosures to each person seeking a referral.

- **Warranties:** Buyers must report any price reduction on the cost report or claim and must provide the Secretary, upon request, the warranty information provided by the manufacturer or supplier. Manufacturers and suppliers must report the price reduction of the item on the invoice or statement submitted to the buyer and must not pay any remuneration to any individual or entity for any medical, surgical, or hospital expense incurred by a beneficiary other than for the cost of the item itself.

- **Discounts:** If the entity reports the costs on a required cost report, discounts are not prohibited if the discount is earned based upon goods and services bought within a single year, the buyer claims the discount in the year earned or the following year, the buyer reports the discount, and the buyer provides, upon request, information provided by the seller. If the buyer is a HMO or CMP, then there is no need to report the discount except as provided under the risk contract. For all other entities, discounts are not prohibited if they are made at the time of the sale or service, the buyer reports the discount when the item is separately reimbursed, and the buyer provides, upon request, any information provided by the seller.

- **Payments to Group Purchasing Organizations (GPO):** These payments are not prohibited if there is a written agreement for which items and services are furnished and the agreement contains certain specifications. Where the entity receiving the goods or services is a health care provider, the GPO must disclose in writing the amount received from each vendor with respect to purchases made by or on behalf of the entity.

- **Waiver of Beneficiary Deductible and Co-Insurance Payments for Inpatient Hospital Services Under the Prospective Payment Plan:** The hospital must not claim the amount reduced or waived as a bad debt for payment purposes and it must offer the waiver without regard to the length of stay or diagnostic related group for which the claim is filed. The waiver must not be made as part of a price reduction agreement between the hospital and third party payer, unless the agreement is part of a contract for items or services under a Medicare supplemental policy.

- **Increased Coverage, Reduced Cost-Sharing Amounts, or Reduced Premium Amounts Offered by Health Plans:** Risk-based HMOs, CMP, and prepaid plans must offer the same increased coverage, reduced cost-sharing, or premium to all enrollees. If the health plan is not risk-based then the plan must not claim the cost as a bad debt for payment purposes.

- **Price Reductions Offered by a Contract Health Care Provided to Health Plans in a Written Agreement for the Sole Purpose of Furnishing Covered Items or Services:** Certain joint ventures and the ownership of ASCs are permitted between various physicians as well as certain physicians and hospitals. Certain other requirements must be met in order to fit with the safe harbor.

- **Obstetrical Malpractice Insurance Subsidies in Underserved Areas:** Obstetrical malpractice insurance subsidies in underserved areas (rural or urban) protects payments made to provide malpractice insurance to practitioners in underserved areas that engage in obstetrical practice as a routine part of his or her medical practice in a primary care HPSA if the standards listed are met.

- **Referral Agreements for Specialty Services:** Referral agreements for specialty services allows physicians to agree to refer a patient to the other party for the provision of specialty services covered by a Medicare or a state health care program in return for an agreement by the other party to refer that patient back at a mutually agreed upon time or circumstance as long as the four standards listed are met.

- **Cooperative Hospital Service Organizations:** Cooperative hospital service organizations (CHSO) protect payments made between a tax-exempt CHSO and its tax-exempt patron hospital, where the CHSO is wholly owned by two or more patron hospitals, as long as payments from the patron hospital are for the purpose of paying for the bona fide operating expenses of the CHSO or if the CHSO makes a payment to the patron hospital, the payments are for the purpose of paying a distribution of net earnings as required by the IRS.
Similarly, there are several exceptions to the Stark law that do not have corresponding antikickback statute safe harbors. These exceptions are as follows:

- **Physicians’ Services:** Ownership and compensation arrangement prohibitions do not apply to physicians’ services provided personally by another physician in the same group practice as the referring physician.

- **Prepaid Plans:** Ownership and compensation arrangement prohibitions do not apply to services furnished to an individual enrolled in the organization if the services are furnished by an organization with a contract under § 1876 and described in § 1833(a)(1)(A). The prohibitions do not apply to services furnished to an individual enrolled in the organization if the organization is receiving payments on a prepaid basis.

- **Hospital Ownership:** A prohibited ownership or investment interest does not include designated health services provided by a hospital if the referring physician is authorized to perform services at the hospital and the ownership or investment interest is in the hospital itself (and not merely in a subdivision of the hospital).

- **Hospitals in Puerto Rico:** A prohibited ownership or investment interest does not include designated health services provided by a hospital located in Puerto Rico.

- **Remuneration Unrelated to the Provision of Designated Health Services:** A prohibited compensation arrangement does not include remuneration that is provided by a hospital to a physician if such remuneration does not relate to the provision of designated health services.

- **Certain Group Practice Arrangements with a Hospital:** A prohibited compensation arrangement does not include an arrangement between a hospital and a group under which designated health services are provided by the group but are billed by the hospital if the requirements listed in the statute are met.

- **Payments by a Physician for Items and Services:** A prohibited compensation arrangement does not include payments made by a physician to a laboratory in exchange for the provision of clinical laboratory services, or to an entity as compensation for other items or services if the items or services are furnished at a price that is consistent with fair market value.

- **Academic Medical Centers:** A prohibited compensation arrangement does not include payments to faculty of academic medical centers that meet certain conditions. These conditions, listed in the rule, ensure that the arrangement poses essentially no risk of fraud or abuse.

- **Fair Market Value:** Certain compensation relationships that are based upon fair market value are not prohibited. This exception is available for compensation arrangements between an entity and either a physician or any group of physicians as long as the compensation arrangement meets the requirements set out in the rule.

- **Nonmonetary Compensation Up to $300:** A prohibited compensation arrangement does not include noncash items or services that have a relatively low value and are not part of a formal written agreement as long as the items or services do not exceed $50 per gift and an aggregate of $300 per year. The compensation must also be made available to all similarly situated individuals, regardless of whether these individuals refer patients to the entity for services. The compensation must not be determined in any way that would take into account the volume or value of the physician’s referrals to the entity.

Health care attorneys have debated whether it would be enough to meet an exception to the Stark law to be protected from prosecution under the antikickback statute, even if the relationship at issue did not meet one of the safe harbors. In the Preamble to Phase I of the final regulations governing the Stark law (the Final Rule), the CMS makes it fairly clear that it believes that compliance with a Stark law exception is not enough to protect a relationship under the antikickback statute. It repeatedly states in the Preamble that relationships that are permitted under the Stark law could still be a violation of the antikickback statute and “may merit prosecution,” although it points out the conduct prohibited by the Stark law may not violate the antikickback statute. CMS goes on to state that the Stark law “provides only a threshold check against fraud and abuse,” but relationships still may involve an impermissible kickback.

Several of the Stark law exceptions, as defined in the Final Rule, require compliance specifically with the antikickback statute or compliance with one of its safe harbors. Moreover, CMS has stated that it is considering an exception for relationships that fit “squarely into an Antikickback safe harbor.” CMS has stated it will address this issue in Phase II of the final Stark II regulations. Presented below are some of the Stark law’s exceptions...
that CMS discusses in the Preamble in relation to the antikickback statute:

- **Indirect Compensation Exception.**[^154] This exception to the Stark law, created in the Final Rule, protects compensation arrangements in which there is at least one entity between the referring physician and the entity providing the designated health service. One of the elements of this exception is that the arrangement cannot violate the antikickback statute.

- **Employment Exception.**[^155] One of the requirements for the employment exception is that employees’ compensation not vary with the volume or value of referrals made to the employer. CMS states that if the relationship otherwise complies with the requirement of the exception, the fact that the employer requires referrals to certain providers will not vitiate the exception, so long as certain other requirements are made. CMS goes on to specifically “caution that these mandatory arrangements could still implicate the antikickback statute, depending on the facts and circumstances.”

- **Lease and Personal Services Exceptions.**[^156] CMS, in the Final Rule states its approval of lease and personal services arrangements in which the payment to or by the physician is on a per-use basis, rather than a fixed monthly, annual or similar fee. CMS states that its opinion would not change even if the physician is generating referrals. CMS points out, however, that these arrangements may violate the antikickback statute. Obviously, this would be particularly true if per-use payments vary with the volume or value of the physician's referrals.

