Phantom Billing, Fake Prescriptions, and the High Cost of Medicine

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THE MAJOR HEALTH CARE FRAUD LAWS

Kickbacks, Self-Referrals, and False Claims

The current and former owners of a Miami hospital agreed to pay $15.4 million to settle federal and state civil suits over kickbacks paid to physicians for patient admissions. Other patients—some of whom were from assisted-living facilities owned by the perpetrators—were admitted to the hospital for unnecessary treatments.¹

An Atlanta hospital and two physician-owned businesses agreed to pay $6.37 million after being accused of violating the physician self-referral statute as a way of increasing their Medicare reimbursements. The government claimed that the hospital had purchased platelet products from one of the businesses at an inflated price and had paid the other business fees that exceeded fair market value.²

A hospital group based in South Texas agreed to pay the U.S. government $27.5 million to settle violations of the federal antikickback, self-referral, and false claims acts. Between 1999 and 2006, the group paid doctors for patient referrals—in violation of the antikickback law—and disguised this arrangement through a series of sham contracts, medical directorships, and lease agreements—in violation of the antireferral law. Because this case also involved Medicare billings, the hospital group violated the federal false claims act. A former employee turned whistle-blower received $5.5 million for reporting the false claims and assisting federal prosecutors.³

These cases involve violations of two major federal laws—the antikickback statute and the Stark Law—both of which prohibit certain conflicting business
relationships in the health care field—and the false claims acts, which punish those filing false or fraudulent claims against the government. In this chapter I discuss these laws as well as several other major laws that have a direct impact on health care in the United States.

Federal Fraud Laws and Health Care

When criminals commit fraud, they usually also commit the facilitating crimes—conspiracy, mail and wire fraud, money laundering, tax evasion, lying to federal officials, perjury, and obstruction of justice—described in the previous chapter. There are, however, five laws that are specific to health care fraud: the anti-kickback statute, the Stark Law prohibiting self-referrals by physicians, the false claims statutes, the Health Insurance Portability and Accountability Act, and the Federal Food, Drug and Cosmetic Act.

With the establishment of the Medicare and Medicaid programs in 1965 and the fee-for-service emphasis of these programs, perpetrators of health care fraud turned their attention to the deep pockets of the federal and state governments. Simultaneously, Congress, state legislatures, the health care professions, and health insurers began to pay serious attention to health care fraud and abuse. By the mid-1980s, the U.S. Department of Health and Human Services, Office of the Inspector General had become the primary enforcement agency in the battle to abate health care fraud. The OIG has the authority to investigate and enforce Medicare and Medicaid fraud and abuse laws through administrative agency proceedings. Other federal agencies, including the U.S. Department of Justice, U.S. Department of Defense, and the FBI also become involved in specific fraud cases. Since Medicaid is jointly administered by the federal and state governments, most states have Medicaid fraud units.

The Antikickback Statute

Practices long regarded as unethical among health care providers were made illegal under the 1972 antikickback law. This statute prohibits the solicitation or receipt of payments (kickbacks) in return for referring patients to purchase products or services paid for by Medicare, Medicaid, or other federally funded health care programs. A hospital that offers kickbacks to an ambulance company for transporting accident victims to their hospital instead of to a more conveniently located or better equipped one violates the antikickback statute as does a laboratory that offers payments to doctors in exchange for directing blood work to their labs instead of to a competitor’s lab.

Kickbacks for referrals have the potential to compromise the quality of patient care by giving doctors, podiatrists, or whoever is involved, an incentive to
deliver treatment that is not needed, to prescribe drugs that are unproven for a particular illness, or to charge for services that may have not been delivered. Patients are at risk for harm when their treatments are based not on their efficacy but on the amount of money these treatments funnel into their doctor's back account. Moreover, kickbacks drive up the cost of operating federal health care and private insurance programs.

Violations of the antikickback statute constitute a felony punishable by a maximum fine of $25,000, five years in prison, or both. Under the Balanced Budget Act of 1997, the OIG may impose an additional penalty of up to $50,000 per illegal kickback and damages of up to three times the amount of the kickback.6

On the surface, the antikickback law appears to be straightforward: a violation of the statute occurs, for example, when a person extracts or accepts a fee for patient referrals or when a doctor gets money under the table for purchasing medical equipment. A typical case arose in 2009 when four medical-device firms were accused of paying kickbacks to heart surgeons and hospitals for buying surgical products used to correct irregular heartbeats. These kickbacks were illegal because they resulted in excessive charges to the Medicare program.7 In U.S. v. Hancock, the U.S. Court of Appeals (7th Circuit) rejected an earlier district court opinion, favoring instead a broad definition of kickbacks, bribes, and rebates. Hancock upheld the conviction of a group of chiropractors who had received “handling fees” for referring blood and tissue samples to a laboratory.8 The antikickback statute was again amended in 1980 to require a conviction only if the perpetrator “knowingly and willfully” violated the law.

