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Qui Tam: False Claims Act and New Fraud Provisions

By **David Freedman, MD, JD, FAAEM,** Emergency Medicine Physician, Chelsea Community Hospital, Chelsea, MI; Attorney, Miller, Canfield, Paddock & Stone PLC, Ann Arbor, MI.

Let there be no mistake, the government is serious about the health care fraud problem. While most of the well-publicized False Claims Act cases in emergency medicine have involved billing companies and contract groups where the effect on individual physicians was only indirect (e.g., lost income when the contract group has to fund its False Claims Act settlement), individual emergency physicians may be held personally liable for false claims submitted on their behalf. Not knowing what was billed on your behalf will not be a valid defense. Every HCFA 1500 form submitted under your name contains your certification that the service billed was medically necessary and was either personally rendered or rendered by an employee incident to your professional services. If you did not provide the service billed for, or the service provided was at a lower level than that which was billed (i.e., the claim was "upcoded"), you will have submitted a false claim for which you may be civilly and/or criminally liable.

Because of the qui tam provisions of the False Claims Act, the government is aided in its pursuit of health care fraud by all manner of whistle-blowers (e.g., coworkers and disgruntled employees) who are authorized by the statute, in certain circumstances, to pursue False Claims Act lawsuits on behalf of the federal government. In effect, the qui tam provisions of the False Claims Act allow private individuals to act as "private attorneys general" and bring False Claims Act suits on behalf of the government. These whistle-blowers are incentivized by rewards of up to 30% of the amount recovered for the government, plus attorney fees and costs.

If you are not familiar with the term "qui tam" and what it means, you should be. And you, or your organization, should have in place an effective compliance plan that will prevent your commission of health care fraud and, thereby, proactively protect you from qui tam and other health care fraud liability.

In this issue we will outline the provisions of the False Claims Act, in particular its qui tam provisions; several specific potential False Claims Act issues (e.g., waiver of co-payments and deductibles); review the new fraud and abuse provisions of the Health Insurance Portability and Accountability Act of 1996; and discuss vari-

ous strategies to avoid False Claims Act liability (including the implementation of an effective corporate compliance plan).

Introduction

It is absolutely essential that all physicians, no matter their area of practice and no matter their level of administrative involvement, have basic familiarity with the False Claims Act. Reference to the False Claims Act (FCA) usually is to the federal civil False Claims Act that imposes civil liability, albeit so substantial in some cases as to be quasi-criminal in its sanctions.[1] Stated in its simplest terms, the FCA imposes liability on any person (including corporations) who knowingly submits a fraudulent request for payment to the federal government.

The FCA is not the only weapon in the government's arsenal to combat health care fraud—far from it. The government also has various criminal statutes that may be applied to individuals who submit false health care claims. Among these is a criminal false claims act, not to be confused with the FCA, which is the primary focus of this article. In addition, civil monetary penalties are also available administratively as penalties for the submission of false health care claims.

While the FCA, the federal criminal false claims act, and the civil monetary penalties provisions are applicable only to fraud related to federal health care programs, the Health Insurance Portability and Accountability Act of 1996 (HIPAA) created five new federal criminal offenses that are applicable to private health plans as well as public plans. In addition, there are also numerous other federal criminal statutes which, like the FCA, were not originally intended to address health care fraud, but nonetheless are available to federal prosecutors (e.g., mail fraud, money laundering). Finally, states have their own false claims acts, insurance fraud statutes, and other fraud statutes that may be applied to individuals who submit false health care claims. The state health care fraud statutes often mirror their various federal namesake statutes.

It is a matter of some dispute as to how much money is lost to the federal government as a result of health care fraud. There is, however, no argument that the amount is substantial, certainly in the billions of dollars. As a result, various government agencies, including the Department of Justice, have made the fight against health care fraud and abuse a top priority. As mentioned above, the FCA is only one weapon in the government's arsenal to combat health care fraud and abuse. In fiscal year 1997, $1.2 billion was awarded or negotiated as a result of criminal fines, civil settlements, and judgments in health care fraud matters.[2] Over half of this amount involved judgments or settlements related partially or completely to allegations in *qui tam* cases. Included in this total is the $7.75 million paid by EmCare, Inc. to settle allegations that it overcharged Medicare, Medicaid, the Federal Employees Health Benefits Program, and CHAMPUS, by submitting false claims through its third-party medical billing service, Emergency Physicians Billing Services. This settlement was the consequence of a *qui tam* case brought by a former employee of the billing company. In addition, 363 defendants in 217 criminal cases were convicted, and more than 1000 individuals and businesses were excluded from participation in federal health programs due to criminal convictions. The bottom line is that the government is extremely serious about fighting health care fraud, if not always fair and effective in its actions, and there are ever-increasing resources committed to this effort.