- **Durable Medical Equipment Exception.**[^157] As part of the in-office ancillary services exception CMS permits the dispensing of certain durable medical equipment (DME) by physicians in their offices for patients to use in their homes. CMS specifically points out that the arrangement may not violate the antikickback statute. CMS discusses specifically the issue of the DME company using consignment closets in the physician’s office. This is a situation in which the DME company provides the physician with the DME at no cost. The physician does not pay for the DME until he or she dispenses it. CMS states, with regard to consignment closets, that the DME “raise significant questions” under the antikickback statute.

- **Fair Market Value Exception.**[^158] CMS creates a new exception in the Final Rule for compensation arrangements between an entity and a physician for services provided by the physician to the entity. This is one of the exceptions that specifically requires, among other things, that the relationship either (i) meet a safe harbor to the antikickback statute, (ii) not violate the antikickback statute, or (iii) that the relationship be “approved by the OIG pursuant to a favorable advisory opinion.”

- **Medical Staff Incidental Benefits.**[^159] Another new exception created by the Final Rule pertains to incidental benefits provided by a hospital to its medical staff members. These incidental benefits must be of low value. Once again, CMS points out that any such relationship should be also reviewed to ensure compliance with the antikickback statute. This includes professional courtesy discounts.

- **Services Provided to Hospitals “Under Arrangement”.**[^160] In the Preamble, CMS discusses a comment that suggested a special exception be created for compensation related to services provided to a hospital “under arrangement.” CMS declines to create such a special exception because of significant issues under the antikickback statute associated with services rendered to a hospital under arrangement. CMS states that it will monitor such relationships for abuse and that they remain subject to the Antikickback Statute.

Based on the above, it is clear that CMS does not believe that compliance with the Stark law would necessarily mean compliance with the antikickback statute or protect parties from prosecution under the antikickback statute. Although CMS does not enforce the antikickback statute directly, the Final Rule was approved by the OIG prior to publication and, therefore, undoubtedly reflects the OIG's opinion on this issue as well. Consequently, this counsels health care providers in financial relationships with referral sources or providers to whom they refer, to carefully review the implications for the relationships under both Stark law and the antikickback statute.

### False Claims Act

The Civil False Claims Act (the FCA) was originally enacted in 1863 and amended significantly in 1986. Liability under the FCA is statutory and requires a showing that one of the relevant statutory provisions has been violated. In recent years, the FCA increasingly has been employed in matters of health care fraud. This is due, in part, to the greater awareness and publicity of fraud and abuse in the health care system, which brings forth individuals who

[^154]: False Claims Act
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serve as *qui tam* relators (“whistle-blowers”). The penalty structure of the FCA provides penalties for each claim.\(^{161}\) This makes the FCA especially favorable in health care cases where providers typically submit thousands of claims, racking up high FCA penalties. The federal government, previously hostile to *qui tam* actions, has become more solicitous of such cases. This change is likely due to a recognition that detection and investigation of complex frauds, such as health care fraud, requires “insiders” who can provide detailed information about the facts and participants. *Qui tam* relators are a good source of insiders. Additionally, it makes sense for prosecutors to use the FCA instead of criminal prosecution because it is more difficult to prove intentional commission of health care fraud. Not only is the burden of proof less in an FCA case (preponderance, rather than beyond a reasonable doubt), but the *mens rea* requirement (knowingly, recklessly disregarding the truth) is less than “willfulness,” which must be proven for many criminal causes of action.

Liability under the FCA arises under one or more of seven subsections of 31 USC § 3729(a), although not are all applicable to most medical practices.

**Section 3729(a)(1)**

Section 3729(a)(1) is one of the most commonly cited sources of liability under the FCA, and provides that “[a]ny person who knowingly presents, or causes to be presented, to an officer or employee of the United States government or a member of the armed forces of the United States a false or fraudulent claim for payment or approval...is liable to the United States government.” Most courts have ruled that the essential elements to a cause of action under § 3729(a)(1) include the presentation of a claim for payment or approval to the United States government, falsity or fraudulence of the claim, and knowing presentation of the claim.

Courts are split over whether an additional element, damages, is required to prove liability under § 3729(a)(1). The majority of courts have held that the plaintiff need not prove damages under this section of the FCA. However, many of these courts, finding no need for specific proof of damages, apparently do consider the fact that indirect costs are imposed on the federal treasury by false or fraudulent claims. While some argue that the plain language of the FCA supports those courts finding that damages are a required element (e.g., in setting out the burden of proof, § 3731 [c] refers to damages as a required element), a number of courts have ruled otherwise. The Supreme Court failed to reach this issue in one of its most recent decisions interpreting the FCA, *United States ex rel. Schumer v. Hughes Aircraft Co.*\(^{162}\) As a matter of policy, the imposition of significant penalties in cases in which no economic damages were suffered by the federal government raises serious questions about whether the nature of the statute is transformed into a punitive, rather than remedial, law.

**Section 3729(a)(2)**

Section 3729(a)(2) provides that any person who “knowingly makes, uses or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the government; is liable to the United States government.” For liability to be imposed under § 3729(a)(2), each of the elements of § 3729(a)(1) must also be proven. The relator or government must also demonstrate that a false claim was knowingly presented to the government for payment. The overlap between §§ 3729(a)(1) and (2) is significant. Section 3729(a)(2) may theoretically give rise to greater liability if, for example, numerous false records are made to support a single false invoice to the government. Only the single invoice is subject to liability under § 3729(a)(1), but the underlying records supporting the false claim are arguably individual sources of liability under § 3729(a)(2). In practice, however, courts have almost universally found that penalties are imposed only for each payment demand, rather than for each false document supporting the false claim.

**Section 3729(a)(3)**

Section 3729(a)(3) imposes liability upon any person who conspires to defraud the government by obtaining approval or payment for a false or fraudulent claim. To prove a violation of § 3729(a)(3), the government or relator must demonstrate a false or fraudulent claim to the United States, payment or approval by the government, an agreement to submit the false claim, an act in furtherance of the agreement, and intent to defraud. Unlike §§ 3729(a)(1)-(2), § 3729(a)(3) requires specific intent to defraud the government. The clear language of the statute provides that the claim must be “allowed or paid.” Most courts have noted correctly that damages are a required element of liability under § 3729(a)(3). Proof of all the elements necessary to impose liability under this provision must be proven by a preponderance of the evidence.

**Section 3729(a)(7)**

Section 3729(a)(7), referred to as the “reverse false claim” provision of the FCA, provides liability for any person who “knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the government.” The reverse false claim provision is the newest basis for liability under the FCA, adopted
in 1986 because of a conflict in the case law as to whether or not false statements which resulted in loss to the government were actionable under the pre-1986 FCA in the absence of an affirmative claim for payment. To recover under subsection (a)(7), the government or relator must prove that: (1) an obligation exists to pay money to the United States; (2) a false statement was made; (3) the defendant “knew” (under Section 3729(c)) that the statement was false; (4) the statement was intended to, and did avoid, conceal or decrease the obligation; and (5) this caused some direct financial impact on the federal treasury. Alleged reverse false claims violations have been the source of significant litigation since the 1986 amendments to the FCA.

Standards for Liability
To successfully make out a claim under the FCA, the following elements must be alleged in the complaint: (1) the defendant submitted or caused another person to submit a claim for payment to the federal government; (2) the claim was false or fraudulent and/or the defendant made or used a false or fraudulent record or statement to obtain payment or approval of the false or fraudulent claim; and (3) the person submitting the claim had actual knowledge of its falsity, or acted in reckless disregard of its falsity.163 The two most hotly debated elements of the FCA claim are in the areas that deal with the “falsity” of the claim and “knowledge” requirements.

Knowing, for purposes of the FCA, means that a person, with respect to information either “has actual knowledge of the information”; “acts in deliberate ignorance of the truth or falsity of the information”; or “acts in reckless disregard of the truth or falsity of the information.”164 No proof of specific intent to defraud is required to make out a case.