Defining what constitutes a kickback, bribe, or rebate, however, has posed a problem for the courts. Giving a physician a hundred bucks per referral is obviously a kickback. But is it a kickback for a pharmaceutical sales representative to take a physician to dinner at a fancy restaurant as part of a sales campaign to promote a recently approved drug? What if dinner is not enough to convince the physician to prescribe the drug to her patients? Is it legal to pay her way to an exclusive resort in the Bahamas for a week-long “educational” session on its benefits? What about university medical school faculty having lucrative consulting arrangements with major pharmaceutical and medical equipment firms? Is it a form of kickback for them to skew the results of their research in favor of the corporation that pays their consulting fee if such dishonesty ultimately affects Medicare or Medicaid expenditures?

The Medicare and Medicaid Antifraud and Abuse Amendments (1977) expanded the antikickback statute by including any remuneration—cash or any other object of value—given directly, indirectly, overtly, or covertly.9 Items of value may include free trips to medical conferences, free training for medical office staff, frequent-flier miles, and consulting fees designed to hide kickbacks.

Doctors have argued that they are not influenced by such gifts. Federal legislation, however, is based on the well-known psychological and anthropological
insight that gift giving involves an obligation to reciprocate. We seem hardwired to reciprocate when we receive a “gift”—no matter how small. That is why wine stores give tastings on Saturday afternoons. Wine store managers know that someone who receives the equivalent of an eight-ounce glass of wine will feel somewhat obliged to buy a bottle to return the favor. The gift-exchange phenomenon is found in nearly all sales-customer relationships, including the dealings between physicians and medical equipment or pharmaceutical sales representatives. According to a study of 352 third- and fourth-year students at two medical schools, even giving someone an item of little value, such as a clipboard or a notepad emblazoned with a pharmaceutical brand, can alter one’s preference for a particular product. (In this study the favored product was the anticholesterol drug, Lipitor). If gifts such as a coffee mug or a pen-and-pencil set are enough to sway at least some physicians to prefer one brand over another, one can only imagine the loyalty that a physician might show if given a “free” trip to a Caribbean resort or a set of “complimentary” tickets to a major sporting event.

For this reason, states such as Minnesota, Massachusetts, and Vermont enacted laws that restrict physicians from receiving gifts from pharmaceutical and medical-equipment manufacturers. Many medical schools have also imposed similar prohibitions on their faculty. Impressed with the effectiveness of these state laws, the federal government followed suit by passing the Physician Payments Sunshine Act that goes into effect in 2012. The federal law provides transparency by requiring companies to record and report any payment to a physician in excess of $10. A searchable database of physician payments is supposed to be available by fall 2013.

An example of a kickback scheme involves the ringleader of one of the largest illegal patient-brokering networks in the United States. Patient brokering is simple. Brokers round up patients, often those who are elderly or indigent, and they receive a bounty (or kickback) from health care providers who want to make a fast buck from Medicare or Medicaid. The provider who pays the bounty treats the patient—or pretends to do so—and then submits a claim to a public or private insurer. Prosecutors claim that the ringleader and his partners used bribes, phony employment contracts, and false promises to clients to run their New Jersey patient-brokering business. This criminal enterprise sold referrals to treatment centers—mostly in Florida—for up to three thousand dollars per patient, and the patients often received inappropriate and unnecessary treatments. Between 1989 and 1997, the scheme generated $32 million in illegal kickbacks to the broker. The ringleader was also charged with conspiracy, mail and wire fraud, and obstruction of justice (because he shredded incriminating records that had been subpoenaed by a grand jury). But by assisting in the prosecution of thirty other Medicare fraud cases, however, he received a light, sixteen-month, federal prison sentence. He was also ordered to pay a fine of $250,000 and make restitution of $1.5 million to settle the government’s civil claims against him.
Another patient-brokering case, this one from the Tampa, Florida, area, is also illustrative.

[The broker] was a pitiful sight Thursday in the center of a quiet federal courtroom. The 60-year-old grandmother wept after testifying about being broke, unemployed, afflicted with chronic health problems and the sole caregiver for her frail, 95-year-old mother.... It has been a rapid descent for the Spring Hill woman. Just a few years ago [she was] a well-traveled entrepreneur in a health care cottage industry that raked in millions by matching patients with treatment facilities.... But [her] pitches to patients were often as phony as her Ph.D., a $150 certificate from a California diploma mill.... Her business was brokering patients into treatment for bounties as high as $3,000 a head.... When she collected on patients insured by Medicare or Medicaid, the brokering became a federal crime, one that put the FBI and federal prosecutors in Tampa on the track of one of the largest health care scams in U.S. history.14

Kickbacks often come with a disguise. A fraudster may attempt to hide funds obtained from illegal kickbacks by combining them with funds earned from a legal business. In United States v. Greber, the U.S. Court of Appeals (3rd Circuit) held that “if one purpose of the payment was to induce future referrals, the Medicare statute has been violated.”15 The defendant, an osteopathic physician, was the president and founder of a diagnostic services firm. One device sold by the company was a monitor used for recording a patient's cardiac activity on a computer-monitored tape. Medicare was billed for the monitoring services, and, when reimbursements were received, the company forwarded 40 percent of the Medicare payment (not to exceed $65 per patient) to the referring physician. These payments represented an “interpretation fee” paid to physicians for their initial consultation and for explaining test results to patients. Physicians, however, received these fees even when they did not evaluate the monitoring data. But the fixed percentage paid to the referring physician was more than Medicare allowed for such services. During the trial, the defendant testified that “if the doctor didn't get his consulting fee, he wouldn't be using our service. So the doctor got a consulting fee.” Based on the company’s billing practices, the indictment charged the defendant with giving kickbacks to the referring physicians in violation of the federal antikickback statute. The Greber case established what has become known as the “one-purpose test.” This test, according to the court, stipulates that “if the payments were intended to induce the physician to use [the company’s] services, the statute was violated, even if the payments were also intended to compensate for professional services.”

