CHAPTER 12

FRAUD, ABUSE, AND CORPORATE COMPLIANCE PROGRAMS

After reading this chapter, you will

• understand the basics of federal laws relating to healthcare fraud and abuse and learn that the federal False Claims Act is the major enforcement mechanism against fraud in billing healthcare payers.
• be able to identify the most significant statutes relating to fraud and abuse in federal healthcare payment programs; all three kinds of statutes are complicated and sometimes difficult to interpret.
• know the terms “kickback” and “self-referral” and how they affect hospital operations and realize that antikickback and self-referral laws are also used to punish wrongdoers.
• recognize the benefits of maintaining an active corporate compliance program; these programs can be extremely effective in preventing violations or reducing sentences if malfeasance occurs.

Healthcare organizations must be sensitive to the potential for their employees to be involved in fraud, abuse, and other illicit conduct. They must work to maintain high ethical principles, not only because an image of moral respectability is “good for business” but also because it is, simply, the right thing to do.

This chapter discusses the enforcement climate in healthcare and the various laws aimed at curbing fraud and abuse. Also explored here is the role that corporate integrity programs play in promoting legal compliance and business ethics in a well-run healthcare organization.
Enforcement Climate

The cost of healthcare continues to rise at an alarming rate. The latest data (2004) indicate that total healthcare spending is about $2 trillion (16 percent of the gross domestic product), and a government report ten years ago estimated that as much as 10 percent of that amount could be the result of fraud (intentional deception) or waste and abuse (unsound practices that result in increased costs)\(^1\); see Legal Brief.

Because the government is the largest single purchaser of healthcare services, eliminating fraud and abuse was once called the U.S. Department of Justice’s (DOJ) number two law-enforcement priority, second only to violent crime.\(^2\) (It is now perhaps number three, because the war on terror has taken ascendancy.) Ever more resources have been allocated to the enforcement activities of the DOJ, the United States Attorneys, the Federal Bureau of Investigation, the Office of Inspector General, and other agencies. In addition, state attorneys general conduct their own investigations and prosecutions, often working closely with federal officials. Private citizens who have firsthand knowledge of fraud are even permitted to sue for the government and collect a percentage of the proceeds recovered, if any.

Verdicts and settlements in civil fraud cases can sometimes be for hundreds of millions of dollars (see Table 12.1), and offenders who are prosecuted for criminal offenses can receive massive fines and lengthy jail terms. One example of the severity of the penalties is *United States v. Lorenzo*,\(^3\) in

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**TABLE 12.1**

Examples of Successful Healthcare Qui Tam (Whistle-Blower) Lawsuits

<table>
<thead>
<tr>
<th>Defendant’s Name</th>
<th>Allegation</th>
<th>Settlement</th>
</tr>
</thead>
<tbody>
<tr>
<td>TAP Pharmaceuticals</td>
<td>Illegal kickbacks</td>
<td>$875 million</td>
</tr>
<tr>
<td>HCA, Inc.</td>
<td>False claims</td>
<td>$631 million</td>
</tr>
<tr>
<td>National Health Labs.</td>
<td>Billing for unnecessary tests</td>
<td>$110 million</td>
</tr>
<tr>
<td>Lovelace Health Systems</td>
<td>False claims in cost reports</td>
<td>$24.5 million</td>
</tr>
<tr>
<td>SmithKline Beecham Labs.</td>
<td>Billing for unnecessary lab tests</td>
<td>$13 million</td>
</tr>
<tr>
<td>Beverly Enterprises</td>
<td>Durable med. equipment fraud</td>
<td>$20 million</td>
</tr>
</tbody>
</table>

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which a dentist billed Medicare for “consultations” on nursing home residents. Although Medicare does not cover dental services or routine physicals, Dr. Lorenzo billed the government for his cancer-related examination of each patient’s oral cavity, head, and neck, all of which is standard dental practice. The government proved that Dr. Lorenzo had submitted 3,683 false claims, resulting in overpayment of $130,719.20. The court assessed damages of nearly $19 million, almost 150 times the amount of the overpayment.

A second example is United States v. Krizek. Among other things, Dr. Krizek, a psychiatrist, charged the government for a full session (45 to 50 minutes) regardless of whether he spent 20 minutes or two hours with a patient. He argued that in practice the time evened out and the government was not harmed. In one instance, however, it was shown that he submitted 23 claims for full sessions in a single day. Dr. Krizek was fined $157,000 and assessed $11,000 in court costs. Other examples include criminal convictions and civil fines of more than $100 million each levied against Caremark International, Corning (Damon) Laboratories, Roche Laboratories, and National Medical Enterprises ($379 million) and a settlement in excess of $30 million with the University of Pennsylvania. In the largest settlement to-date, Columbia/HCA paid approximately $850 million.

In such a volatile climate, it is little wonder that in the late 1990s prevention of fraud and abuse became a serious topic for healthcare executives, and it will continue to be viewed seriously in the foreseeable future. A basic understanding of the major criminal and civil fraud statutes is therefore essential. Some of the most obvious types of healthcare fraud and abuse are as follows:

• filing claims for services that were not rendered or were not medically necessary;
• misrepresenting the time, location, frequency, duration, or provider of services;
• upcoding—assigning a higher payment than the procedure or diagnosis warrants;
• unbundling—the practice of billing as separate items the services that are actually performed as a battery of services, such as laboratory tests;
• violation of the “three-day rule”—the rule stating that outpatient diagnostic procedures performed on any of the three days before hospitalization are deemed to be part of the Medicare diagnosis-related group payment and are not to be billed separately;
• payment of “kickbacks” to induce referrals or the purchase of goods or services;
• billing for services said to have been “incident to” a physician’s services but that in fact were not provided under the physician’s direct supervision; and
• self-referral—the practice of physicians referring patients for services to entities in which they have a financial interest.