Case 1. On November 20, 1998, a federal district court judge in the Western District of Oklahoma, handed down her judgment in the liability phase of the Emergency Physicians Billings Services, Inc. (EPBS) case, a case undoubtedly familiar to most emergency physicians.[3] The case, a *qui tam* action, was originally brought by a former employee of EPBS. While a number of emergency physician contract groups were included as defendants, prior to trial all defendants, except Dr. McKean (the chairman and CEO of EPBS) and EPBS, were dismissed. Some of those

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defendants were dismissed pursuant to quite significant monetary settlements (e.g., $7.75 million in the case of EmCare, Inc.). The government's filings in the EPBS case indicated that it was requesting damages of at least $90 million plus civil penalties that could total $1 billion.

The case involved the billing of emergency department evaluation and management (E/M) services under criteria established in 1992 by the American Medical Association in the Physicians' Current Procedural Terminology. These criteria included a requirement that, in order to receive reimbursement, a physician must document the performance of certain work components in the areas of history, examination, and medical decision making. Certain minimum documentation was specified and required for each of the five levels of reimbursement for E/M services.

In the course of the testimony in the case, it was established that "the philosophy and practice of EPBS, until notified of this lawsuit [was] to code based on the 'service rendered' *without regard to what was documented*."[4] That is, charts were coded based on a level of service that presumably was rendered (presumptive coding) without regard to whether the documentation in the medical record supported that level of service. The defendants were unable to explain to the court how they could tell that the service for which they presumptively coded had in fact actually been rendered if it was not documented in the chart. Interestingly, the evidence established that "no coder ever contacted a physician with questions regarding a chart."[5] To compound defense counsel's difficulties in defending the case, in a videotaped internal training session that was introduced into evidence, Dr. McKean had explained to his coders that "documentation is purely a red tape crap issue."[6]

After the trial, the judge ruled that the remaining defendants, Dr. McKean and EPBS, had submitted false claims to the government with the requisite intent and, therefore, were liable under the FCA. The issue of damages had been bifurcated from the issue of liability and a subsequent damages hearing was ordered to be held.

Commentary. *This case, including the various substantial settlements prior to the verdict, should serve as a stark warning to all physicians to make serious efforts to comply with all reimbursement requirements. In this case, the fact that there was a videotape of Dr. McKean instructing his staff to the effect that they should code charts without regard to the documentation in the medical record, and the defendant used billing code modifiers, which, according to the defendants' own coding manual, indicated that documentation was lacking for the level of service billed, certainly complicated defense of the case.*

History of the False Claims Act

Unlike the criminal offenses created by HIPAA (discussed below), which are obviously explicitly directed at health care fraud, the FCA was not originally intended to address health care fraud at all. Rather, it was passed in 1863 to address the abusive practices of government defense contractors during the Civil War and was commonly known at that time as the Lincoln Law. The FCA was relatively dormant from the late 1800s until the 1940s, at least as to *qui tam* actions.[7] With renewed interest in the 1940s, again primarily related to defense-contractor fraud, the number of *qui tam* suits increased. As discussed below, the FCA was significantly amended in 1943 and again in 1986 as to who was qualified to bring a *qui tam* action under the act.

Overview of the False Claims Act

The FCA provides for the imposition of civil liability on any person who "knowingly presents, or causes to be presented, to an officer or employee of the United States government or a member of the Armed Forces of the United States, a false or fraudulent claim for payment or approval."[8] It is also illegal to knowingly make, use, or cause to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the government,[9] or "to conspire to defraud the government by getting a false or fraudulent claim allowed or paid."[10] There is no liability under the FCA if the defendant can show that the false claim was due to an "honest mistake" or to mere negligence.