Other court rulings indicate that expected future payments, in order to be deemed illegal kickbacks, must be fairly specific and not based merely on an uncertain expectation of remuneration. In United States v. McClatchey a federal
district court jury found that a group of hospital administrators and physicians had conspired to sell hospitals “batches of nursing home patients.” One of the defendants served as chief operating officer and senior vice president of a medical center, and later as a senior vice president of its parent corporation. Two doctors who operated a medical practice that provided care to patients in nursing homes were also involved. In January 1985, the medical center entered into a one-year contract with the two doctors, paying them a total of $150,000 to serve as “co-directors of gerontology services.” The financial officer of the medical center testified that the negotiations for the 1985 contract had been “backwards;” first setting the fee with the doctors and only then agreeing to the services they were expected to provide. As it turned out, the doctors began referring large numbers of their patients to the medical center. In June 1986, the center entered into a second one-year agreement with the doctors that paid them a combined $150,000. The medical center continued the $150,000 salary each year through 1993, with the exception of 1990, when each doctor received only $68,750. Although the hospital tried to shelter this arrangement with a sham contract for services, it was established that the two physicians did not provide the services.

Health care fraud and abuse cases often involve complex medical arrangements that must be evaluated through a proliferating array of complex laws. In McClatchey, the federal district court judge was unfamiliar with the relevant laws and did his best to give the defendants the benefit of the doubt during evidentiary rulings and jury instructions. The federal district court granted a motion for acquittal on the basis that no reasonable jury could have concluded beyond a reasonable doubt—that the defendant intended to violate the antikickback law.

On appeal, the 10th Circuit Court disagreed with the lower court’s decision, but said that “defendants...cannot be convicted merely because they hoped or expected or believed that referrals may ensue from remuneration that was designed wholly for other purposes. Likewise, mere oral encouragement to refer patients or the mere creation of an attractive place to which patients can be referred does not violate the law. There must be an offer or payment of remuneration to induce.”16 Still, defining what amounts to an intentional violation of the antikickback law remains uncertain. As McClatchey and other court rulings indicate, each case will have to be examined in light of its specific facts, circumstances, transaction structure, and financial impact.17

Complicating matters further is the fact that Congress has established a number of exceptions to the antikickback statute, known as “safe harbors.”18 Safe harbors encompass business practices such as investments in medically underserved areas, price discounts, referral services, bona fide employment relationships, deductible and coinsurance waivers, investments in ambulatory surgical centers, and certain equipment rentals. For example, it is permissible to pay recruitment
fees to physicians as a means of attracting them to medically underserved areas. The physician must earn at least 75 percent of his or her revenues by serving patients in the underserved area, and the safe harbor is limited to three years.

Another safe harbor that has been the target of criticism pertains to group-purchasing organizations—known as GPOs. GPOs are used by networks of health care providers, such as a group of hospitals, to make bulk purchases of supplies. Large-volume purchases—at least in theory—should lower unit costs and save health institutions, consumers, and taxpayers substantial sums of money. The antikickback law comes into play because the expenses associated with GPOs are covered by the vendors who supply them with products. This arrangement might be regarded as a kickback of sorts—except for the fact that these purchasing arrangements have been protected by a safe harbor. Several members of Congress, however, have questioned the legality of the GPOs and are threatening to rescind the safe harbor—a devastating turn of events for medical-supply vendors.19

Because of the complexity and uncertain application of the laws regulating federal health care programs, physicians may be fearful of making an illegal kickback by mistake.20 As one observer noted, “The myriad, cumbersome rules governing state and federal health care programs are not a model of clarity. At times prudent health care providers will attempt in good faith to comply fully with the rules, but because of the inherent ambiguity in the rules, will act in accordance with an incorrect interpretation of the law.”21

Going back to McClatchey, it is hard to know whether the former administrator, who was released from federal prison in March 2004, was the perpetrator of a felony or the victim of his own inability to decipher the antikickback statute. The judicial system claimed he was the first, but another observer views him as the victim.