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The major statutes that these kinds of activities may violate include the civil and criminal False Claims Act, the antikickback law, and the Stark self-referral laws. Depending on the facts of the case, mail- and wire-fraud statutes; the Racketeer Influenced and Corrupt Organizations Act; money-laundering statutes; and laws relating to theft, embezzlement, bribery, conspiracy, obstruction of justice, and similar matters may also be implicated. This chapter focuses on the major healthcare fraud statutes and does not address the kinds of laws noted in the previous sentence. Readers should be aware, however, that myriad legal standards (both state and federal) apply to healthcare organizations. The importance of competent legal counsel and a process to prevent criminal activity cannot be overemphasized.

**False Claims Act**

The major weapon in the federal government’s arsenal in the “war” on fraud and abuse is the civil False Claims Act (FCA). The federal statute provides that a person is liable for penalties if he

- “knowingly presents, or causes to be presented, to an officer or employee of the United States a false or fraudulent claim for payment or approval”;
- “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”;
- “conspires to defraud the Government by getting a false or fraudulent claim allowed or paid”; or
- “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.” (This last provision was added in 1986 to deal with “reverse false claims,” situations in which a person attempts to avoid paying money owed to the government.)

Most states have similar laws. Violations of the federal law result in penalties ranging from $5,000 to $10,000 per claim plus three times the amount of damages sustained by the government, if any. The costs of bringing the action are charged to the defendant. If the claim was false, penalties and costs can be assessed even if the claim was not paid and the government suffered no damages. Interestingly the FCA was enacted during the Civil War to stem the practice of certain persons to overcharge the Union Army for goods and services. Apparently what a “claim” is was better known then than it is now because the term is not defined in the statute. In healthcare, however, what
amounts to a “claim” has been a matter of some dispute. For example, each procedure code on a billing form could be considered a separate claim. Therefore, each false code could result in up to $10,000 in penalties. Twenty false CPT codes would, by this line of reasoning, allow a penalty of up to $200,000 to be assessed, plus damages and court costs. This issue was addressed in the appeal of Krizek, in which the U.S. Court of Appeals for the D.C. Circuit held that each billing form was one claim irrespective of the number of false codes contained on it. The court felt that the form was merely one request for payment of the sum total it represented. This result seems logical, and it is consistent with other cases defining a claim as “a demand for money or for some transfer of public property.”

Another interesting question is, what kind of intent is required for the statute to be violated? As pointed out in the aforementioned list, the defendant’s acts must have been done knowingly to constitute an offense. First-year law students are painfully aware of the kind of Socratic dialog that could attend the issue of what “knowingly” means; here is an example:

Professor Miller: Mr. Showalter, what if I sign a claim form, put it in a stamped envelope, and mail it to Medicare. Have I knowingly submitted that claim?

Student Showalter: Um…I guess so. Unless you were drunk or mentally incompetent, you knew what you were doing. You were mailing in the claim form and expecting to get paid.

Professor Miller: How much did I expect to get paid?

Student Showalter: Whatever amount is on the form.

Professor Miller: What if I didn’t look at the amount but just signed a bunch of forms my staff gave me at the end of the day? And what if those forms had errors on them?

Student Showalter: Well….

Professor Miller: Well, what? Are those false claims? The ones that have errors on them, I mean?

Student Showalter: Uh…. Well, they’re erroneous. But if you didn’t know they had errors and just assumed that your staff were doing their jobs correctly….

Professor Miller: Assumed!? Is that the kind of thing I should assume?

Student Showalter: Uh….

Professor Miller: Okay, let me put to you another case. Let us suppose that I know there are occasional errors on our claims—some over, some under—but I think that at the end of the year they will all balance out, sort of the “no harm, no foul” kind of approach to billing. And suppose I think that the
False Claims Act only applies to *intentionally* overbilling the government, which I haven’t done. What do you say now?

*Student Showalter* [musing]: Hmm! You knew you were submitting a bill, but you didn’t know that the particular bill was wrong, and you didn’t know that submitting incorrect bills is illegal when you should have had a system in place to check them for errors. Good question!

And so this dialog goes for 10 or 15 uncomfortable minutes.

In legal circles this issue is known as one of scienter—knowledge by a defendant that her acts were illegal or her statements were lies. In 1986, Congress addressed this question by amending the FCA to say that “no proof of specific intent to defraud is required” and that “knowingly” with respect to a claim means either (a) actual knowledge of its falsity, (b) deliberate ignorance of its truth or falsity, or (c) reckless disregard of its truth or falsity.10 As stated in the committee report accompanying the 1986 amendments,

The Committee is firm in its intentions that the act not punish honest mistakes or incorrect claims submitted through mere negligence. But the Committee does believe the civil False Claims Act should recognize that those doing business with the Government have an obligation to make a limited inquiry to ensure the claims they submit are accurate.11

The *Krizek* case shows how this standard is used. Although Dr. Krizek was not personally involved in the billing process, the court found that he had submitted the claims “knowingly”:

These were not “mistakes” [or] 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.12

This standard requires healthcare providers, and their top management and governing board members, to have mechanisms in place to verify the accuracy of their organization’s claims. A further incentive to do so, as if one were needed, is the fact that the government may exclude from participation in the Medicare and Medicaid programs any individual (a) who has a direct or indirect ownership or control interest in a sanctioned entity and has acted in “deliberate ignorance” of the information or (b) who is an officer or managing employee of a convicted or excluded entity, irrespective of whether the individual participated in the offense.13 Any excluded person who retains ownership or control or who continues as an officer or a managing employee may be fined $10,000 per day.14 The threat of “exclusion”—the Medicare
and Medicaid programs’ equivalent of the death penalty—and the potential for criminal convictions and massive fines have been major forces in the movement to adopt corporate compliance programs in healthcare organizations.