The government (or a *qui tam* plaintiff) must prove, as an element of the case, that the claim at issue was false. Whether a claim is false is most often an issue of fact that generally requires an exhaustive evaluation of the reimbursement statutes, regulations, carrier manual provisions, and various memoranda and other communications from HCFA and the Medicare carrier. If these regulatory instructions and guidance from HCFA and the Medicare carrier were ambiguous or unclear, such that the defendant's interpretation of the law in the submission of the allegedly false claim was reasonable, even if incorrect, a FCA suit should be dismissed.[11]

The statute of limitations for FCA cases is relatively long, the later of: six years from the date of the illegal conduct or three years after the government knows or should have known about the illegal conduct, but in no event later than 10 years after the illegal activity.[12]

Definition of "Knowingly"

In order to prevail in a FCA case, the government (or a *qui tam* plaintiff) must prove that the defendant "knowingly" submitted a false claim to the government. The definition of "knowingly" is specified in the statute and includes:

1. Actual knowledge of the falsity of the claim;
2. Acting in deliberate ignorance of the truth or falsity of the claim; and
3. Acting in reckless disregard of the truth or falsity of the claim.[13]

Therefore, the lowest level of knowledge that can result in FCA liability is reckless disregard. Submission of a false claim because of mere negligence is an insufficient level of intent and cannot result in FCA liability. One should not, however, take too much comfort in the protection of false claims that are merely negligent. The difference between reckless and deliberate ignorance on the one hand and merely negligent on the other is an issue of fact, and often a close call, and would likely be left to the jury to determine only after completion of a trial. This is not the issue upon which an attorney would want to exclusively base a FCA defense.

It is not a defense to a FCA suit to claim that you had no specific knowledge of the FCA or that you had no specific intent to defraud the government.[14] It is only necessary for the government, or a *qui tam* plaintiff, to prove that the defendant submitted a claim that was false and that such a claim was submitted with the requisite level of intent (i.e., at least reckless disregard). The legislative history of the 1986 amendments to the FCA makes it clear that defendants may be found liable under the FCA if "they act like an ostrich with its head in the sand."[15]

The HCFA 1500 Form

The HCFA 1500 Form, upon which claims for Medicare Part B payment are submitted, is a critical document in the context of billing compliance and potential FCA liability. Among the various sections of the form is a provider certification where the provider makes the following certification:

> "I certify that the services shown on this form were medically indicated and necessary for the health of the patient and were personally rendered by me or were rendered by me incident to my professional service by my employee under immediate personal supervision . . . "

Therefore, by signing and submitting the form, the physician makes an affirmative representation that the services for which the claim was submitted were actually provided. For example, if a level 5 service is listed on the form, the physician is affirmatively certifying that each and every component of a level 5 service was, in fact, performed.

Each and every item on the HCFA 1500 Form must be honestly and accurately completed. Arguably, any incorrect statement entered on the form could potentially render the claim false. For example, the knowing or reckless entry of an incorrect diagnosis on the form (Box 23A) by itself, could in certain circumstances render the claim false. Some physicians base their HCFA 1500 Form diagnosis on what they feel will justify the diagnostic studies and/or treatment they provided, realizing that Medicare will pay for certain diagnostic studies and treatment only if they are felt to be medically necessary for the particular diagnosis. If the claim would not have been paid had the actual diagnosis been entered (i.e., the test was not medically necessary for the specified diagnosis), and it was paid because of the knowing substitution of a false diagnosis, the claim is a false claim and the provider could be subject to FCA liability.

All physicians should review the HCFA 1500 Form, particularly the certifications on the front and back of the form. The current version of the HCFA 1500 Form contains the following warning on the reverse side:

> "Any person who knowingly files a statement of claim containing any misrepresentation or any false, incomplete or misleading information may be guilty of a criminal act punishable under law and may be subject to civil penalties."

The signature space on the front of the form contains the following statement: "I certify that the statements on the reverse apply to this bill and are made a part thereof." If any of the certifications is not true, the claim may be a false claim.

Damages

Liability for a FCA violation may result in treble damages to the government.[16] As imposing as treble damages may sound, this is not the most serious potential liability under the FCA. Generally, a FCA suit will be brought challenging a pattern of billing. As a result, there may be hundreds, if not thousands, of individual claims at issue. In many FCA cases, these claims will be for relatively small amounts and, therefore, even with trebling of the amount, the total amount of the treble damages may not be very large. However, in addition to treble damages, the FCA currently provides for civil penalties of $5,000-$10,000 per claim. This is what really makes the FCA frightening and which converts the FCA, at least as to penalty, into a quasi-criminal statute.

Because of these civil penalties, it would take only a hundred false claims to result in potential liability of more than a million dollars. In a case alleging upcoding (e.g., as to E/M codes) in a relatively busy emergency department (ED), there could easily be several hundred or more claims at issue in a single year. While the government has generally pursued contract groups and third-party billing companies (most likely as a matter of "prosecutorial" efficiency), there is no reason that the government cannot pursue individual emergency physicians. If a false claim has been made, it is the individual physician

whose name appears on the HCFA 1500 Form who will have falsely certified to the government that the claim was valid.