The world of health care is no longer real. From [his] perspective, it's not even close. Although he wakes up every morning and falls asleep every night thinking of nothing else, he still can scarcely believe what has happened to him. Were it not for the emotional support of his family and friends, and the financial and legal support of [his former employer], he would have been utterly destroyed, not merely devastated as he is now. And he is still not sure why any of this happened….His own descent into criminality is as confusing to him as it is to the casual observer. Let's see, he helped set up a model program for the sickest of the sick; one that was carefully drafted by the best attorneys in the field to comply with an absurdly vague law; one that cost Medicare no more than it ought to have; one that profited [him] not a dime; one that did little in the way of revenue or glory for his highly respected, not-for-profit employer; one that is being defended vigorously by just about every thinking person in the health care field.
Still, this was all “bad,” claimed the prosecutor, Tanya Treadway (“not available for comment”), because “the defendants got together and treated the patients like commodities.” But if the truth be told, it was the Medicare program that insisted on the notion of paying “per head,” of “capitizing” in healthcare-speak, of treating patients like mindless commodities and not like the independent, thinking customers they once used to be.22

A reading of the federal regulations suggests why gaining a clear understanding of the safe harbor provisions can be a challenge, especially for health care professionals with limited legal knowledge. The practice of ambulance replenishing is an example of a simple arrangement between an emergency room and an ambulance operator that has been made exceedingly complex by detailed federal regulations. Ambulance companies may provide patients with drugs and supplies during transport to a hospital. Hospitals, in turn, often agree to replace these items after the ambulance has arrived, a practice that prepares operators for their next trip. Although replenishment appears to be a commonsense practice, it may also be a source of criminal liability under the antikickback statute. Problems arise when a hospital gives something of value (drugs or supplies) to a business (the ambulance company) when that business is a source of federal program revenue (because the ambulance operator makes a decision to bring Medicare or Medicaid patients to Hospital A instead of to Hospital B). In late 2004, the OIG issued the final safe harbors rule addressing the ambulance replenishing issue.23 A reading of these sometimes arcane provisions makes one wonder how even the most honest health care provider can avoid running afoul of the law.

The Stark Law

The Stark Law is a federal statute regulating the self-referral activities of physicians.24 Unlike the criminal antikickback law, the Stark Law imposes only civil damages.

The origins of the Stark Law can be traced to the late 1980s when the OIG and other parties began to study the expanding array of physician business interests. These studies revealed that doctors were referring patients to health care businesses (e.g., laboratories, nursing homes, ambulatory surgical centers) in which the doctors also had a financial interest.25 The growing concern over these conflicts of interest led to legislative proposals by California Congressman Fortney “Pete” Stark and to the passage of the Stark Law in December 1989. The ensuing two decades have been marked by a series of revisions to this complex law.

In its most basic form, the Stark Law prohibits physicians from referring Medicare or Medicaid patients who require designated health services to a business in which the physician (or the physician’s immediate family member) has
a financial relationship. The statute is complex because the lists of designated health services, financial relationships, and exceptions are broad.

The statute is also controversial. Proponents of the Stark Law claim that physician self-referrals— as with kickbacks— lead to corrupt medical judgments, diminishing the quality of patient care. Opponents of the law claim that self-referrals by physicians can improve working relationships among a network of health care providers, hospitals, clinics, pharmacies, therapists, laboratories, and equipment dealers. These efficiencies, they argue, enhance the quality of patient care.

The Stark Law addresses three fundamental questions. First, is the physician referring a Medicare or Medicaid patient for a “designated health service”? If the referral involves neither a Medicare nor a Medicaid patient, or if the referral does not involve a designated health service, then the Stark Law is not applicable. That is, the Stark Law is not concerned with reimbursements for referrals that are paid for by private insurers, although some states have enacted mini Stark Laws that do prohibit such reimbursements.

The original Stark Law applied only to clinical laboratory services, but the list of designated health services has since been expanded to include inpatient and outpatient hospital services, radiology services, durable medical equipment and supplies, physical and occupation therapies, home health services, prosthetics, and outpatient prescription drugs. Any physician request for a treatment, service, prescription, consultation, or product payable under Medicare or Medicaid may constitute a referral. Referrals within a physician group are also covered by the statute.

The second question pertaining to the Stark Law is whether the physician (or an immediate family member) has a financial interest in the business furnishing the designated health service. If the referral involves no personal or family financial interest, then the Stark Law does not prohibit it. Financial interests include any direct or indirect ownership or investment relationship. Stock ownerships, partnership interests, compensation arrangements, rental contracts, personal-service arrangements, salary payments, gifts, or gratuities all represent potential financial interests under the Stark Law.

The third question relates to Stark Law exceptions. As it turns out, dozens of permissible financial relationships exist between physicians and the businesses receiving their designated health service referrals. Physician compensation is at the heart of the Stark Law. Compensation paid to a referring physician must be set in advance, reflect market value, and must not take into account the volume or value of referrals made by the physician. The Stark Law also gives group practices greater autonomy when allocating or dividing revenues among physicians. Some common, but limited, exceptions to the Stark Law include those for managed-care plans, academic medical centers, in-office ancillary services, bona fide employment relationships, physician recruitment, and physicians practicing in locations designated as health-professional shortage areas.
But the safe harbor hatches have been tightened. The Stark Law was amended because of concerns by the Centers for Medicare and Medicaid Services (CMS) over improper referral arrangements that could lead to abusive overutilization. As of October 2009, additional restrictions were placed on physician-hospital business relationships—known as “under arrangements”—in which hospitals have contracts with physician-owned entities to provide a wide range of laboratory, imaging, or other ancillary services. Restrictions were also placed on the leasing arrangements of property owned by doctors in which the lease payments—known as “per use” or “per click” payments—were based on the amount of designated health services rendered at that location.