FCA cases are usually investigated by the Office of Inspector General and brought by a U.S. attorney or the DOJ itself. An unusual feature of the statute, however, allows private citizens to sue on their own behalf and on behalf of the government to recover damages and penalties. These qui tam (whistle-blower) lawsuits have become an important factor in FCA enforcement because, if successful, the plaintiff (a “relator” in legal parlance) can share in the amount of the award (see Table 12.1).

Any person with information about healthcare fraud can be a qui tam plaintiff, and “person” is defined to mean “any natural person, partnership, corporation, association, or other legal entity, including any State or political subdivision of a State.” The plaintiff must file the complaint, which is immediately sealed and thus not made public pending an investigation, and file a copy with the U.S. attorney general and the appropriate U.S. attorney. The government then has 60 days, plus extensions for good cause, in which to determine whether to pursue the case. If the government decides to take over the case, the relator will receive between 15 percent and 25 percent of the amount recovered. If the government declines to pursue the matter, the relator may still do so and, if successful, will receive up to 30 percent of the recovery.

From October 1, 1986 to September 31, 2005, the DOJ recouped more than $6.5 billion from Medicare-related qui tam cases, and whistle-blower plaintiffs received more than $1 billion of that amount (according to the organization Taxpayers Against Fraud). These figures include only those cases involving the DOJ itself; they do not include Medicare cases prosecuted by individual U.S. attorneys’ offices or recoveries by the states in Medicaid claims.

The potential qui tam plaintiff must meet certain conditions to file suit. The plaintiff must be the first to file, there must not already be any governmental proceeding relating to the same facts, and the suit must not be based on matters that have been publicly disclosed (unless the relator is the “original source” of those disclosures). If these jurisdictional barriers are met and the facts of the case warrant recovery, the qui tam plaintiff can proceed to assist the government or pursue the case individually, often to significant financial advantage.

Federal law provides a remedy for whistle-blowers who are discharged, demoted, harassed, or otherwise discriminated against because of their having filed a qui tam case. Given the financial incentives and the protection against employment-related retaliation, the qui tam lawsuit has become a popular and effective means of combating fraud and abuse.

Occasionally, qui tam plaintiffs have argued in healthcare-related cases that a claim involving a kickback or self-referral (described in more detail in
the following section) violates the FCA, even though the claim itself is not “false” on its face. The roots of such an argument can be traced to \textit{United States ex rel. Marcus v. Hess},\textsuperscript{17} a World War II-vintage case in which a governmental contractor’s claims were held to be false because the contract under which they were submitted was entered into as a result of collusion. Similarly, in \textit{United States ex rel. Woodard v. Country View Care Center, Inc.},\textsuperscript{18} the defendants had submitted Medicare cost reports that included payments to “consultants” that were actually kickbacks. Not too surprisingly, because the defendant’s reimbursement was based on the cost reports, the court held that the FCA applied. \textit{United States v. Kensington Hospital},\textsuperscript{19} filed after the advent of the prospective payment system, brought a new twist to the argument. The defendants asserted that because their Medicaid reimbursement was a set amount, the government could not have suffered any loss, and the cost of the kickbacks did not make the claims false. Citing \textit{Marcus} and other cases, the court disagreed, holding that the government was not required to show actual damages to prove an FCA violation.

In neither \textit{Country View} nor \textit{Kensington Hospital} did the plaintiffs specifically base their claim of FCA liability on the kickback or self-referral statute. Some subsequent cases, however, have done so and have survived initial scrutiny by the courts. For example, in \textit{United States ex rel. Pogue v. American Healthcorp},\textsuperscript{20} a trial court refused to dismiss an FCA case based on violations of the kickback and Stark self-referral laws. The court agreed with the relator’s contention that “participation in any federal program involves an implied certification that the participant will abide by and adhere to all statutes, rules, and regulations governing that program.”\textsuperscript{21} The court held in effect that Stark violations create prohibited financial relationships and that, therefore, the FCA applies.\textsuperscript{22}

In summary, the proposition that an FCA case can be based solely on violation of the antikickback or self-referral laws seems to have gained some acceptance, but the ultimate resolution of the issue remains in doubt. Clearly, relators and the government will continue to make this argument until the point is conclusively established or rejected. In the meantime, it remains an ominous threat for healthcare organizations because the cost of litigating such cases is high and the potential exists for massive penalties. The resulting pressures to settle, rather than litigate, FCA cases may mean that the issue will remain unresolved for some time.\textsuperscript{23}

In addition to the civil FCA, another provision of federal law makes false claims a criminal offense.\textsuperscript{24} If convicted, an organization can be fined $500,000 or twice the amount of the false claim, whichever is greater. An individual can be fined the greater of $250,000 or twice the amount of the false claim and can be sentenced to up to five years in prison. The standards of proof are higher, of course, in criminal prosecutions than in civil cases. In a civil FCA action the standard is a “preponderance of the evidence.” But in
a criminal FCA case the government must prove beyond a reasonable doubt that the defendant knew the claim was false. Therefore, and because the penalties in civil actions are already quite severe, criminal false-claims cases are brought less frequently than their civil counterparts.