A 1998 Justice Department memorandum concerning the handling of health care false claims cases listed a series of factors that should be evaluated in determining whether a claim was made “knowingly.” The memorandum included the following factors:

1. Notice to the Provider: Was the provider on actual or constructive notice, as appropriate, of the rule or policy upon which a potential case would be based?
2. The Clarity of the Rule or Policy: Under the circumstances, is it reasonable to conclude that the provider understood the rule or policy?
3. The Pervasiveness and Magnitude of the False Claims: Is the pervasiveness or magnitude of the false claims sufficient to support an inference that they resulted from deliberate ignorance or intentional or reckless conduct rather than mere mistakes?
4. Compliance Plans and Other Steps to Comply with Billing Rules: Does the health care provider have a compliance plan in place? Is the provider adhering to the compliance plan? What relationship exists between the compliance plan and the conduct at issue? What other steps, if any, has the provider taken to comply with billing rules in general, or the billing rule at issue in particular?
5. Past Remedial Efforts: Has the provider previously on its own identified the wrongful conduct currently under examination and taken steps to remedy the problem? Did the provider report the wrongful conduct to a government agency?
6. Guidance by the Program Agency or its Agents: Did the provider directly contact either the program agency (e.g., CMS) or its agents regarding the billing rule at issue? If so, was the provider forthcoming and accurate and did the provider disclose all material facts regarding the billing issue for which the provider sought guidance? Did the program agency or its agents, with disclosure of all relevant, material facts, provide clear guidance? Did the provider reasonably rely on such guidance in submitting the false claims?
7. Prior Audits or other Notice: Have there been prior audits or other notice to the provider of the same or similar billing practices?
8. Other Information: Is there any other information that bears on the provider’s state of mind in submitting the false claims?165

Three Major Categories of FCA Cases
FCA cases fall into one of three major categories, “classic” false claims, “standard of care” false claims, and “tainted” claims. “Classic” false claims are those where the services for which reimbursement is being requested were either never provided or were not provided as claimed, or were not provided by the individual whose provider number appears on the reimbursement form or perhaps are duplicate claims for the same service. Under these circumstances, “[n]o certification, implied or otherwise, is necessary when the liability stems from the defendants’ activities of billing for procedures which they did not perform. This would plainly constitute
fraud." These “classic” false claims are reflected in the following cases:

**Classic FCA Cases**

In *United States v. Krizek*, the United States filed suit against George Krizek, a psychiatrist, and his wife, Blanka Krizek, for violations of the civil FCA. The government alleged that between 1986 and 1992 Dr. Krizek submitted 8002 false or unlawful requests for reimbursement in an amount exceeding $245,392. The government alleged, *inter alia,* the Krizeks “upcoded” the reimbursement requests, that is they billed the government for more extensive services than were, in fact, rendered.167

The Court found that because of a “seriously deficient” system of recordkeeping the Krizeks “submitted bills for 45–50 minute psychotherapy sessions . . . when Dr. Krizek could not have spent the requisite time providing services, face-to-face, or otherwise.”168 For instance, on some occasions within the seven-patient sample, Dr. Krizek submitted claims for more than 21 hours of patient treatment within a 24-hour period.169 The court stated, “While Dr. Krizek may have been a tireless worker, it is difficult for the Court to comprehend how he could have spent more than even ten hours in a single day serving patients.”170 The Court stated that these false statements:

“were not ‘mistakes’ nor merely negligent conduct. Under the statutory definition of ‘knowing’ conduct the court is compelled to conclude that the defendants acted with reckless disregard as to the truth or falsity of the submissions. As such, they [were] deemed to have violated the False Claims Act.”171

Accordingly, both Dr. Krizek and his wife, Blanka Krizek, were found to have violated the FCA. The court remanded the case back to the circuit court for a recalculation of damages consistent with its written decision.172

In *US v. Cabrera-Diaz*, Dr. Cabrera, a physician, provided anesthesia services to patients. Anesthesia services are covered services under Medicare, Part B. As Dr. Cabrera’s Part B carrier, Triple S Inc. conducted a post-payment audit of the claims for anesthesia service provided by Dr. Cabrera to Medicare patients between 1994 and 1995. For statistical purposes, Triple S selected a random sample of 230 claims filed by Dr. Cabrera for the year 1994 and 231 claims for the year 1995.173

Once a valid random sample was chosen, Triple S requested the hospital medical records associated with those patients in the sample. The medical records of 73 of the patients included in the sample were unable to be produced. Therefore, the entire amount paid to Dr. Cabrera for those 73 claims was considered as an overpayment.174

Next, the remaining claim forms were compared to the time reported in the records obtained from the hospital. This audit revealed that Dr. Cabrera had overstated, falsely reported, unsupported or undocumented the anesthesia time in all but six of the 461 sampled claims. In 1994, looking only at the sample data, Dr. Cabrera billed for 99,270 minutes of anesthesia time, when the evidence provided to Triple S only supported 21,371 minutes, for a difference of 77,899 minutes. In 1995, again using only the sample data, Dr. Cabrera billed for 90,930 minutes of anesthesia time, when the evidence provided to Triple S only supported 20,987 minutes, for a difference of 69,943 minutes.175

The amount overpaid to Dr. Cabrera based on the overstated, falsely reported, unsupported anesthesia time was $75,338.75 in 1994 and $56,448.99 in 1995, on the sampled claims only.176 The results of the audit were then extrapolated to the universe of claims paid to Dr. Cabrera for 1994 and 1995. The result was an estimated overpayment to Dr. Cabrera of $237,600.39 for 1994 and $211,773.89 for 1995.177

Equally important, the audit revealed that in all but six (455 of the 461) of the sampled claims the anesthesia time had been overstated, falsely reported, unsupported or undocumented. The court found that these results were enough to demonstrate that Dr. Cabrera had either actual knowledge or constructive knowledge of the falsity, in that he acted in reckless disregard of the truth.178

Dr. Cabrera failed to appear, answer, plead, or otherwise defend this case after more than 120 days after receiving personal notice. As a result, the court entered a default judgment against Dr. Cabrera for treble damages in the amount of $1,348,122.80.179

In *US v. Mackby*, Peter Mackby was the owner and managing director of a physical therapy clinic called Asher Clinic. Asher Clinic’s operations included treatment of Medicare Part B beneficiaries. After a three-day bench trial, the district court found that Mackby knowingly caused false claims to be submitted to Medicare between 1992 and 1996 in violation of the FCA.180

Medicare pays for physical therapy services under Part B “when rendered by a physician, by a qualified employee of a physician or physician-directed clinic, or by a qualified physical therapist in independent practice.” A “physical therapist in independent practice” (PTIP) is defined in relevant part as one who “renders services free from the administrative and professional control of an employer such as a physician, institution, agency, etc.”182 Medicare caps the amount it will pay a PTIP on behalf of...
any one Medicare beneficiary in any calendar year. From 1992 through 1993, the limit was $750 per year. From 1994 through 1996, the limit was $900 per year. There is no payment limit on physical therapy services furnished by or under the supervision of a physician or incident to a physician's services.

In 1982, defendant Peter Mackby formed a partnership with Michael Leary, a licensed physical therapist, for the purposes of owning and operating Asher Clinic. Subsequent to the formation of the partnership, Asher Clinic billed Medicare Part B for services provided to Medicare patients by various physical therapists employed by Asher Clinic, using Leary's PIN. Consequently, Medicare checks were sent to Asher Clinic made payable to Michael Leary. Consequently, Medicare patients by various physical therapists employed by Asher Clinic, using Leary's PIN. Consequently, Medicare checks were sent to Asher Clinic made payable to Michael Leary, RPT.184

In June 1988, Mackby purchased Leary's interest in the clinic. He incorporated the clinic under the name M1 Enterprises, and became its sole officer and shareholder. Mackby, a nonprofessional, did not provide any physical therapy or other services to patients.185

After taking over complete control of the clinic, Mackby directed Medicom, the clinic's billing service, to substitute the PIN of his father, Dr. Judson Mackby, for Leary's PIN on the clinic's Medicare Part B claims. Mackby also told Maridy Barnett, the clinic's office manager, to use his father's PIN in billing third-party payers, including Medicare.186

The court found that Dr. Mackby did not know that his PIN was being used by Asher Clinic to bill Medicare for physical therapy services. It is undisputed that Dr. Mackby never provided medical services at or for Asher Clinic, never referred any patients to the clinic and was never involved with the care or treatment of its patients.187