The Stark Law is a strict liability statute, meaning that the physician's liability does not depend on actual negligence or on intentional harm. Civil monetary penalties may be imposed up to $15,000 for each knowing violation, or $100,000 per arrangement, depending on the seriousness of the violation. Under both the antikickback and self-referral provisions, the OIG may exclude a provider from future participation in federal programs such as Medicare or Medicaid.

Although Stark Law prosecutions are rare, the settlements have been large. In May 2006, one of the nation's largest durable medical equipment suppliers entered into an agreement with the OIG, under which the supplier agreed to pay $10 million. The settlement resolved allegations that it used a nationwide scheme to pay physicians kickbacks for patient referrals. It claimed that the company gave referring physicians items such as sporting and entertainment tickets, gift certificates, sporting goods and fishing trips, meals, advertising expenses, office equipment, and medical equipment. The illegal kickbacks also came disguised as payments for consulting agreements. Furthermore, the OIG also claimed the DME supplier violated the Stark Law by accepting referrals from parties to the illegal consulting agreements. “This significant settlement is an important example of OIG's continuing effort to eliminate illegal kickback practices and violations of the Self-Referral Law,” said Inspector General Daniel R. Levinson. He added, “[T]he OIG will continue to pursue aggressively those who undermine the integrity of the Medicare program.”

Given the complex provisions and exceptions of the Stark Law, its strict liability provisions, and its potentially large monetary penalties, health care providers must be extremely careful to ensure they are in compliance.

**False Claims Statutes**

When it comes to the military, stories abound of the seven hundred dollar toilet seats, the exorbitant development costs that led to the B-2 bomber being “worth five times its weight in gold,” and the abuses of cost-plus contractors and their runaway expenses. But now it is the health care industry that has taken center
stage in false claims cases. The term “false claim” is broad. It pertains to the filing of a claim seeking funds or the reimbursement of funds from the federal government under false pretenses. Such claims include charging outrageous prices for products or services, billing for substandard products or services, or billing for products or services not provided.

Under the criminal false claims act, a person or an organization filing a false claim to obtain money from the United States government may face criminal prosecution or a civil suit. The criminal statute encompasses both false and fraudulent claims. The former might be charges for a medical service or product that was not provided and the latter might be charges for an unnecessary medical service or product.

The criminal false claims statute is popular among federal prosecutors, easily understood by juries, and backed with ample case precedent. It also contains its own conspiracy provision that carries heavier penalties (twice the maximum sentence) than the federal conspiracy statute discussed earlier.

The False Claims Act (FCA) is a civil statute regarded as the U.S. government’s primary antifraud law. As they go about their daily business, employees of a dishonest government contractor may suspect that the federal government is being cheated and billed fraudulently for products or services. Under the FCA, individuals with insider knowledge (known in legalese as “relators”) may bring civil action against those who knowingly submit (or cause the submission of) fraudulent claims against the federal government. Such actions are known as whistle-blower or qui tam suits.

In some cases, the U.S. Department of Justice (DOJ) assumes primary responsibility for prosecution. In most cases, however, the DOJ declines to prosecute, leaving the individual whistle-blower free to pursue the case without DOJ assistance. If the suit is successful and damages are recovered, whistle-blowers may receive a monetary reward—usually between 15 and 25 percent of the total recovery. To qualify for a reward, insiders must base their allegations against the defendant on information not otherwise available to the government. If this “inside information” is already known to government investigators—often a contentious issue—then it becomes part of the public domain and the whistle-blower is not eligible for a portion of the settlement.

The FCA (also known as the Lincoln Law) was enacted during the Civil War in response to the Union Army’s problems with unscrupulous suppliers. It fell into disuse until 1986 when Congress revamped the FCA to make it a more potent weapon against crooked defense contractors.

By the 1990s, health care fraud became the most prominent of the FCA suits. From fiscal years 1987 through 2005, the DOJ received 8,869 cases, 5,129 of which were whistle-blower cases filed in ninety-two U.S. district courts. The HHS agencies were named in 54 percent of the cases compared to 29 percent for
the Department of Defense. A total of $15 billion was recovered in these cases, and whistle-blowers garnered $1.6 billion in settlement rewards. (The distribution of awards is skewed, with the average settlement being $1.7 million and the median settlement $123,885.) Health care fraud cases constituted about 46 percent (1,145 out of 2,490) of all whistle-blower cases. The largest health care whistle-blower recovery during this period was $568 million, and the largest award to a whistle-blower was almost $96.6 million. Health care fraud recoveries under the FCA were $2.2 billion in 2006, $1.5 billion in 2007, $1.1 billion in 2008, and $1.6 billion in 2009.

The FCA recognizes two categories of "falsity." "Literal falsity" arises when a person submits inaccurate or misleading information to the federal government to obtain payment. A health care provider who bills Medicare or Medicaid for services not provided to a patient has committed a literal falsity. A Washington, D.C.-area ambulance company owner was charged with filing $1.6 million in false Medicaid claims. The owner sought reimbursement from Medicaid for transportation services that, according to at least eleven patients, were never provided. Investigators also discovered that three patients were deceased at the time the defendant claimed to have transported them.