**Antikickback Statute**

In 1972 concerned about the high cost of healthcare and the potential for overutilization of healthcare services, Congress prohibited any person to solicit, receive, offer, or pay any form of remuneration in return for or to induce referrals for healthcare goods or services for which Medicare or Medicaid would make payment. Effective January 1, 1997, the statute was amended to cover payment by any federal healthcare program. Violations of the antikickback law are felonies punishable by criminal fines of $25,000 per violation or imprisonment for up to five years, or both. In addition, the Office of Inspector General has the authority to exclude from Medicare and Medicaid programs those persons who have violated the act. This action can be taken without criminal prosecution and using the more lenient “preponderance of the evidence” standard. Finally, a 1997 amendment provides for civil penalties of $50,000 per violation plus three times the amount of the remuneration involved, in addition to the possible criminal sanctions already noted.

The statute contains numerous exceptions to the prohibition of remuneration to induce referrals. The prohibition does not apply to the following:

- properly disclosed discounts that are reflected in the cost reports,
- amounts paid by an employer to an employee to provide healthcare services,
- certain amounts paid by a vendor to agents of a group purchasing entity,
- waivers of coinsurance for Public Health Service beneficiaries, and
- certain remuneration through a risk-sharing arrangement (e.g., under capitation).

In addition, a 1987 amendment required the U.S. Department of Health and Human Services to promulgate regulations “specifying those payment practices that will not be subject to criminal prosecution [or] provide a basis for exclusion…..” These regulations provide for certain “safe harbors”—categories of activities in which providers may engage without being subject to prosecution—but they are very technical and are interpreted quite narrowly. The safe harbors are as follows:

- fair market value leases for rental of space or equipment;
- fair market value contracts for personal services;
purchase of physician practices;
• payments to referral services for patients, so long as the payment is not related to the number of referrals made;
• properly disclosed warranties;
• properly disclosed discounts that are contemporaneous with the original sale;
• bona fide employment relationships;
• discounts available to members of a group purchasing organization;
• waivers of coinsurance and deductibles for indigent persons;
• marketing incentives offered by health plans to enrollees; and
• price reductions offered by providers to health plans.

These regulations are quite technical, and an in-depth analysis of their provisions is beyond the scope of this chapter. Suffice to say that although the antikickback statute is one of the most important laws affecting healthcare today, it is also, unfortunately, one of the most complicated and ambiguous. Congress itself recognized this fact when it wrote in 1987: “[T]he breadth of the statutory language has created uncertainty among health care providers as to which commercial arrangements are legitimate, and which are proscribed.” Unfortunately, although the 1987 amendments that led to the safe harbors were intended to provide guidance and clarity, much uncertainty persists.

**What Is a Referral?**

The problem is illustrated by considering the meaning of the word “referral.” Unfortunately, neither the statute nor its implementing regulations define the term, so we are left with considerable uncertainty regarding one of the statute’s key terms. For example, is it a referral when one member of a multispecialty group practice sends a patient to another member of the same group? If the referring physician’s compensation depends in part on the volume of services he orders from other group members, is he receiving referrals and is the group paying for referrals? These questions have not been answered because no enforcement action has been taken to-date regarding intragroup referrals, but a literal reading of the statute calls the practice into question. The creation of a group practice safe harbor under the Stark self-referral laws (discussed in the next section) seems to suggest that regulators believe a referral has occurred under those circumstances. After all, if it is not a referral, why have a safe harbor for it? Because intragroup referrals are not Stark violations, the government may refrain from taking enforcement action under the antikickback law for the same behavior. Whether this proves to be the case remains to be seen, of course.

A similar situation is involved when a medical group owns a hospital. Under traditional indemnity insurance plans, the physicians benefit financially if they admit patients to their own hospital, yet distribution of the hospital’s prof-
its to the physician-owners would appear to violate the literal language of the statute. A proposed regulatory safe harbor for such situations was abandoned in 1993. Thus, the issue remains unresolved.

**What Is Remuneration?**

*Hanlester Network v. Shalala* illustrates what amounts to remuneration as an inducement for referrals.¹³² In *Hanlester* physicians were limited partners in a network of three clinical laboratories, to which they referred their patients for laboratory work (see Figure 12.1). The laboratories contracted with Smith Kline Biotechnology Laboratories (SKBL) to manage the facilities for a fee of $15,000 per month or 80 percent of the laboratories’ collections, whichever was greater. (As it turned out, the 80 percent figure was usually higher than the fixed monthly fee.) Because performing the tests at SKBL’s own laboratories was more economical, 85 percent to 90 percent of the Hanlester labs’ testing was done at SKBL. The Ninth Circuit held that even though the cash payments under the arrangement flowed from the Hanlester labs to SKBL, among other things, the arrangement was a scheme by which SKBL in effect had offered a 20 percent discount (the prohibited remuneration) for the physicians’ referrals to the SKBL labs. (Note that today the arrangement would also violate self-referral laws.)

Although neither the statute nor the regulations defines remuneration, it is clear that the law reaches the provision of anything having a monetary value. The 20 percent “discount” in *Hanlester* is one example. Likewise, the provision of free goods or services has an economic value and would be prohibited.¹³³ Furthermore, there is no exception for remuneration of a minimal nature. In one case, a physician was excluded from the Medicare program for having received a kickback in the amount of $30.¹³⁴

Beyond prohibiting payment of remuneration to induce referrals, the antikickback law prohibits payment of remuneration to induce or in return for

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**FIGURE 12.1**

Hanlester Network Structure

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“purchasing, leasing, or ordering of, or arranging for or recommending the purchasing, leasing, or ordering of, any good, facility, service, or item for which payment is made in whole or in part by a federal healthcare program.”35 For example, it would be illegal for a company that provides patient transportation to provide remuneration to the hospital employee who arranges for patient transportation to encourage that employee to choose that particular company. But is it illegal for a hospital or clinic to provide free transportation to patients who are otherwise unable to come to the facility? In United States v. Recovery Management Corp. III, a psychiatric hospital pleaded guilty to an antikickback violation after it gave patients free airfares to and from the hospital as an inducement to choose the facility.36 This case illustrates the fact that the antikickback statute applies even where no literal “referral” per se is involved (the referral in this case being the patient’s choice of the facility), and it applies to the provision of anything of value that induces patients or providers to purchase or order services.