For approximately eight years, Asher Clinic submitted claims to Medicare for physical therapy services using Dr. Mackby's PIN. Medicare reimbursement checks were made payable to “M. Judson Mackby, MD” and sent to the Asher Clinic address. Asher Clinic used a rubber endorsement stamp containing Dr. Mackby's name to endorse and deposit Medicare payments to its bank account.188

Dr. Mackby's PIN was inserted in boxes 24k and 33 on the Asher Clinic forms. While the purpose of box 24k is not specified on the form itself, Medicare bulletins sent to Asher Clinic state that the box is to be used for the PIN of the performing physician or supplier. Placing Dr. Mackby's PIN in box 24k indicated that Dr. Mackby was the performing physician or supplier and therefore constituted a false statement. Box 33 is clearly labeled as requiring the PIN or group number of the physician or supplier providing the treatment, and Dr. Mackby was neither of these. Therefore, placing his PIN number in this box was a false statement as well.189

The court found that by instructing Medicom, Asher Clinic's Medicare billing service, and Ms. Barnett, Asher Clinic's office manager, to use Dr. Mackby's PIN, he “caused” the claims to be submitted to Medicare. In so doing, he caused the claims to be submitted with false information.190

Lastly, the court found an obligation on the part of Mackby's to be familiar with the legal requirements for obtaining reimbursement from Medicare for physical therapy services, and to ensure that the clinic was run in accordance with all laws. By breaching this obligation, he acted in reckless disregard or in deliberate ignorance of those requirements, either of which was sufficient to charge him with knowledge of the falsity of the claims in question. See Krizek above (in failing “utterly” to review false submissions prepared by his wife, doctor acted with reckless disregard).191

Standard of Care FCA Cases

The second major category of cases includes those where the Medicare Part B category of services were in fact provided, but that the quality of care involved in the procedure is alleged to fall below that required by the Medicare program. These cases are premised on implied false certification of compliance with applicable standards of care, and are therefore called “standard of care” false claims and are displayed using the following cases:

In United States ex rel. Aranda v. Cnty. Psychiatric Ctrs. of Okla., Inc.,192 the government brought an FCA action on behalf of a psychiatric patient who was under the care of the defendant. The government alleged that the defendant knowingly failed to provide a reasonably safe, secure and quality environment for its residents and yet implicitly certified that it did by way of submitting bills to Medicare when it had previously agreed to abide by all statutes, rules, and regulations required under the Medicare programs. The hospital submitted a motion to dismiss, which was denied by the court, stating that the failure of the hospital to meet recognized professional standards could conceivably constitute an FCA violation.193 Thereafter, the case was settled and the government's theory was never challenged on a fully developed set of facts.

In United States ex rel. Luckey v. Baxter Healthcare Corp., a qui tam action was brought by the plaintiff, a former laboratory technician, against her former employer (Baxter). The plaintiff alleged that she had communicated to Baxter that its failure to test colorless blood plasma samples for saline contamination created a risk of inaccurate results that were later transmitted to the Food and Drug Administration (the FDA). Raising an implied cer-
tification theory, the plaintiff argued that Baxter’s non-compliance with the regulatory standard of care put the defendant in violation of federal statutes and regulations.\textsuperscript{196} In effect, the plaintiff argued that every time the defendant submitted a claim to the federal government, it implicitly claimed adherence to those regulations, and therefore, its claims were necessarily fraudulent.

The court declined to accept this argument stating that “[e]quating ‘imperfect tests’ with ‘no tests’ would strain language past the breaking point.”\textsuperscript{197} In addition, according to the record, there was no indication that the government was anything less than 100% satisfied with the product or the representations made in relation to the sale.\textsuperscript{198} Moreover, there is nothing in the record to even suggest that Baxter had the required intent to deceive the government.\textsuperscript{199} The record simply indicates that there is a dispute as to “whether Baxter’s testing protocols could be improved.”\textsuperscript{200} Accordingly, the court granted Baxter’s motion for summary judgment.

In \textit{United States ex rel. Mikes v. Straus}, a \textit{qui tam} action was brought by a former physician employee (the Relator) of defendant Straus’ medical group practice. The Relator alleged that Straus violated the FCA by submitting Medicare payments for spirometry tests, which did not meet the standard of care. It was alleged that the defendant knew the machinery was not calibrated correctly and yet nonetheless conducted and billed the federal health care program for the tests. Therefore, the Relator alleged that all Medicare claims amounted to false claims under the FCA.\textsuperscript{201} The district court, on the defendant’s motion, entered summary judgment for the defense stating that FCA liability pertaining to certification of compliance with regulatory and industry standards could only exist, as a matter of law, where “the claimant’s adherence to the relevant statutory or regulatory mandates lies at the core of its agreement with the government.”\textsuperscript{202}

The district court determined that the Relator failed to establish that Medicare reimbursement was in any way tied to compliance with § 1320c-5(a) of the Social Security Act (the SSA). Essentially, the court adopted the \textit{Luckey} (see above) analysis and declined to follow the \textit{Aranda} (see above) court’s rationale.

The district court’s decision to grant summary judgment was affirmed on appeal.\textsuperscript{203} In evaluating the Relator’s claim of implied false certification, the circuit court construed § 1395y(a)(1)(A) together with § 1320c-5(a). Section 1395y(a)(1)(A) of the Medicare statute states that “no payment may be made under [the Medicare statute] for items or services which...are not reasonable and necessary.” Because there is an express condition of payment—that is, “no payment may be made”—it explicitly links Medicare payments to the requirement that the particular item or service be “reasonable and necessary.”\textsuperscript{204} Accordingly, defendants’ submission of the claim forms implicitly certified the procedure as “reasonable and necessary.”

On the other hand, § 1320c-5(a) contains no such express condition of payment. Instead, § 1320c-5(a) simply states that “it shall be the obligation” of a practitioner who provides a medical service “for which payment may be made...to assure” compliance with the section. Therefore, §1320c-5(a) appears to act prospectively, setting forth obligations for a provider to be eligible to participate in the Medicare program.\textsuperscript{205}

Accordingly, the court reasoned that § 1320c-5(a) is a condition of participation in the Medicare program. Since § 1320c-5(a) does not expressly condition payment on compliance with its terms, defendants’ certifications on the CMS 1500 forms are not legally false. Consequently, defendants did not submit implicitly false claims by requesting reimbursement for tests that allegedly were not performed according to the recognized standards.\textsuperscript{206}

Alternatively, the Relator alleged that the defendant violated the FCA by submitting claims for worthless services. A worthless services claim is a distinct claim which alleges that the services provided were so lacking that, for all practical purposes, it is the equivalent of no performance at all.\textsuperscript{207}

The court stated that the “requisite intent is the knowing presentation of what is known to be false,” not simply the result of negligence or innocent mistake.\textsuperscript{208} Mere allegations that the defendant submitted Medicare claims knowing they did not conform to the ATS guidelines were alone insufficient to satisfy the standard for a worthless services claim. The idea of presenting a claim known to be false does not mean the claim is incorrect as a matter of accounting, but rather that it is a lie.\textsuperscript{209}

Overwhelming evidence of the defendants’ genuine belief that their services had real medical value caused the court to conclude, as a matter of law, they did not submit their claims with the requisite scienter. Therefore, the court concluded, there was no triable issue of fact sufficient to bar summary judgment.\textsuperscript{210}

In \textit{United States ex rel. Swafford v. Borgess Med. Ctr.},\textsuperscript{211} Swafford was a registered vascular technologist employed by defendants. Accordingly, plaintiff participated in venous ultrasound studies ordered by defendant physicians and observed defendants’ practices regarding the submission of Medicare/Medicaid reimbursement forms for ultrasounds performed on defendant physicians’ patients.