To prove literal falsity, a definable gap must exist between the services or products billed to Medicare or Medicaid and the services or products actually proffered by the health care provider. A psychiatrist, for example, who bills Medicare for ten hours of counseling when she provided only seven hours of counseling has created a literal falsity. As the definable gap widens, the likelihood of a FCA violation also increases.

Interpreting unclear regulations in an advantageous light, however, is not necessarily a violation of the FCA. An air-ambulance service billed a federal program for mileage based on statute rather than on nautical miles. Billings based on statute miles gave the air-ambulance operator an additional 15 percent in billable miles. Since the law did not prohibit the use of statute miles in air-ambulance billings, the operator did not violate the FCA.

Some health care providers, on the other hand, may deliberately file a false claim because of a disagreement with a government policy. An ophthalmologist might feel entitled to file a Medicare claim for a routine eye examination (not covered by Medicare) when that examination was performed in preparation for a patient's cataract surgery (which is covered by Medicare). But by "pulling a fast one" and slipping an uncovered procedure into a claim with a covered procedure, the ophthalmologist has committed Medicare fraud. Such claims may also arise if a health care provider disputes the government's interpretation of a regulation and, instead, files a claim based on his or her personal interpretation of the regulation. As noted by the court in Visiting Nurses Ass'n. of Brooklyn v. Thompson, however, "the FCA would be rendered toothless overnight if parties claiming federal funds
were permitted to rely on any reasonable interpretation they might prefer, even if it directly conflicted with an agency’s official interpretation of the same law."  

“Falsity by implicit certification” arises when a business omits information from a claim or fails to adhere to regulatory guidelines or standards. The federal government has brought a series of civil actions against nursing home operators for violations of the federal False Claims Act. According to government prosecutors, if a nursing home submits Medicare or Medicaid claims for care that the government later finds to be substandard, then the claims are false for that reason alone. Substandard care fails to achieve a professionally recognized level of quality. Care may be regarded as conforming to an accepted standard, however, even if it does not always achieve its intended result (e.g., a patient dies despite receiving excellent care).

This category of falsity occurred in Covington v. Sisters of the Third Order of St. Dominic of Hanford. Auditors for Blue Cross of California, the fiscal administrators of the Medicare program in that state, applied an incorrect geographical adjustment to compute Medicare reimbursements to a California hospital. Although the hospital was located in a rural area, it received the higher reimbursement rates paid to urban hospitals. Hospital personnel knew for several years of the incorrect overpayments, yet they continued to accept and use the funds in violation of the FCA.

A major requirement of the FCA is that the health care provider must “knowingly” submit a false claim. In most instances, health care providers, such as a corrupt nursing home manager, are aware of the aforementioned gap between the services actually provided and the services described on the billings. Cases exist, however, in which poor administrative practices lead to erroneous Medicare or Medicaid claims and FCA violations.

A health care provider may file bogus claims because of his or her “reckless disregard” for the truth. Consider, for example, a psychiatrist who operated a practice in the Washington, D.C., area. The federal authorities accused him of violating the FCA when he delegated the task of patient and insurance billings to his wife and a hired clerk. Their poor record keeping and slipshod billing practices led to federal program reimbursement claims that were frequently ludicrous. Many billings were made for an unrealistically high number of hours. On three separate occasions, bills were submitted for the impossible feat of providing more than twenty-four hours of services in a single day. The government originally sued the psychiatrist and his wife for $81 million. After a three-week trial and extensive appeals, they were ordered to pay over $250,000 in penalties. Whether they deliberately violated the law or whether they were guilty only of sloppy billing is hard to know. The case, however, became an albatross around the doctor’s neck and it plagued him until, due to health reasons, he had to close his practice.

The U.S. Supreme Court in a June 2008 opinion may have narrowed—at least temporarily—the application of the False Claims Act to health care fraud cases. In
CHAPTER 2

Allison Engine Co. v. United States, the Court was asked to decide whether persons or businesses not billing the federal government directly for services or products can be held liable for fraud under the FCA. The justices clarified that the whistle-blowers bringing a FCA action must show the defendant intended to defraud the United States and not just an intermediate business. According to the Court:

It is insufficient for a plaintiff asserting a . . . claim to show merely that the false statement's use resulted in payment or approval of the claim or that Government money was used to pay the false or fraudulent claim. Instead, such a plaintiff must prove that the defendant intended that the false statement be material to the Government's decision to pay or approve the false claim. . . . Similarly, it is not enough . . . for a plaintiff to show that the alleged conspirators agreed upon a fraud scheme that had the effect of causing a private entity to make payments using money obtained from the Government. Instead, it must be shown that they intended "to defraud the Government." Where their alleged conduct involved the making of a false statement, it need not be shown that they intended the statement to be presented directly to the Government, but it must be established that they agreed that the statement would have a material effect on the Government's decision to pay the false or fraudulent claim.47

Allison Engine involved Navy shipbuilders and subcontractors, not health care organizations. But the Supreme Court's decision could discourage FCA whistle-blower cases against health care defendants who were not involved directly in defrauding the federal government. Congress, however, has introduced the False Claims Correction Act that, if enacted, could negate the Supreme Court's decision in Allison Engine and increase the power of FCA whistle-blowers.48