Case 2. In *United States v Diamond*,[17] a physician was convicted on a total of 39 criminal health care fraud related counts. Fifteen of these were for mail fraud and 24 were for violations of the criminal false claims act. After the completion of the criminal trial, the government filed a FCA suit against the physician. The court first ruled that, based upon the previous criminal health fraud convictions, the defendant could not contest his FCA liability as to those claims. Then, the court went on to consider the amount of the damages.

The damages sustained by the government totaled only $549.04 (approximately $14.07 per claim). At the time of these false claims, liability under the FCA was less than it is currently (double damages plus $2,000 per claim then vs treble damages plus $5,000-$10,000 per claim now). The court awarded total damages of $79,098.08 (double damages of $1,098.08 plus penalties of $78,000), 144 times the total amount of the false claims.

Commentary. *There may, perhaps, be a point where a civil penalty becomes constitutionally excessive. It remains clear, however, that courts will impose civil penalties that far exceed the actual damages sustained by the government. These civil penalties, as in Diamond, may be many times the amount of the actual damages.*

Qui tam Actions

While we have largely abandoned the use of Latin terms in medicine, every physician must be aware of two key Latin words—*qui tam*—and what they stand for.[18] The *qui tam* provisions of the FCA encourage all employees, consultants, colleagues, or any other individual who is knowledgeable regarding a physician's or other health care entity's billing practices to blow the whistle on improper billing. The incentive is the receipt of up to 30% of the amount recovered by the government, and the total amount recovered can easily reach into seven figures, as discussed above. As anyone might imagine, there are attorneys who specialize in *qui tam* lawsuits who have built extremely successful practices bringing FCA suits against physicians and other health care entities.

The FCA provides for two different types of lawsuits. First, the government may initiate FCA lawsuits through the office of the Attorney General of the United States. Second, FCA lawsuits may be brought by private persons, *qui tam* plaintiffs who may file actions in the name of the United States government.[19] In such cases, the *qui tam* plaintiff initially serves a copy of the complaint on the government together with a written voluntary disclosure of substantially all material information and evidence.[20] The complaint is sealed and not made available to the public for at least 60 days.[21] The 60-day period of sealing may be, and often is, extended for a significant period of time (even years) at the request of the government.[22] The file remains sealed until the court orders otherwise.

In order to bring a FCA case, the *qui tam* plaintiff must be an "original source" of the information on which the claim is based. In the original version of the FCA (1863) this was not required. In response to a rising number of "parasitic lawsuits," in which private persons copied information contained in government indictments or those already in the possession of the government and then sue under the FCA, the FCA was amended in 1943 to require courts to dismiss *qui tam* cases if the plaintiff's case was "based on evidence or information the government had when the action was brought."[23] This amendment, however, overshot in the opposite direction in that plaintiffs were now barred from bringing *qui tam* suits if the information was already in the hands of the government, even when the plaintiff had provided the information to the government in the first place. As a result, the FCA was amended again in 1986 and now prohibits *qui tam* actions based on publicly disclosed information unless the *qui tam* plaintiff was the original source of the information.[24]

Within the 60-day period (or such other time as allowed by the court), the government must either proceed with the action and the United States Attorney will conduct the case (in such cases, the government is said to have intervened), or notify the court that the government declines to take over the action, in which case the *qui tam* plaintiff may pursue the action in the name of the United States.[25]

The government may dismiss a *qui tam* action, notwithstanding the objections of the *qui tam* plaintiff, so long as the *qui tam* plaintiff has been notified by the government of its filing of a motion to dismiss and the *qui tam* plaintiff has been afforded the opportunity for a hearing on the motion to dismiss.[26] The government may also settle the action, notwithstanding the objections of the *qui tam* plaintiff, if the court determines after a hearing that the proposed settlement is fair, adequate, and reasonable under all the circumstances.[27]

As incentive to initiate FCA suits, the FCA provides a substantial reward to the successful *qui tam* plaintiff, otherwise know as the "Relator". If the government intervened in the case, the Relator receives 15-25% of the government's recovery, whether it was achieved through a favorable judgment or a settlement.[28] If the government declined to intervene, the successful Relator is entitled to 25-30% of the government's recovery, again whether it was achieved through a favorable judgment or a settlement.[29] In addition, the unsuccessful defendant must pay the *qui tam* plaintiff's reasonable expenses, as well as reasonable attorneys' fees and costs.[30] In Fiscal 1997, for example, a total of $33 million was paid to successful *qui tam* plaintiffs.[31]