The practice of waiving coinsurance and deductible amounts is similarly prohibited as an inducement for referrals, except in limited circumstances (such as in documented cases of financial need). The 1996 Health Insurance Portability and Accountability Act (HIPAA; the Kassebaum-Kennedy Act) added civil money penalties that can apply to any person who “offers...or transfers remuneration...that such person knows or should know is likely to influence [the recipient] to order or receive [goods or services] from a particular provider, practitioner or supplier....”37 HIPAA defines remuneration to include

the waiver of coinsurance and deductible amounts (or any part thereof), and transfers of items or services for free or for other than fair market value. The term remuneration does not include—

(A) the waiver of coinsurance and deductible amounts by a person if—
   (i) the waiver is not offered as part of any advertisement or solicitation;
   (ii) the person does not routinely waive coinsurance or deductible amounts; and
   (iii) the person—
      (I) waives the coinsurance and deductible amounts after determining in good faith that the individual is in financial need;
      (II) fails to collect coinsurance or deductible amounts after making reasonable collection efforts; or
      (III) provides for any permissible waiver as specified in section 1128B(b)(3) [of the Social Security Act] or in regulations issued by the Secretary;
(B) differentials in coinsurance and deductible amounts as part of a benefit plan design as long as the differentials have been disclosed in writing to all beneficiaries, third party payers, and providers...; or
(C) incentives given to individuals to promote the delivery of preventive care as determined by the Secretary in regulations so promulgated.38

Thus, the waiver of coinsurance and deductibles may be permissible in some cases that meet these criteria, but routinely waiving those amounts (especially if advertised in the hope of stimulating business) would appear to violate the antikickback statute as an inducement for referrals.

The Intent Issue
As noted earlier, Congress has provided that “no proof of specific intent to defraud is required” under the FCA. But what kind of intent is required when providing remuneration to induce referrals under the antikickback statute? Must the sole purpose of the remuneration be to induce Medicare and Medicaid referrals for it to be illegal? Or is it sufficient for the government to show that one of multiple purposes was to do so? This question was at the heart of United States v. Greber and United States v. McClatchey (see The Court Decides at the end of this chapter). In both cases, payments were made that had legitimate purposes but also could be viewed as being intended to induce referrals. In each case the court held that the statute was violated if one purpose was to induce referrals even if the remuneration was also given for other legitimate purposes.

“Stark” Self-Referral Laws

The Ethics in Patient Referrals Act (EPRA),39 first enacted in 1989 and amended in 1993, was championed by Rep. Fortney “Pete” Stark of California. Its purpose, like that of the antikickback statute, is to discourage overuse of healthcare services and thus reduce the cost of Medicare and Medicaid programs. As stated by the Healthcare Financing Administration (HCFA, now the Centers for Medicare and Medicaid Services [CMS]):

Congress enacted this law because it was concerned that many physicians were gaining significant financial advantages from the practice of referring their [Medicare and Medicaid] patients to providers of health care services with which they (or their immediate family members) had financial relationships. For example, if a physician owns a separate laboratory that performs laboratory tests for his or her patients and shares in the profits of that laboratory, the physician has an incentive to overuse laboratory services. Similarly, if a physician does not own any part of an entity but receives compensation from it for any reason, that compensation may be calculated in a manner that reflects the volume or value of referrals the physician makes to the entity.
The reports of 10 studies in the professional literature, taken as a whole, demonstrate conclusively that the utilization rates of medical items and services generally increase when the ordering physician has a financial interest in the entity providing the item or service. These self-referrals generate enormous costs to the Medicare and Medicaid programs and jeopardize the health status of program beneficiaries.40

The provisions of the two eponymous “Stark” laws (usually referred to in the singular) are extremely complicated, and their application must be analyzed on a case-by-case basis. The law can, however, be summarized as follows.

In general, Stark prohibits a physician (a medical doctor, doctor of osteopathy, dentist, podiatrist, optometrist, or chiropractor) from referring Medicare or Medicaid patients for certain “designated health services” to entities with which the physician or an immediate family member has a financial relationship. “Financial relationship” is defined as a compensation arrangement or an ownership or investment interest, such as through equity or debt. If such a relationship exists, the physician may not, unless an exception applies, refer patients to the entity for the following kinds of services:

- clinical laboratory services;
- radiology services, including MRIs, CAT scans, and ultrasound;
- radiation therapy services and supplies;
- physical and occupational therapy services;
- durable medical equipment and supplies;
- parenteral and enteral nutrients, equipment, and supplies;
- prosthetics, orthotics, and prosthetic devices and supplies;
- outpatient prescription drugs;
- home health services;
- outpatient prescription drugs; and
- inpatient and outpatient hospital services.