For patients suspected of suffering from risk factors for blood clots, defendant physicians would order a venous
ultrasound study. Using ultrasound, the patient’s venous system would be examined to determine the presence or absence of certain “normal” characteristics for five blood clot risk factors. Typically, the procedure would be performed by either a technician or a technologist, who would then indicate the presence or absence of the factors on a worksheet. The technician/technologist was assigned to determine either the presence or absence of the characteristics, and to indicate either “positive” or “negative” for each factor.212

Defendant physicians would review the technician/technologists’ worksheet, and then prepare a final report setting forth their findings and conclusions. Afterward, defendant physicians signed the following statement prior to submitting the results for reimbursement: “I certify that the services listed above were medically indicated and necessary to the health of this patient and were personally furnished by me or my employee under my personal direction.”213

Plaintiff alleged defendant physicians did not review any hard copy data (videotape results) generated by the studies. Instead, plaintiff contends the physicians merely reworded the technician’s or technologist’s “worksheet” to prepare a physician’s ultrasound report. Defendant physicians then billed the government for these “interpretations” which, according to plaintiff, constituted mere plagiarism of the worksheet prepared by the technician/technologist.214

Defendants sought summary judgment from the district court claiming that there was no issue of material fact, and that they should prevail as a matter of law. To succeed under a FCA theory, a plaintiff must establish at least three elements: first, that the defendant knowingly presented or caused to be presented a claim to the United States for payment or approval; second, that the claim was false or fraudulent; and third, that the defendant knew the claim was false or fraudulent.215

The parties did not dispute that defendants presented “claims” as defined under the FCA by submitting CMS 1500 forms seeking reimbursement from Medicare. Therefore, there is no genuine issue of material fact as to the first element of the FCA claim.216

As to the second element of the FCA claim, plaintiff argued that defendants’ practices fell short of the standard of care by: (1) failing to review the underlying data of the ultrasound studies—the photographs, prints or videotape of the ultrasounds taken by the technologist/technician; (2) assuming the accuracy of the worksheet information provided by the technician/technologist, a number of whom lack working knowledge of physics; and by (3) failing to perform an independent review of the hard copy data, thus increasing the risk of unnoticed interpretative error. Therefore, by submitting claims for reimbursement that represent substandard care, plaintiff argued defendants presented false claims under the FCA.217

The court concluded that the plaintiff could not demonstrate a genuine issue of material fact with respect to false claims under the FCA, even if he could demonstrate defendants’ practice failed to conform to the applicable standard of care.218 The court agreed with the Seventh Circuit decision in Luckey v. Baxter Healthcare Corp.219 when it stated that “[e]quating ‘imperfect tests’ with ‘no tests’ would strain language past the breaking point.” Consequently, the court found no genuine issue of material fact regarding the falsity of the claim.220

The court next considered the issue of scienter. To succeed under the FCA, a relator need not demonstrate specific intent to defraud the government. The FCAs scienter requirement, set forth in § 3729(b), requires either “actual knowledge” that one is submitting a false or fraudulent claim for payment or approval, acts in deliberate ignorance of the truth or falsity of one’s false claim, or ‘acts in reckless disregard of the truth or falsity of the claim.”221

Accordingly, the plaintiff must demonstrate more than mere innocent mistakes or negligence on the part of defendants. Furthermore, “what constitutes the offense is not intent to deceive but knowing presentation of a claim that is either fraudulent or simply false. The requisite intent is the knowing presentation of what is known to be false.”222

Plaintiff conceded that on at least three occasions defendant contacted CMS seeking any “published guidelines” specific to the procedures in dispute. The answer from CMS was that no such published guidelines existed. The court concluded that this evidence demonstrated that defendants evinced concern and investigated the question of what procedures were required to submit a proper claim for reimbursement. Consequently, the court ruled that there was no genuine issue of material fact as to scienter.223

Finding no genuine issues of material fact at issue in the case, the court ruled in favor of the defendant’s motion for summary judgment. On appeal, the Court of Appeals for the Sixth Circuit affirmed the lower court decision finding no error in the granting of summary judgment.224

Tainted Claim FCA Cases

The third major category of FCA-based improper Medicare Part B reimbursement claims involves patients obtained, and services provided, which result from violations of the federal antikickback statute or the federal Stark law.225 These cases involve procedures that are billed to Medicare
Part B which are entirely proper except for the fact that the services, and therefore the subsequent claim, resulted from an illegal kickback or remuneration or self-referral arrangement. These are the so-called “tainted” claims.

In US ex rel. Pogue v. Am. Healthcorp, Inc.,226 the plaintiff, Pogue, filed a qui tam action under the FCA naming as defendants his former employer, Diabetes Treatment Centers of America (DTCA); American Healthcorp, Inc. (AHC), parent company of DTCA; West Paces Medical Center (West Paces); five individual physicians; and a number of John Doe defendant hospitals and physicians.

Plaintiff alleged that defendants were involved in a scheme by which individual physicians would refer their Medicare and Medicaid patients to West Paces for treatment in violation of federal antikickback and self-referral statutes. As a consequence of these referrals, plaintiff alleged that defendants caused to be submitted to the government false and fraudulent claims. Plaintiff alleged that these claims are false and fraudulent because had the government been aware of these violations, defendants would not have been able to participate in the Medicare and Medicaid programs.227

The defendants filed a motion to dismiss for failure to state a claim upon which relief can be granted. The court ruled that Pogue failed in his complaint to allege either actual damages or that defendants’ conduct was fraudulent with the purpose of inducing payment from the government. Consequently, the district court granted the defendants’ motion to dismiss.228

Upon plaintiff’s motion for reconsideration, the court vacated its earlier order to dismiss the complaint, holding that plaintiff need not allege actual damages in order to recover under the FCA and that plaintiff need not show false claims, but only that defendants’ conduct was fraudulent with the purpose of inducing payment from the government.229

Plaintiff, in Pogue, relied on the decision in Ab-Tech Constr., Inc. v. United States,230 wherein the government brought a counterclaim under the FCA against a company that had been awarded a government contract for construction of a building pursuant to the Small Business Administration’s (SBA) program for minority-owned businesses. The purpose of the SBA program was to assist minority-owned businesses in gaining the skill and experience necessary to be competitive in the marketplace. Consequently, the SBA required approval of any management agreement, joint venture, or other agreement relevant to the performance of a subcontract formed under the SBA program. The government alleged that the plaintiff had entered into a financial arrangement with a non-minority-owned enterprise without getting SBA approval, and thereby submitted false claims in the form of payment vouchers for services performed. The court agreed finding that “the payment vouchers represented an implied certification by [the plaintiff] of its continuing adherence to the requirements for participation in the [SBA] program.”231 Stating that the FCA reaches beyond monetary claims that fraudulently overstate the amount due, the court reiterated that the FCA extends “to all fraudulent attempts to cause the government to pay out sums of money.”232

By deliberately withholding from SBA knowledge of the prohibited contract arrangement with the non-minority-owned enterprise, the plaintiff not only dishonored the terms of its agreement with that agency but, more importantly, caused the government to pay out funds in the mistaken belief that it was furthering the aims of the SBA program. In effect, “the government was duped” by the plaintiff’s active concealment of a fact vital to the integrity of that program. The withholding of such information—information critical to the decision to pay—is the essence of a false claim.233

Pogue argued that Ab-Tech governed in his case as well. The payment vouchers at issue in Ab-Tech were not themselves false in that the work was performed according to specifications and the government was properly charged. Rather, the court found that the plaintiff’s assertion that he had complied with the regulations governing the SBA program, when in reality it had not, rendered the payment vouchers false. Similarly, Pogue argued that although there is no allegation that defendants overcharged Medicare, or charged it for services not rendered, defendants’ failure to comply with Medicare laws prohibiting kickbacks and self-referrals rendered the Medicare claims submitted by defendants false or fraudulent. The court agreed.

Secondly, Pogue had not alleged that the government suffered any loss due to defendants’ alleged illegal activities. He had not asserted that the alleged kickbacks or self-referral profits were improperly included in the claims submitted by defendants to the government, nor any other facts that would suggest that the claims were somehow tainted. Apparently, the government would have paid these health care charges regardless of who performed the services and regardless of the reason the patients chose the provider.

Nonetheless, the court in Ab-Tech, and in the related case of US v. Inc. Vill. of Island Park,234 found that the defendants had violated the FCA despite a lack of risk to government funds. In Ab-Tech, the court noted that the government had suffered no loss because it still received a building built to its specifications.235 In Island Park, the
government would have paid the same amount for subsidized housing regardless of who eventually occupied those homes. In its ruling, the court said that the FCA “is violated not only by a person who makes a false statement or a false record to get the government to pay a claim, but also by one who engages in a fraudulent course of conduct that causes the government to pay a claim for money.” Therefore, Pogue alleged, the FCA clearly prohibits fraudulent acts even if they do not cause a loss to the government.