Waiver of Coinsurance and Deductibles

Submission of Medicare claims when the patient's coinsurance and/or deductible has been waived may be construed as false claims. Except in documented specific instances of poverty, the safest practice is to never waive insurance copayments and/or deductibles (Medicare or any other payor). In 1991, the Department of Health and Human Service's Office of Inspector General (OIG) issued a Special Fraud Alert, addressing coinsurance and deductible waivers for Medicare patients.[32] The OIG's analysis is as follows:

> A provider, practitioner, or supplier who routinely waives Medicare co-payments or deductibles is misstating its actual charge. For example, if a supplier claims that its charge for a piece of equipment is $100, but routinely waives the co-payment, the actual charge is $80. Medicare should be paying 80% of $80 (or $64), rather than 80% of $100 (or $80). As a result of the supplier's misrepresentation, the Medicare program is paying $16 more than it should for this item.[33]

The FCA, of course, only applies to claims submitted to the government. However, waiver of coinsurance and deductibles for non-government payor patients is also a compliance risk for a number of reasons. For example, waiver of coinsurance and deductible for a patient covered by a third-party payor could be seen as an overstatement of the actual charge and, therefore, be a violation of the physician's provider contract or, worse yet, criminal Health Care Fraud, as provided for in HIPAA. As discussed below, the Health Care Fraud provision of HIPAA applies not only to federal health care programs, but to "any health care benefit program."

Providing professional courtesy to a physician colleague by billing "insurance only" is also potentially problematic. This time-honored tradition, already becoming less common, may soon go the way of the nuclear medicine brain scan and pneumoencephalogram. In the context of professional courtesy, not only do all the potential violations of law applicable to a non-physician patient apply, if the physician-patient is in a position to refer patients to the treating physician who provided the discount, a potential violation of the federal anti-kickback statute could be alleged. If one purpose of the provision of the discount was to induce the referral of patients covered by federal health care programs, the statute would have been violated, no matter the existence of other legitimate purposes. Unlike the FCA, the federal anti-kickback statute is a criminal statute, violation of which is a felony.

If a third-party medical billing company is used, it would not be able to bill Medicare or any other payor if the copayment and/or deductible had been waived, without violating its compliance plan, assuming its compliance plan conformed to the OIG's Compliance Program Guidance for Third-Party Medical Billing Companies, which provides that:

> Discounts and professional courtesy may not be appropriate unless the total fee is discounted or reduced. In such situations, the payer (e.g., Medicare, Medicaid or any other private payer) should receive its proportional share of the discount or reduction.[34]

The safest practice, from a compliance standpoint, is, unfortunately, to abandon professional courtesy. If, however, professional courtesy is provided, the entire fee should be waived, not just the coinsurance and deductible. By waiving the entire fee, there cannot be a claim that a provider's submission of his or her usual fee represents an overstatement of the actual charge.

Health Insurance Portability and Accountability Act of 1996

HIPAA created five new federal criminal health care fraud offenses: Health Care Fraud,[35] Theft or Embezzlement in relation to health care,[36] False Statements relating to health care matters,[37] Obstructing Criminal Investigations,[38] and Money-Laundering relating to federal health care offenses.[39] As with any criminal offense, the United States Attorney must prove all elements of the offense beyond a reasonable doubt. This requirement will likely make use of these criminal statutes relatively rare, in comparison to the use of the FCA, where the government can recover huge civil penalties (up to $10,000 per claim) by proving its case under the lesser burden applicable in a civil case—preponderance of the evidence.

Health Care Fraud, one of the new federal health care crimes, provides that:

> Whoever knowingly and willfully executes, or attempts to execute, a scheme or artifice . . .
> 1) to defraud any health care benefit program; or
> 2) to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody and control of any health care program—
>
> shall be fined under this tile or imprisoned not more than 10 years, or both. If the violation results in serious bodily injury . . . , such person shall be fined under this tile or imprisoned not more than 20 years, or both; and if the violation results in death, such person shall be fined under this tile, or imprisoned for any term of years or for life, or both.[40]

Clearly, this is not a violation that one would want to be charged with.

The False Statements relating to health care matters provision criminalizes the knowing and willful making of false statements in connection with the delivery of, or pay-

ment for, health care benefits. For example, dictating or checking off on the chart that a patient's social history, family history, and review of systems was normal when you never asked (WNL) is now potentially a federal felony. It cannot be emphasized enough that physicians must be extremely careful and honest at all times in the creation of medical records and reimbursement claims. The penalty for violation of the False Statements statute is a fine and up to five years in prison.