Health Insurance Portability and Accountability Act of 1996

Mention the acronym "HIPAA" in a hospital or health care institution and you will hear the most amazing—often wrong-headed—assertions about what the law does and does not allow. The Health Insurance Portability and Accountability Act of 1996—a difficult-to-fathom law—is probably best known for its safeguarding the privacy of patient medical information. Even in this area, it is often misunderstood. How many people know or understand, however, that the law also targets people who commit health care fraud?49 Most important, the HIPAA and the Medicare Integrity Program are used to review and investigate Medicare expenditures and to safeguard these expenditures against fraud, abuse, and waste. The HIPAA prohibits health care frauds against public insurers (Medicare and Medicaid) as well as frauds against private insurers affecting interstate
commerce. The Act targets the embezzlement, theft, or misappropriation of the money, property, or other assets of a health care benefit program. It also makes it a federal offense for a person to achieve eligibility for Medicaid benefits by disposing of their personal assets.

Concealing material facts or making false statements regarding health care delivery and insurance claims is also a HIPAA violation. The HIPAA’s long reach is illustrated by the conviction of three individuals who staged automobile accidents to take advantage of the New York Comprehensive Motor Vehicle Insurance Reparations Act. The defendants arranged for passengers in these accidents to sign their claims over to health care providers or to the defendants. On appeal, the defendants claimed the HIPAA applied only to health care professionals and that the New York state no-fault automobile insurance program is not a health care benefit within the meaning of the federal law. Citing the language and legislative history of the HIPAA, the U.S. Court of Appeals (2nd Circuit) rejected both contentions and affirmed the federal district court’s health care fraud convictions. By receiving medical benefits in conjunction with the feigned injuries, the appeals court said that the no-fault insurance contracts of vehicle owners in New York qualify as a “health care benefit program” under the HIPAA:

In sum, the federal health care fraud statute applies to defendants’ participation as passengers in staged automobile accidents designed to profit from New York’s no-fault automobile insurance regime. We recognize that this holding authorizes the application of the federal health care fraud statute to circumstances that are atypical of the health care fraud case law, which to date has concerned itself more exclusively with conduct within the medical community. Despite this factual twist, it is clear that defendants’ conduct falls squarely within the unambiguous terms of the statute and therefore the statute applies in the circumstances presented by this case.

The HIPAA also links health care fraud specifically to the facilitative crimes of obstruction of justice and money laundering, and it expands antikickback provisions to other federal programs such as the military TRICARE program. As with the antikickback and Stark laws, the HIPAA provides exceptions and safe harbors, most notably for managed-care arrangements. People committing frauds under HIPAA are subject to fines as well as to imprisonment for up to ten years. If a HIPAA violation results in serious bodily injury, the defendant may be imprisoned for up to twenty years. Defendants engaging in frauds resulting in death are subject to life imprisonment.

In 1972 Congress enacted federal fraud enforcement provisions in the Social Security Act. This act, which HIPAA broadened considerably in 1996, encompasses a variety of previously discussed crimes and statutes directed at all federal
health care programs, not just the prominent Medicare, Medicaid, TRICARE, Veterans Affairs, or the federal employee-benefits programs. The statute covers false statements, misrepresentations, kickbacks, false statements with respect to the operation of a health care institution, illegal patient admittance and retention practices, and the wrongful disclosure of individually identifiable health information.

The Federal Food, Drug, and Cosmetic Act

In 1937 doctors in fifteen states had, in good faith, prescribed a drug called Elixir Sulfanilamide to patients. One hundred and five of these patients, mostly children, died. It was later discovered that the drug, in tablet form, worked well against streptococcal infections. But an unscrupulous Tennessee firm had processed it in liquid form using diethylene glycol, a highly toxic chemical analogue of antifreeze. As one of the prescribing doctors, A. S. Calhoun, wrote at the time:

Nobody but Almighty God and I know what I have been through these past few days. I have been familiar with death in the years since I received my M.D. from Tulane University School of Medicine with the rest of my class of 1911. Covington County has been my home. I have practiced here for years. Any doctor who has practiced more than a quarter of a century has seen his share of death.

But to realize that six human beings, all of them my patients, one of them my best friend, are dead because they took medicine that I prescribed for them innocently, and to realize that the medicine which I had used for years in such cases suddenly had become a deadly poison in its newest and most modern form, as recommended by a great and reputable pharmaceutical firm in Tennessee: well, that realization has given me such days and nights of mental and spiritual agony as I did not believe a human being could undergo and survive. I have known hours when death for me would be a welcome relief from this agony. (Letter by Dr. A. S. Calhoun, October 22, 1937)

Also during the 1930s, journalists were giving a great deal of press to dangerous medical products such as Banbar, a worthless “cure” for diabetes; Lash-Lure, an eyelash dye that blinded some women; Radithor, a radium-containing tonic that caused a slow and painful death for its users; and Wilhide Exhaler, a fake cure for tuberculosis and other pulmonary diseases. The public outcry over these scandals resulted in the passage of the Federal Food, Drug, and Cosmetic Act of 1938 (FDCA).