Violations of the Stark law can result in various sanctions, including denial of payment for the services, an obligation to refund any payments made, civil money penalties of up to $15,000 for each illegal referral, and possible exclusion from Medicare and Medicaid programs. In addition, a physician or entity that enters into a scheme to bypass Stark can be fined up to $100,000 for each such arrangement and can be excluded from the programs. Stark also imposes an obligation on each entity that provides designated health services to report the names and identification numbers of all physicians who have a compensation arrangement or an ownership or investment interest in the entity to the Secretary of Health and Human Services. Failure to do so can result in a civil money penalty of up to $10,000 for each
day for which reporting was required. Unlike the antikickback law, which requires proof that the defendant acted “knowingly and willfully,” making a prohibited referral is a per se violation of Stark and no proof of intent is required (see Legal Brief). The fact that a defendant acted in good faith or that she was unaware of the law is not a defense. The antikickback and Stark laws differ in one other respect: the former applies to anyone, whereas the latter applies only to physicians.

The basic provisions of Stark are extremely broad and complex, as the government recognizes:

The law is...complex because it attempts to accommodate the many complicated financial relationships that exist in the health care community. The prohibitions are based on the general principle that if a physician has a financial relationship with an entity that furnishes items or services, he or she cannot refer patients to the entity. However, the law provides numerous exceptions to this general principle, and it is the exceptions that contain the most detailed and complicated aspects of the law. The exceptions are complicated because they attempt to achieve a balance that allows physicians and providers to maintain some of their financial relationships, but within bounds that are designed to prevent the abuse of the Medicare and Medicaid programs or their patients.41

**Statutory Exceptions**

As the previous quotation shows, Congress provided for certain exceptions to the self-referral ban because without them the law’s sweeping language would have made many legitimate, laudable, and even necessary arrangements illegal. For example, the law excepts referrals for services provided by other physicians in the same group practice and most in-office ancillary services furnished “personally by the referring physician, personally by a physician who is a member of the same group practice...or personally by individuals who are directly supervised by the physician or by another physician in the group practice....”42 Such in-office ancillary services must, however, be billed by the physician or the group practice,43 and they must be provided in the group’s building or in another building used by the group for the centralized provision of such services.44

Likewise, because the financial incentive for self-referral does not exist with prepaid health plans (health maintenance organizations, for example), the statute does not apply when a physician refers members of such plans for designated health services.45 It also does not apply to referrals for services
provided by a hospital in which the physician has an ownership or investment interest and at which the physician is authorized to perform services.\textsuperscript{46} It is notable that physicians who are merely employed by a hospital rather than owners or investors cannot avail themselves of this exception; instead, a more detailed exception relating to employment relationships is provided later in the statute.\textsuperscript{47}

In addition to the aforementioned exceptions, there are exceptions for certain kinds of financial relationships.\textsuperscript{48} The financial relationships that will not trigger Stark can be summarized as follows:

- owning stocks or bonds in a large, publicly traded company or mutual fund;
- owning or investing in certain rural providers or hospitals in Puerto Rico;
- reasonable rent for office space or equipment;
- amounts paid under fair and bona fide employment relationships;
- reasonable payments for personal services provided to the entity or for other services unrelated to the provision of designated health services;
- compensation under a legitimate “physician incentive plan,” such as by withholds, capitation, or bonuses in managed care;
- reasonable payments to induce a physician to relocate to the hospital’s service area;
- isolated transactions, such as a one-time sale of property or a practice;
- an arrangement that began before December 19, 1989, in which services are provided by a physician group but are billed by the hospital; and
- reasonable payments by a physician for clinical laboratory services or for other items or services.

These exceptions to Stark are much more complicated than this simple list implies. They have been the subject of much controversy and have generated many ambiguities. For example, it is unclear whether the “isolated transactions” exception would apply to the purchase of a physician’s practice where payment for the practice is made in installments rather than in a lump sum. CMS takes the position that the exception would not apply and that installment payments are prohibited, but because the question has not been litigated, it stands unresolved as an example of the law’s ambiguity.

One can see another example of ambiguity in the case of plans for a patient’s care by a home health agency (HHA). A physician employed by a hospital that owns an HHA would presumably want to order home health services from the hospital’s own HHA. The question now is, does the physician’s financial relationship with the hospital also amount to a financial relationship with the HHA? HCFA opined privately in 1996 that it does, and therefore the physician cannot refer to the HHA. This opinion had not been the basis for enforcement, but proposed regulations issued in January 1998 seem to perpetuate this view. Specifically, in addressing the physician “ownership or investment interest”
exception, the regulations indicate that the physicians may refer to hospitals in which they have an ownership or investment interest, but only for services provided by the hospital. They may not avail themselves of the “ownership or investment” exception with regard to services provided by the hospital-owned HHA. This interpretation, of course, raises a whole new set of ambiguities. What are “services provided by the hospital,” for example? If the hospital uses a separate provider number to bill for some services (e.g., radiology), are those services considered to be provided by the hospital or by a separate entity?

As this example shows, each attempt at “guidance” and “clarification”—although helpful in some respects—adds new uncertainties, increases healthcare providers’ unease, and makes the practice of law in this area extremely difficult (or quite profitable, depending on your point of view). Because of the ambiguities and complexities involved, the importance of expert legal counsel cannot be overemphasized.

**Corporate Compliance Programs***

In any corporation, violations of law can lead to criminal convictions and financial penalties. Healthcare organizations are no exception. Punishment can be levied against both the perpetrators and the corporation itself, even if the crime occurred at the lowest levels and was contrary to express company policy. Even though they may never have authorized the act or had knowledge of it, officers and managers may be held personally accountable if they deliberately or recklessly disregarded the possibility that illegal conduct might occur. It is, therefore, clearly a mistake for executives to believe “what I don’t know can’t hurt me.”