Of critical importance is the fact that, while the FCA only applies to claims submitted to the government, the new federal health care crimes created by HIPAA extend to private health care programs as well. Fraud against private insurers was not without redress prior to HIPAA. However, the applicable statutes were not ones directed specifically at health care fraud. For example, third-party payors could demand repayment or terminate the physician's provider contract, non-specific federal criminal statutes could be invoked (e.g., mail fraud), and various state laws address insurance fraud.

HIPAA also created new whistle-blower incentives for individuals to report suspected fraud and abuse violations. Section 203 of HIPAA provides for incentive payments for providing information that leads to recoveries, or civil or criminal sanctions, under the Medicare program. Unlike the original source requirement for *qui tam* plaintiffs, an individual may recover under this section without proving that he or she was an original source of the information.

In addition, HIPAA provided substantial additional funding for the war against health care fraud. As a result of this increased funding, the Department of Justice hired 295 additional attorneys and agents in fiscal 1997 devoted exclusively to combating health care fraud. The Department, as of 1997, had a total health care fraud workforce of 551. The newly added staff included 60 criminal assistant United States Attorneys (AUSAs), 30 civil AUSAs, 23 paralegals, 30 auditor/investigators, 23 support positions, and a health care fraud coordinator in the Executive Office for the U.S. Attorneys' Office of Legal Education. The Department of Justice's Civil Division received an additional 33 positions, the Criminal Division an additional four positions, and the Justice Management Division an additional four positions. The workforce today is even larger.

Violations of Other Laws as False Claims Act Violations

The government, or a *qui tam* plaintiff, may attempt to bring a FCA case based upon the defendant's alleged violation of another law, for example, the federal anti-kickback statute or the Stark Law. The theory in these cases is that, because of a violation of a law, other than the FCA, the claim for payment should not have been made. Therefore, the claim becomes a false claim. This is not a fully settled area of the law, and there is substantial controversy as to whether the government should be able to automatically "piggy-back" a FCA action onto another alleged violation. Be aware, however, that this remains a possibility.

Compliance Plans

All medical groups should have an effective compliance plan in place that should be drafted by, or in conjunction with, experienced legal counsel. While the plan should contain all the essential provisions of the OIG's model compliance plans, it should be tailored to the particular individual or group. The OIG has issued four model compliance plans that should be referred to in drafting a compliance plan for a medical group: Clinical Laboratories, Hospitals, Home Health Agencies, and Third-Party Medical Billing Companies. While there has not yet been a model compliance plan issued for physician practices, the key elements of a compliance plan are standard and review of those model plans that have already been drafted can be instructive.

The first requirement of any compliance plan is that it must be something that can and will be followed. It makes absolutely no sense to have a corporate compliance plan in place, no matter how good it is on paper, if your organization will not closely follow it. Compliance programs should, at a minimum, contain certain basic elements articulated by the OIG in its Compliance Program Guidance for Hospitals:

1. Written standards of conduct and policies that address substantive areas of concern and promote the organization's commitment to compliance;
2. Designation of a chief compliance officer and other appropriate bodies charged with the responsibility of operating and monitoring the compliance program who report directly to the CEO and the governing body;
3. A regular, effective training program for all affected employees;
4. Maintenance of a process, such as a hotline, to receive complaints, together with procedures to protect the anonymity of complainants and to protect whistle-blowers from retaliation;
5. Development of a system to respond to allegations of improper or illegal activities and appropriate disciplinary action against employees who violate compliance policies, applicable statutes, regulations, or federal health care program requirements;
6. Use of audits and/or other evaluation techniques to monitor compliance and assist in the reduction of identified problem areas; and

7. Investigation and remediation of identified systemic problems and the development of policies addressing sanctions, including possible termination, of problem employees.[41]

A well-designed compliance plan, reasonably adhered to, should go a long way toward preventing false claims and potential FCA lawsuits. In addition, if a FCA suit is brought, the existence of a proper compliance plan will allow the defense attorney to argue that there could not have been a FCA violation because the requisite level of intent (at least reckless disregard) was not present.

Always consult with or retain legal counsel in drafting a compliance plan. Perhaps even more importantly, always retain legal counsel to conduct or supervise any internal investigation or analysis of potentially suspect billing data triggered by your compliance plan to ensure the best chance of maintaining confidentiality of the material through the exercise of attorney-client privilege.