The court concluded that the FCA was intended to govern not only fraudulent acts that create a loss to the government but also those fraudulent acts that cause the government to pay out sums of money to claimants it did not intend to benefit. Consequently, in order to bring his claim under the FCA, Pogue had to show that defendants engaged in the fraudulent conduct with the purpose of inducing payment from the government. If defendants’ fraudulent conduct was not committed with the purpose of inducing payment from the government, that conduct does not operate to taint their Medicare claims and render the claims false or fraudulent under the FCA.

In the present case, Pogue sufficiently alleged that the government would not have paid the claims submitted by defendants if it had been aware of the alleged kickback and self-referral violations. Thus, Pogue alleged that defendants concealed their illegal activities from the government in an effort to defraud the government into paying Medicare claims it would not have otherwise paid. Thereafter, the court granted Pogue’s motion to reconsider and vacated its earlier decision dismissing the case.

The Pogue case was later transferred to the United States District Court for the District of Columbia pursuant to 28 USC § 1407(a), which provides for transfer of the actions pending in different courts to a single district to permit coordinated or consolidated pretrial proceedings. The defendant in Pogue again raised defenses similar to the ones earlier raised before the United States District Court for the Middle District of Tennessee. The District of Columbia court rejected these defenses and made it clear in its decision that the violation of the Medicare antikickback and self-referral laws can form the basis for a violation of the FCA. The court’s opinion went to great lengths to demonstrate that the “implied certification” theory of liability under the FCA has not been rejected by the other courts. The court concluded that this theory of liability was viable where compliance with laws such as the antikickback statute and the Stark law would affect the government’s decision to pay on claims to the Medicare and Medicaid programs.

In US ex rel. Scott Barrett v. Columbia/HCA Healthcare Corp., the United States District Court for the District of Columbia followed in the footsteps of the Pogue court ruling that violations of the antikickback statute can form the basis of a FCA violation and reaffirming its view that implied certification is a viable FCA theory in the DC Circuit. In so ruling, the court stated that the “implied certification of compliance with the statute or regulation alleged to be violated must be so important to the contract that the government would not have honored the claim presented to it if it were aware of the violation.”

In US ex rel. Thompson v. Columbia/HCA Healthcare Corp., James M. Thompson, MD, alleged that defendants submitted false or fraudulent claims under the FCA by submitting Medicare claims for services rendered in violation of the Medicare antikickback statute, and two versions of a self-referral statute. He further alleged that defendants made false statements to obtain payment of false or fraudulent claims in violation of the FCA by falsely certifying in annual cost reports that the Medicare services identified therein were provided in compliance with the laws and regulations regarding the provision of health care services. Specifically, Thompson alleged that defendants violated the Medicare antikickback statute by inducing physicians to refer Medicare patients to Columbia/HCA hospitals.

On remand from the Fifth Circuit Court of Appeals, the district court denied the defendants’ motion to dismiss and motion for summary judgment. First, the court concluded that plaintiffs had stated a claim for violation of the FCA by defendants’ alleged false certification that the Medicare services identified in the annual hospital cost reports complied with the laws and regulations dealing with the provision of health care services. The alleged prohibited financial relationships among defendants and referring physicians made the certifications false statements. In addition to highlighting express statements in the relevant statutes and CMS form 2552, plaintiffs provided evidence that CMS relied on the certifications in determining the issues of payment and retention of payment as well as continued eligibility for participation in the Medicare program. The evidence established a clear nexus between the certifications and the injury to the government.

The second issue is whether the Stark law’s express prohibition on payment for services rendered in violation of its own terms makes such alleged violations actionable under the FCA. The court concluded that it does. The court ruled that Thompson had successfully stated a claim under the FCA for violation of the express terms of § 1395nn of the Stark law in alleging that the govern-
ment was injured by Columbia defendants' submissions for Medicare payments which they knew they were statutorily prohibited from receiving because the claims came out of an alleged scheme of illegal self-referrals among the Columbia entities and physicians linked by illicit financial relationships. The court agreed with plaintiffs that a pecuniary injury to the public is not required for an actionable claim under the FCA. In addition, the court found additional monetary losses to the government in investigative and administrative costs requiring expenditure of government funds.  

The court further found that Thompson had also stated a claim for a violation of the FCA based on the alleged scheme of self-remuneration in violation of the antikickback statute, which prohibits the making of any false statements, failing to disclose material information, or making false statements or representations to qualify as a certified Medicare provider in applying for Medicare payments.

Thompson alleged that the explicit certifications of compliance with relevant health care laws and regulations were false and fraudulent and provided evidence that the government conditioned its approval, payment and defendants' retention of payment funds on those certifications. The court agreed that Thompson presented evidence of injury to the government and alleged that the government would not have paid the claims submitted by these defendants, in knowing violation of the statutory provisions, had it known of the alleged self-referral and kickback violations, which defendants allegedly concealed from the government.

The Thompson court cited Pogue concluding that the FCA “was intended to include not only situations in which a claimant makes a false statement or submits a false record in order to receive payment but also those situations in which the claimant engaged in fraudulent conduct in order to receive payment.” Thus, it concluded “that the False Claims Act was intended to govern not only fraudulent acts that create a loss to the government[,] but also those fraudulent acts that cause the government to pay out sums of money to claimants it did not intend to benefit.” Consequently, the court denied the defendant’s motion to dismiss.

In US ex rel. Barmak v. Sutter Corp., David Barmak brought an FCA claim against defendants alleging that defendants fraudulently obtained Medicare overpayments by waiving co-payments for sales of continuous passive motion exercisers and related equipment, by forging certificates of medical need, and by paying kickbacks to hospitals and doctors for patient referrals. As a result of a six-year investigation by the United States Attorney’s Office, the government decided to intervene only on the claims regarding waiver of co-payments.

On defendant’s motion to dismiss, the court ruled that the complaint was so vague and overbroad that it failed to meet the specificity requirements of Federal Rules of Civil Procedure 9(b), which states that “[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity.”

In addressing the plaintiff’s attempt to claim violations of the antikickback statute as a basis for an FCA claim, the court stated that it was “not convinced that a qui tam plaintiff can use the FCA as a vehicle for pursuing a violation of the antikickback statute in this circuit.” The court went on to state that it was “aware that some courts have permitted it, but that it remains a hotly disputed and controversial area of the law.”

First and foremost, the court pointed out that the antikickback statute is a criminal felony statute. As such, the court claimed that there is absolutely no private right of action provided and the statute is to be enforced by the Department of Justice (DOJ). Furthermore, the court stated that it has “no reason to believe, nor have the parties provided any, that Congress intended to subvert the DOJ’s exclusive jurisdiction over the antikickback statute by grafting the FCA’s qui tam provisions onto it.” This is a strong departure from the earlier decisions in Pogue and Thompson discussed above. Most importantly, the court indicated that it was “unwilling to presume…that a violation of the antikickback statute is ipso facto a violation of the FCA.”

In this particular case, assuming a right of action, the plaintiff failed to plead a causal relation between the violation of the antikickback statute and violation of the FCA. As stated by the court, the plaintiffs “have not alleged any certification of compliance with the antikickback statute, or that the government relied on such certification in making payments to defendants.” Consequently, the court dismissed plaintiff’s claims for illegal kickbacks in violation of the antikickback statute.