One of the most effective tools to minimize the exposure of an organization and its board and management is an effective corporate compliance program (CCP; see Legal Brief on page 374). An effective CCP helps healthcare organizations develop effective internal controls that promote adherence to federal and state laws and the program requirements of federal, state, and private health plans. Adoption and implementation of voluntary compliance programs significantly assist in the prevention of fraud, abuse, and waste while helping the organization achieve its mission: providing quality care to patients. Programs promoting legal compliance and corporate integrity guide the governing body, top management, other employees, and healthcare professionals in the efficient management and operation of the entity. They are especially critical as an internal control in the reimbursement and payment areas, where claims and billing operations can be the

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source of fraud and abuse and the focus of governmental scrutiny.

The CCP concept gained prominence after the publication of the federal government’s *Sentencing Guidelines for Organizations*, which is used by federal judges during the sentencing phase of a trial when a corporation has been convicted of a violation of law. The Guidelines are intended to provide a measure of uniformity and predictability in federal criminal sentences. Although criminal violations can relate to many legal topics (such as antitrust, taxation, the environment, employment, and breach of patient confidentiality), the most publicized category of illegal activity in healthcare may be fraud. Federal and state governments crack down on healthcare fraud because by some estimates up to 10 percent of the U.S. annual healthcare spending may result from fraudulent activity or abusive billing practices. (Like other law enforcement agencies, fraud squads “follow the money.”) Lawsuits and prosecutions have led to penalties in the hundreds of millions of dollars in individual cases, and fines of hundreds of thousands of dollars are not uncommon (see, for example, Table 12.1).

To protect against this frightening scenario, most providers have established systematic efforts to prevent, detect, report, and correct criminal misconduct and to provide ongoing review of policies, procedures, and operations. Often called “corporate compliance programs,” proper CCPs address the healthcare organization’s potential vulnerability in all areas of law and ethics, not just fraud and abuse. If the CCP is implemented effectively and is supported and encouraged by its governing board and top management, the program becomes powerful evidence that the organization took steps to prevent violations by its employees and agents. It also demonstrates good faith and moral respectability—critical factors in determining what penalties will be assessed, be they criminal or civil in nature, if a violation is found.

Without a CCP, a convicted organization will incur much stiffer penalties and will usually face a court-imposed compliance program more severe than the Guidelines require. Under the Guidelines, however, an organization with an effective CCP will benefit from penalty reductions of up to 95 percent. Assume that two hospitals, each with 3,000 employees, are convicted of defrauding Medicare through coding errors. (Note that the size of the organization is a factor in the Guidelines’s sentencing formula.) Assume further that the frauds resulted in overpayment of $1.6 million to each facility. Hospital A does not have

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**Legal Brief**

In this text, the term “corporate compliance program” is used because it has purchase in the field. Having said that, it seems to me that “compliance” has a rather tinny and reactive connotation—that is, “OK, we’ll comply if we have to.”

If I were naming such a program I would prefer a more assertive, good-citizen, we’re-on-the-side-of-the-angels term—one that includes words like “integrity,” “ethics,” and “responsibility,” for example.
a CCP; in fact, its management was found “willfully ignorant” of the existence of the fraudulent activity. (Willful ignorance is an aggravating factor in the formula). Hospital B, on the other hand, has an effective CCP, discovered the fraud, and reported it to the authorities immediately. Table 12.2 shows the potential penalties for the two hospitals, according to the formula of the Guidelines.

In addition to reducing the organization’s punishment in the event a violation occurs, an effective CCP may also provide early detection of conduct that could lead to governmental enforcement efforts, whistle-blower litigation, or other actions. The CCP’s preventive activities allow management to take corrective action before suit is filed and to show due diligence if the matter goes to trial.

Despite the cost of compliance programs, which usually involve a separate executive-level department and budget items, the benefits of a CCP far outweigh the potential disadvantages. In addition to improving the accuracy of billing—the original focus of most programs—a compliance department becomes an internal resource for myriad issues relating to law and ethics. A CCP enables the entity to do the following:

- demonstrate the hospital’s strong commitment to honest, ethical, and responsible corporate conduct;
- improve the quality of patient care;
- identify weaknesses in internal systems and management;
- provide an accurate view of employee and contractor behavior relating to fraud and abuse;

<table>
<thead>
<tr>
<th>TABLE 12.2</th>
<th>Effect of a CCP on Penalty Computations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Base fine (usually the amount of the overpayment)</td>
<td>Hospital A (no CCP)</td>
</tr>
<tr>
<td>Culpability score (determined from a table)</td>
<td></td>
</tr>
<tr>
<td>Base score (identical for all defendants)</td>
<td>5</td>
</tr>
<tr>
<td>Willful ignorance factor (aggravating)</td>
<td>4</td>
</tr>
<tr>
<td>Effective CCP factor (mitigating)</td>
<td>0</td>
</tr>
<tr>
<td>Self-reporting factor (mitigating)</td>
<td>0</td>
</tr>
<tr>
<td>Total culpability score</td>
<td>9</td>
</tr>
<tr>
<td>Culpability multiplier range (CMR) (from a table)</td>
<td>1.8 to 3.6</td>
</tr>
<tr>
<td>Minimum fine (low CMR × base fine)</td>
<td>$2,880,000</td>
</tr>
<tr>
<td>Maximum fine (high CMR × base fine)</td>
<td>$5,760,000</td>
</tr>
</tbody>
</table>
• identify and prevent criminal and unethical conduct;
• create a centralized source for distributing information on healthcare statutes and regulations;
• develop a process that allows employees to report potential problems;
• develop procedures that allow the prompt, thorough investigation of the alleged misconduct;
• initiate immediate and appropriate corrective action; and
• minimize the loss to the government from false claims and thus reduce the hospital’s exposure to civil damages and penalties, criminal sanctions, and administrative remedies, such as program exclusion.