False Claims Act Dos and Don'ts

Do's

1. Have an effective compliance plan in place and follow it.
2. Scrupulously adhere to all statutes, regulations, and HCFA and carrier directives regarding billing. When in doubt, consult with a health care attorney who is knowledgeable in billing issues.
3. Always consult immediately with experienced legal counsel should you ever receive an investigative demand, subpoena, or any other inquiry from any government agency.
4. Recognize the wide variety of individuals who are prospective *qui tam* plaintiffs: disgruntled current and/or former employees or independent contractors, offended nurses or other ancillary personnel, past, present, and future competitors, jilted lovers or angry relatives, and plaintiff's attorneys.
5. Stay up to date on reimbursement regulations and policies.
6. If you use a third-party medical billing company, make sure it has a compliance plan which conforms to the OIG's model plan and is following it.
7. If you don't see your HCFA 1500 Forms, you should. At least understand what you are certifying.
8. Have your attorney give a presentation to your group on health care fraud and clarify any issues which are not clear to you.
9. Remember that committing health care fraud is both expensive and criminal.

Don'ts

1. Never talk to a government investigator, or respond to government inquiries regarding any billing issues, without first consulting with appropriate legal counsel.
2. Never discuss government inquiries or investigations directly with consultants or accountants. If such resources are required for an audit, have your attorney retain them, in order to attempt to bring them within the attorney-client privilege.
3. Don't expect to successfully rely on the following excuses as defenses to a FCA case (from comments made by James G. Sheehan, Assistant U.S. Attorney, Eastern District of Pennsylvania):
   I relied on the billing service
   I relied on the billing consultant who set up my practice
   I am a physician on salary; I had nothing to do with the billing
   My partner supervised the billers.
4. Never dismiss an employee's complaint regarding billing irregularities; the next person they talk to may be a plaintiff's attorney or a government investigator.
5. Never make up your own reimbursement rules or code modifiers, no matter how logical and reasonable you think they might be.
6. Don't get overly enamored with your own argument as to why your interpretation of a billing requirement in an arguably ambiguous situation is reasonable. Rest assured, there will be another side to the argument that the government may take. In such situations, consult with a reimbursement attorney for a more objective viewpoint.
7. Don't waive copayments or deductibles, especially for Medicare or other federal health care program patients.

Department of Justice Guidelines for False Claims Act Enforcement

In response to complaints by various types of health care providers and members of the House and Senate that the government has been unfairly heavy-handed in its enforcement of the FCA and the realization that reimbursement regulations and guidelines are often far less than clear, the Department of Justice has promulgated guidelines for United States Attorneys in their determination as to whether the requisite level of intent (i.e., knowingly, with deliberate ignorance, or in reckless disregard) was present when an allegedly false claim was submitted. In a June 3, 1998 memorandum, the Deputy Attorney General in charge of the Civil Division, announced a list of relevant facts that must be considered by United States Attorneys in determining whether an allegedly false claim had been made with the required level of intent:

1. Did the provider receive notice of the rule or policy upon which the FCA case is based?
2. Is it reasonable to conclude that the provider understood the allegedly violated rule or policy?
3. Is there a pervasiveness or magnitude of false claims sufficient to support an inference that they resulted from deliberate ignorance or intentional or reckless conduct, rather than mere mistake?
4. Does the provider have in place a compliance plan that is being adhered to?
5. Did the provider previously, on its own, identify the wrongful conduct and take appropriate steps to remedy the problem and report the wrongful conduct to a government agency?
6. Did the provider directly contact HCFA or its agents and, after providing accurate information and disclosing all relevant facts, receive guidance that would support its claims?
7. Has the provider previously been audited, or otherwise investigated, or put on notice as to the billing practice in question?
8. Is there any other relevant information that bears on the provider's state of mind in submitting the allegedly false claim?[42]

Beware Parallel Actions

It is often difficult to tell exactly what the government is investigating when a subpoena is issued or a government agency otherwise initiates an investigation. It is, therefore, critical that, upon the receipt of a subpoena or any other investigative inquiry by the government or an entity acting on behalf of the government (e.g., the Medicare carrier), that legal counsel be immediately consulted. There are a number of things that your legal counsel will do: 1) attempt to determine what type of violation the government may be alleging; 2) attempt to limit the scope of the investigation; 3) ensure that no documents protected by the attorney-client privilege, or any other relevant privilege, are turned over to the government; 4) attempt to determine whether there is any risk of a parallel criminal proceeding; 5) provide attorney-client privilege protection of your internal investigation and data-collection process; and 6) ensure that you respond appropriately within all relevant deadlines and that all your rights are protected during the investigative process.