Restitution Regarding FCA and Receipt of Referral Fees

In 2001, the Eleventh Circuit reviewed a criminal conviction regarding the district court’s decision ordering a physician to pay restitution to Medicare for monies received in exchange for patient referrals in violation of the federal antikickback statute. The issue on appeal was whether a physician receiving remuneration for making patient referrals should be ordered to pay restitution in the amount of the illegal remuneration.
In *United States v. Liss*, a Florida laboratory (CCL) and its employees developed a scheme to defraud Medicare by paying doctors to refer their Medicare patients in return for kickbacks. CCL created consulting agreements with doctors acting as testing review officers (TROs). The agreements allowed the doctors to authorize lab work for an individual without the need to seek authorization from the individual’s own physician. As such, the TRO agreements served to disguise the kickbacks that were given in return for the patient referrals.257

In August 1996, CCL signed a TRO agreement with a co-defendant physician named Michael Spuza, in which Spuza was paid $600 a month. Between August 1996 and April 1998, CCL paid $12,000 to Spuza under the TRO agreement. In addition, CCL made 28 equipment sublease and office rental payments on behalf of Spuza totaling $55,371.36. Medicare reimbursed CCL $269,004.73 as a result of the referrals made by Spuza for clinical laboratory work. The court found that all the associated referrals were made for legitimate medical reasons.258

The government claimed that according to the anti-kickback statute Spuza was required to pay the full amount of remuneration it had been paid by CCL for the referrals. The court agreed with the government’s argument, but failed to make any findings of fact on the issue. Accordingly, Spuza was ordered to pay $55,371.36 in restitution.259

On appeal, Spuza contended that the district court erred in ordering him to pay restitution because the government offered no evidence to suggest that the Medicare program suffered any loss attributable to the illegal remuneration from CCL. Spuza argued that because the referrals made to CCL were medically necessary and because he was not involved in fraudulent billing, it was error for the court to assume that Medicare suffered a loss which was attributable to his receipt of remuneration.260

According to *United States v. Martin*,261 an award of restitution must be based on the amount of loss actually caused by the defendant’s conduct. The government bears the burden of proving the amount of the loss.262 In Spuza’s case, the government offered no evidence to prove that the Medicare program suffered any loss attributable to Spuza’s receipt of remuneration. The amount paid by Medicare to CCL was not affected by what CCL did with the money it received. Although CCL may owe restitution if it fraudulently billed for the services allegedly referred by Spuza, billing fraud is not a part of Spuza’s offense conduct.263

The court found there was no basis for such an assumption of loss to Medicare because the medical necessity of the referrals is unquestioned. Accordingly, the court vacated the district court’s restitution order.264

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**Antitrust Laws and the Health Care Industry**

Antitrust laws were established to promote and protect competition, thereby ensuring lower consumer prices and new and better products available at market. In a freely competitive market, businesses tend to lower prices and create better quality products in an effort to attract a greater number of consumers. The idea is that greater competition and an increased potential for profits will spur product innovation and more efficient methods of production, both of which benefit the ultimate consumer.

While operating within a competitive market, there is no need for government intervention. On the other hand, when competitors collude to fix prices, limit output, divide business between them, or make other anti-competitive arrangements that provide no benefits to consumers, the government has the power to act to protect the interests of consumers and taxpayers.

In response to changes in the health care industry, many health care providers are merging or consolidating their practices. These mergers can potentially have a negative effect upon competition among providers within the health care industry, and thereby, run the risk of violating antitrust laws.265 The antitrust laws under which mergers in the health care industry are most likely to be challenged are Section 1 of the Sherman Act and Section 7 of the Clayton Act.

**The Sherman Act**

Enacted in 1890 and named after the late US Senator John Sherman, the Sherman Act266 was designed to curb the public’s concerns about the dangers of concentrating economic power in the hands of a limited number of individuals, predatory practices used by companies to restrain rivals, and extreme methods used by companies to achieve unjust ends or eliminate competitors.

Section 1 of the Sherman Act provides that “[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several states, or with foreign nations, is declared to be illegal. Every person who shall make any contract or combination or conspiracy hereby declared to be illegal shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding $10,000,000 if a corporation, or, if any other person, $350,000, or by imprisonment not exceeding three years, or by both said punishments, in the discretion of the court.”267 Examples of such activities include such things as horizontal price fixing, competitively motivated
group boycotts, tying agreements, and other broadly interpreted activities unreasonably affecting commerce. By its very definition, Section 1 does not reach those actions that are unilateral in nature.

A preliminary question for analyzing a particular practice under Section 1 of the Sherman Act is whether the practice in question requires the concerted effort of two or more parties. In horizontal markets, courts generally consider conduct between competitors a per se violation when that conduct includes price fixing, market division, group boycotts, and coerced tie-in agreements.

On the other hand, if it is determined that the conduct in question is not a per se violation, then the court will apply the “rule of reason” analysis. This means that the court will balance the harmful conduct against pro-competitive activity such as the activity's effect on lowering costs. In applying this analysis, the court will consider the following factors: market share, ease of market entry, competitive effects, and efficiencies achieved by the questioned activity.

An example of an illegal combination would be an explicit agreement between producers to limit their output in such a way as to artificially “fix” the price of their product above the market-clearing price found in a truly competitive market. This is not to say that the Sherman Act cannot be violated without an explicit agreement between competitors. Implicit collusion can be construed as violating the law. Two companies need not have direct communication to violate the Sherman Act; the publication of pricing information in an effort to establish an implied understanding to “fix” prices can be sufficient.

The Clayton Act

Enacted in 1914, the Clayton Act outlawed price discrimination, tying and exclusive dealing contracts, mergers of competing companies, and interlocking directorates. Section 7 of the Clayton Act deals with mergers of two or more entities. It prohibits mergers and acquisitions where the effect “may be substantially to lessen competition” or tends to create a monopolistic environment in the market. According to the Hart–Scott–Rodino Act, parties to certain mergers and acquisitions must notify the federal government in advance if the parties and the transaction are of a sufficient size, as defined by the statute.

In 1950, Congress modified Section 7 of the Clayton Act to prohibit one company from acquiring part or all of assets of a competitor if it could result in substantially lessening competition or creating a monopolistic market. Prior to the 1950 amendment, the Clayton Act only prevented a corporation acquiring stock of a competitor, not other assets. In 1980, Congress further amended Section 7 of the Clayton Act, extending its reach to any person subject to Federal Trade Commission (FTC) jurisdiction, thus adding partnerships and sole proprietorships.

Unlike the Sherman Act, acts prohibited by the Clayton Act were not subject to criminal penalties, but rather only civil remedies. Where the Department of Justice (DOJ) directly enforces actions of the Sherman Act, both the DOJ and the FTC have the authority to enforce the Clayton Act. In addition, private parties may seek treble damages for injuries resulting from Section 7 violations.

Hart–Scott–Rodino Act

The Hart–Scott–Rodino Antitrust Improvements Act of 1976 modified the Clayton Act to require parties to a merger to notify the FTC and the DOJ prior to entering into certain transactions. A premerger notification must be filed if two parties merge, one party acquires the stock or assets of another party, or a new entity is set up to operate an enterprise, and all of the following three conditions are met: (1) at least one participant in the transaction is engaged in or effects commerce; (2) the transaction involves the acquisition of assets or voting securities and either (a) the acquired firm is engaged in manufacturing and has total assets or annual net sales of $10 million or more, and the acquiring firm has annual net sales or total assets of $100 million or more, or (b) the acquired firm has total assets or annual net sales of $100 million or more, and the acquiring firm has total assets or annual net sales of $10 million; and (3) as a result of the transaction, the acquiring firm obtains 15% or more of the voting securities or assets of the acquired firm, or obtains voting securities or assets of the acquired party which in the aggregate exceed $15 million.

Notwithstanding the reporting requirements mentioned above, there are a number of transactions that may be exempt from such requirements, including transactions: between related entities, for investment purposes, by creditors and insurers, involving nonvoting and convertible securities, and those involving acquisitions made in the ordinary course of business. It is also important to be aware of the existence of regulations that explicitly prohibit structuring a transaction to avoid the Hart–Scott–Rodino reporting requirements. The DOJ and FTC keep a sharp lookout for noncompliance with this regulation and are vigilant to prosecute such behavior.

In addition to the notice requirement, for transactions other than cash tender offers, the agencies implemented a 30-day waiting period before a merger could be finalized, or a 15-day waiting period for cash tender offers. The agencies are not prohibited from bringing actions subsequent to the applicable review period, but they
generally do not intervene to undo a merger after the expiration of the review period.