The elements of an effective CCP are as follows:

1. **It must contain established compliance standards and procedures.** This requires management to publish standards of conduct outlining legal and ethical requirements in all areas of the organization’s operations. Such areas include antitrust, document retention, employment and employee benefits, environmental compliance, Medicare/Medicaid fraud and abuse, occupational safety, patient protection, and taxation.

2. **It must be overseen by high-level personnel.** Most organizations assign the function to an individual who reports to the chief executive officer and has a relationship with the governing board and general counsel.

3. **It must provide that no discretionary authority in the organization may be vested in persons who are known (or should be known) to be likely to engage in criminal conduct.** In effect, this means that the organization must have a mechanism (such as routine criminal background checks) to prevent the hiring of persons who, for example, have previously been convicted of healthcare offenses or who have been excluded from federal healthcare programs.

4. **Its procedures and standards of conduct must be effectively communicated to employees and agents of the organization.** This means that the organization must educate all employees and agents about CCP standards and procedures and must continually publicize the topic in employee newsletters and similar media. In effect, the CCP must have the commitment and understanding of everyone in the organization, including not only the board and senior management but also lower-level employees. Without this level of support, the CCP may be viewed as a sham, which could lead to harsher penalties being assessed.

5. **It must establish reasonable methods to achieve compliance with the standards of conduct.** These methods should include ongoing monitoring activities, periodic audits of various operational departments, and encouragement to employees to report suspicious activities (for example, through “hotlines” or anonymous written reports).
6. It must provide for, and the organization must carry out, appropriate and consistent discipline. Discipline includes possible termination of employment for those who violate the standards of conduct or fail to report violations.

7. It must appropriately and consistently respond to violations that are detected. This includes having necessary corrective action in place to prevent recurrence of violations.

Healthcare organizations, including their governing boards and senior management, must take seriously the possibility that criminal violations (including fraud and abuse) may occur and that civil liability may arise in the course of their business. Although the cost of developing a CCP is significant, the consequences of not having one can be dire if illegal or unethical activity occurs, and substantial benefits may accrue in the form of reduced exposure to whistleblower lawsuits and other civil actions. Each healthcare organization, as well as each physician practice, should adopt and implement an effective CCP covering their entire operation.

CCPs are an important part of most healthcare organizations’ operations. They began with an emphasis on detecting and preventing fraud and abuse and complying with regulations. As they have matured, many have become less reactive and are now more proactive in focusing on the ethical integrity of the corporation through education and sharing of information. The compliance officer should be seen as a valuable resource for questions relating to corporate ethics, conflicts of interest, human subject research, privacy and security of healthcare information, and other subjects from antitrust to zoning.

In addition, because of their auditing and monitoring activities, compliance programs can actually become a revenue center for the facility. The general view, which I share, is that hospitals and physicians probably underbill more often than they overbill. This means that they lose revenue (“leave money on the table”) through failure to capture all charges properly. An effective CCP can add to the organization’s net revenue while preventing improper billing practices.

**Chapter Summary**

This chapter deals with one of the most salient issues in healthcare today: the prevention of fraud and abuse in governmental payment programs. Here, the major fraud laws—including the federal FCA, the antikickback statute, and the Stark self-referral laws—are reviewed. The text points out the aggressive enforcement activities of federal and state regulators and the severe monetary and criminal penalties that can be imposed for violations. It also discusses the basics of a CCP, one of the most effective efforts a healthcare organization can undertake to prevent fraud, promote ethical integrity, and improve billing accuracy. Not only are compliance programs
important preventive measures, but they are also valuable resources on a wide range of legal and ethical issues.

**Chapter Discussion Questions**

1. What factors motivate healthcare organizations to maintain programs aimed at compliance and corporate ethics?
2. What kinds of fraudulent or abusive behavior relating to federal healthcare payment programs can occur in hospital operations?
3. What are the most significant statutes relating to healthcare fraud?
4. What do the terms “kickbacks” and “self-referral” describe in the healthcare setting?

**Notes**

7. See, for example, Rex Trailer Co. v. United States, 350 U.S. 148 (1952) and Fleming v. United States, 336 F.2d 475 (10th Cir. 1964).
17. 317 U.S. 537 (1943); see also United States v. Forster Wheeler Corp., 447 F.2d 100 (2d Cir. 1971)—invoices submitted on contract that was based on inflated cost estimates are false claims; United States v. Veneziale, 268 F.2d 504 (3d Cir. 1959)—fraudulently induced contract may create liability when the contract later results in payment by the government.
18. 797 F.2d 888 (10th Cir. 1986).
21. Id. at 1508–1509.
22. Id. at 1513.
23. At least one consent judgment has been entered in a case of this type. In 1994, a company that ran home infusion centers agreed to pay $500,000 in settlement of an FCA case because

25. 42 U.S.C. § 1320a-7(b)(1)(A) and (2)(A).
27. 42 U.S.C. § 1320a-7(b)(7).
29. 42 U.S.C. § 1320a-7(b)(3).
30. 42 U.S.C. § 1320a-7(b).
32. 51 F.3d 1390 (9th Cir. 1995).
35. See 42 U.S.C. §§ 1320a-7(b)(1)(B) and (2)(B).
37. 42 U.S.C. § 1320a-7(a)(5).
38. 42 U.S.C. § 1320a-7(a)(6).
41. Id. at 2400–3403.
45. 42 U.S.C. § 1395nn(b)(3).
47. 42 U.S.C. § 1395nn(e)(2).
50. Although originally considered mandatory, in early 2005 the Supreme Court held (for reasons not relevant here) that the Sentencing Guidelines are only “advisory.” United States v. Booker and United States v. Fanfan, 543 U.S. 220 (2005). The effect of the Guidelines remains as described in the text.