Prior to the passage of the FDCA, drug regulations did not control the premarket toxicity testing of drugs. The FDCA changed the focus of the Food and Drug Administration from a policing agency confiscating adulterated drugs to
a regulatory agency evaluating new drugs.55 Today the FDCA—which still comes under attack for not doing enough to protect patients—is supposed to protect the public from harmful drugs or medical devices through its regulation of the testing, manufacturing, and labeling of drugs and medical devices.56

To ensure new drugs are safe and effective for their intended use, the FDA has mandated a highly structured three-phase clinical-investigation process requiring extensive documentation and record keeping.57 FDA approval is also required when the testing process involves the use of human subjects. Fraud in the testing stage is a primary concern of the FDA, and violations occur when manufacturers or their representatives deviate from rigorous research protocols or falsify data and other relevant information associated with the testing process (a criminal offense). Although generic drugs are subjected to less-extensive testing than new drugs, generic manufacturers have been prosecuted for falsifying information on the FDA application and for making unapproved changes in the manufacturing process. In fact, any change in the manufacturing process, composition, or expiration date of a generic drug requires FDA approval. For example, personnel working in the manufacturing of drugs often must wear special protective clothing; any deviation from this requirement requires the consent of the FDA.

A drug must be manufactured exactly as it was approved by the FDA. To ensure that the composition of a drug has not been altered, the FDA inspects the entire manufacturing operation, including the machines used in each stage of production (e.g., the maintenance and calibration of the machinery), the training programs for employees, the design and construction of the production plant, and the manufacturing environment. If the manufacturing process results in an adulterated product, the product no longer earns FDA approval and its distribution for human consumption is illegal. Fraud in the production process includes altering or falsifying production records to conceal the improper storage or contamination of drugs, to hide unfavorable test results or process failures, to destroy information of interest to inspectors, or to mislabel products.

A drug or device approved by the FDA must be affixed with a label defining its specific use. Promotion by the manufacturer for an off-label use of the drug or device violates the FDCA—although physicians may prescribe a drug for off-label use. A drug is considered misbranded when its label is in any way false or misleading, when it contains inadequate directions for using the drug, or when the dosage or use of the drug as prescribed is dangerous to the patient's health. Information on labels is directed primarily at the health care professional. Based on their training and experience, they are expected to exercise prudence and to avoid being deceived by misbranded or erroneously labeled pharmaceuticals.

Finally, the FDCA prohibits the sale, purchase, or trade—including offers to do so—of a prescription drug sample. Pharmaceutical manufacturers may distribute drug samples only to physicians and designated health care providers.
Other administrative and record-keeping regulations are also associated with the distribution of drug samples. A sales representative cannot, for example, distribute a drug sample without a written request from a physician.

Manufacturers of medical devices are required to meet FDCA standards similar to those imposed on drug manufacturers. Although drugs are lumped into a single category because of their invasiveness, medical devices vary widely in terms of their design and function. For these reasons, medical devices are categorized into three classes. Class I devices (e.g., crutches and coverings for minor wounds) present minimal potential harm to the user and are subject to the least regulatory control. Those requiring more general controls to assure safety and effectiveness (e.g., wheelchairs and tampons) are Class II devices. The most stringent regulatory category for devices, Class III, includes artificial heart valves and pacemakers that support or sustain human life, prevent impairments to human health, or present an unreasonable risk of illness or injury.58

Federal programs such as Medicare and Medicaid, as well as private insurers, do not usually reimburse health care providers or patients for drugs, medical devices, or medical procedures that the FDA has not approved. Physicians may, under some circumstances, prescribe unapproved drugs, although reputable pharmacists may be reluctant to stock such pharmaceuticals. Since Medicare and other programs pay only for “reasonable and necessary” drugs and equipment, providers billing federal programs for unapproved, adulterated, or misbranded drugs may face federal false claims charges. The combination of FDCA and Medicare policy may cut off hope for terminally ill patients who are desperate for a last-ditch, but unapproved, treatment.59 These patients may seek therapies outside the United States, often in Mexico.

The illegal distribution of prescription drugs has become a growing concern. Physicians who write illicit prescriptions, online drug trafficking, pill-mill schemes that divert drugs from their intended use, and doctor-shopping drug abusers have infiltrated health care systems both in the United States and elsewhere. It is difficult, however, to judge when a physician has overprescribed a drug. And pharmacists are not subject to criminal liability as long as they dispense controlled substances within the course of their duties. A pharmacist who is part of a conspiracy to distribute controlled substances illegally or one who turns a blind eye to patently unrealistic medical practices, however, may be subject to criminal prosecution.

Nearly every segment of the vast U.S. health care system is now subject to fraud, antikickback, self-referral, false claims, and food and drug litigation. The laws and accompanying regulations available for fighting health care fraud are lengthy, complex, overlapping, and confusing to honest health care providers who are trying to chart their course through this maze of legislation and regulation.
From the mid-1960s to 2010, the federal government has enacted several major antifraud laws, and it has enhanced its enforcement measures to combat health care fraud and abuse. Despite the expansion and stiff civil and criminal penalties, the payoffs are still too high and the risks of apprehension are still too low to deter the thousands of fraudsters who have both the interest and the skill to steal large sums of money from the treasure chests of Medicare, Medicaid, and private insurance programs. The next chapter illustrates the variety and ever-expanding array of health care fraud and abuse cases.