**Antitrust Safety Zones**

In August 1996, the FTC and DOJ issued a joint statement discussing six newly implemented antitrust enforcement policies regarding mergers and consolidations in the health care industry. The six policies discussed in the joint statement include safety zones related to hospital mergers, hospital joint ventures involving high-technology or other expensive medical equipment, physicians' provision of information to purchasers of health care services, hospital participation in exchanges of price and cost information, health care providers' joint purchasing arrangements, and physician network joint ventures. Safety zones are to antitrust as safe harbors to the antikickback statute, any arrangements that fall outside a safety zone do not necessarily violate antitrust laws, but unless a situation fits squarely within the safety zone, the parties involved can never be sure that they will not be investigated and possibly prosecuted.

The safety zone dealing with hospital mergers is perhaps the most important. With respect to hospital merger safety zones, the DOJ and FTC will not challenge any merger between two general acute-care hospitals if one of the hospitals (1) has an average of fewer than 100 licensed beds over the three most recent years, and (2) has an average daily inpatient census of fewer than 40 patients over the three most recent years, absent extraordinary circumstances. This particular antitrust safety zone will not apply if that hospital is less than five years old.

Historically, antitrust challenges to hospital mergers have been uncommon. That being said, procedures have been established by the FTC and DOJ in which hospitals that are considering a merger can seek an advisory opinion (FTC) or a business review (DOJ) to verify whether they fit within an enumerated safety zone. Responses to such requests are issued within 90 days of submission.

In reaction to changes in the health care industry, many providers and hospitals are responding by merging or consolidating their operations. This being the case, it is important for physicians, and hospitals alike, to be aware of potential antitrust implications involved in their decisions.

### Other Considerations

The legal issues discussed herein have focused almost entirely on federal laws and regulations. This is not to imply that states do not have their own laws pertaining to kickbacks, physician self-referrals, and patient-brokering. It is important to be aware that state laws must also be considered when evaluating certain types of business arrangements, such as those described herein. Consequently, it is of the utmost importance to know about your state's laws and be aware of how they may affect your particular business arrangements.

**Endnotes**

2. OIG Advisory Opinions can be obtained on the Internet at http://www.oig.hhs.gov/fraud/advisoryopinions.html.
5. Id.; 42 C.F.R. § 1001.952.
8. Pursuant to authority under Section 205 of HIPAA and regulations under 42 C.F.R. Part 1008.
9. 42 C.F.R. § 1008.36; 42 C.F.R. § 1008.11; 42 C.F.R. § 1008.31.
10. 42 C.F.R. § 1008.53.
11. 42 C.F.R. § 1008.5(a).
12. 42 C.F.R. § 1008.5(b).
14. Id. at 71–72.
17. 64 Fed. Reg. 63,518, 63,519 (November 19, 1999) (emphasis added).
18. United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Davis, 132 F.3d 1092 (5th Cir. 1998).
19. Kats, 871 F.2d 105 (9th Cir. 1989).
20. Id. at 108.
21. Id.
23. United States v. McClatchey, 217 F.3d 823 (10th Cir. 2000).
24. Id. at 834 (citing the district court's jury instruction 32).
27. Id. at 29 (citing the district court's jury instruction).
28. Id. at 32–33.
30. Hanlester Network v. Shalala, 51 F.3d 1390 (9th Cir. 1995).
31. Id. at 1399.
33. Jain, 93 F.3d at 436.
34. Id.
36. Id. at 838.
39. Id. at 191.
44. 42 C.F.R. § 411.350.
45. 42 C.F.R. § 411.351.
47. 69 Fed. Reg. 16054.
48. 42 U.S.C. § 1395nn(g).
49. Id.
50. 42 U.S.C. § 1395nn(a); 42 C.F.R. § 411.351.
51. See 42 C.F.R. § 411.351.
52. See 42 C.F.R. § 411.355(a).
53. See 42 C.F.R. § 411.351.
54. Id.
55. Id.
57. 42 C.F.R. § 411.354(a).
58. 42 C.F.R. § 411.354(b).
59. 42 C.F.R. § 411.354(b)(2).
60. 42 C.F.R. § 411.354(b)(1).
63. See 42 C.F.R. § 411.354(b)(3).
64. 42 U.S.C. § 1395nn(b)(1)(B).
66. 42 C.F.R. § 411.354(b)(5).
67. 42 C.F.R. § 411.353(e).
68. 42 C.F.R. § 411.354(c)(2).
69. 42 C.F.R. § 411.354(c)(2)(ii).
70. 42 C.F.R. § 411.354(c)(2)(iii).
71. 42 C.F.R. § 411.357(p).
72. See next section for a more complete list of exceptions and comparison to the antikickback statute safe harbors.
73. 42 U.S.C. § 1395nn(b)(1).
75. 42 U.S.C. § 1395nn(b)(2).
76. 42 U.S.C. § 1395nn(b)(3).
77. 42 U.S.C. § 1395nn(c).
78. Id.
82. Id.
83. 42 U.S.C. § 1395nn(e)(2).
84. 42 U.S.C. § 1395nn(e)(3).
85. 42 U.S.C. § 1395nn(e)(4),(5),(6).
86. 42 U.S.C. § 1395nn(e)(7).
87. Id.
88. 42 U.S.C. § 1395nn(e)(8).
89. 42 U.S.C. § 1395nn(1),(2),(3),(5),(7).
91. 42 C.F.R. § 411.357(d).
92. 42 C.F.R. § 411.357(k).
93. 42 C.F.R. § 411.357(m).
94. 42 C.F.R. § 411.357(o).
100. 42 U.S.C. § 1395nn(a)(1); 42 C.F.R. § 411.350.
103. 42 U.S.C. § 1320a–7(b).
104. 42 U.S.C. § 1320a–7a(a).
105. Id.
106. 42 U.S.C. § 1395nn(g)(3).
108. See 42 C.F.R. § 1005.15(d).
109. See 42 U.S.C. § 1395mn(g).
110. Id.
113. 42 C.F.R. § 1001.952(a).
114. 42 U.S.C. § 1395mn(c); 42 C.F.R. § 411.356.
115. 42 C.F.R. §§ 1001.952(b)–(c).
117. 42 C.F.R. § 1001.952(d).
118. 42 U.S.C. § 1395nn(e)(3); 42 C.F.R. § 411.357(d).
119. 42 C.F.R. § 1001.952(e).
120. 42 U.S.C. § 1395nn(e)(6); 42 C.F.R. § 411.357(f).
121. 42 C.F.R. § 1001.952(i).
122. 42 U.S.C. § 1395nn(e)(2); 42 C.F.R. § 411.357(c).
125. 42 C.F.R. § 1001.952(n).
126. 42 U.S.C. § 1395nn(e)(5); 42 C.F.R. § 411.357(e).
127. 42 C.F.R. § 1001.952(p).
129. 42 C.F.R. § 1001.952(u).
131. 42 C.F.R. § 1001.952(f).
132. 42 C.F.R. § 1001.952(g).
133. 42 C.F.R. § 1001.952(h).
134. 42 C.F.R. § 1001.952(j).
135. 42 C.F.R. § 1001.952(k).
136. 42 C.F.R. § 1001.952(l).
137. 42 C.F.R. § 1001.952(m).
138. 42 C.F.R. § 1001.952(n).
139. 42 C.F.R. § 1001.952(o).
140. 42 C.F.R. § 1001.952(s).
141. 42 C.F.R. § 1001.952(q).
143. 42 U.S.C. § 1395mn(b)(3).
144. 42 U.S.C. § 1395mn(d)(3).
147. 42 U.S.C. § 1395mn(e)(7).
149. 42 C.F.R. § 411.357(e).
150. 42 C.F.R. § 411.357(i).
151. 42 C.F.R. § 411.357(k).
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253. Id. at *17.
254. Id. at *17–18.
255. Id.
256. Id.
257. United States v Liss, 265 F.3d 1220, 1224 (11th Cir. 2001).
258. Id. at 1224–25.
259. Id. at 1231.
260. Id.
261. United States v. Martin, 195 F.3d 961, 968 (7th Cir. 1999).
262. 18 U.S.C. § 3664(e); United States v McIntosh, 198 F.3d 995, 1003 (7th Cir. 2000).
263. Liss, 265 F.3d at 1232.
264. Id.
271. See 16 C.F.R. § 801.90.

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