The government may simultaneously initiate civil and criminal investigations against a health care provider. It is now not uncommon for a provider to be simultaneously served with a criminal search warrant and a civil or administrative subpoena. One purpose of this tactic appears to be to frighten providers into settling civil cases under terms they would ordinarily not accept, in return for the government's agreement to drop the criminal investigation, although spokespersons from the United States Attorney's Office absolutely deny that criminal investigations are brought to "leverage" civil settlements.[43] In addition, the civil subpoena may result in the uncovering of information that would not be accessible to a search warrant, which is subject to the higher standard of probable cause that a crime has been committed for its issuance.

References

1. 18 U.S.C. § 287.
2. The material in this paragraph was obtained from the Department of Justice's Health Care Fraud Report for Fiscal

Year 1997 (DOJ 1997 Annual Report).
3. *United States of America ex rel. Kevin K.T. Trim v J.D. McKean and Medical Consultants*, 31 F.Supp. 1308 (W.D. Okl. 1998).
4. Id. at 1312 (emphasis added).
5. Id.
6. Id.
7. Carolyn J. Paschke. *The qui tam Provision of the Federal False Claims Act: The Statute in Current Form, Its History and Its Unique Position to Influence the Health Care Industry*, 9 J. L. & Health 163 (1994-95).
8. 31 U.S.C. § 3729(a)(1).
9. 31 U.S.C. § 3729(a)(2).
10. 31 U.S.C. § 3729 (a)(3).
11 See, e.g., *United States v Garfinkel*, 29 F.3d 1253 (8th Cir. 1994).
12. 31 U.S.C. § 3731(b).
13. 31 U.S.C. § 3729(b).
14. Id.
15. See, *United States v Entin*, 750 F.Supp. 512 (S.D. Fla. 1990).
16. 31 U.S.C. § 3729(e).
17. 657 F.Supp. 1204 (S.D.N.Y. 1987).
18. *qui tam* is an abbreviation of the Latin *qui tam* pro domino rege quam pro se ipso in hac parte sequitur, which means "who brings action for the king as well as himself."
19. 31 U.S.C. § 3730(b).
20. 31 U.S.C. § 3730(b)(2).
21. 31 U.S.C. § 3730(b).
22. 31 U.S.C. § 3730(b)(2).
23. 31 U.S.C. § 3730(b)(4) (superceded).
24. 31 U.S.C. § 3730(e)((4).
25. 31 U.S.C. § 3730(b)(4).
26. 31 U.S.C. § 3730(c)(2)(A).
27, 31 U.S.C. § 3730(c)(2).
28. 31 U.S.C. § 3730(d).
29. Id.
30. Id.
31. DOJ 1997 Annual Report, supra, note 2.
32. 50 Fed. Reg. 65,372 (Dec. 19, 1994).
33. Id. at 65,374.
34. Compliance Program Guidance for Third-Party Medical Billing Companies, 63 Fed. Reg. 70138, 70143 n.43 (November 30, 1998) (emphasis added).
35. 18 U.S.C. § 1347.
36. 18 U.S.C. § 669.
37. 18 U.S.C. § 1035.
38. 18 U.S.C. § 1518.
39. 18 U.S.C. § 1956(c)(7).
40. 18 U.S.C. § 1347.
41. The Office of Inspector General's Compliance Program Guidance for Hospitals, 63 Fed. Reg. 8,987 (February 23, 1998)
42. Eric H. Holder, Jr., Deputy Attorney General, "Guidance on the Use of the False Claims Act in Civil Health Care Matters," Memorandum dated June 3, 1998.
43. *Medicare Compliance Alert* Vol. 11 No. 9 (May 3, 1999).

Physician's CME Questions

5. Which of the following is not true?
   A. Health care fraud is a potentially criminal act.
   B. False Claims Act penalties are $2,000 per claim.
   C. False statements on the HCFA 1500 Form may be criminal
   D. Deliberate ignorance is not a defense to a False Claims Act lawsuit.

6. Which new federal health care crimes were created by HIPAA?
   A. Health Care Fraud.
   B. False Statements related to health care matters.
   C. Money-Laundering relating to health care offenses.
   D. All of the above.

7. In order to be liable under the False Claims Act, a false claim must have been submitted:
   A. Knowingly.
   B. With deliberate ignorance of the truth or falsity of the claim.
   C. In reckless disregard of the truth or falsity of the claim.
   D. Any of the above.

8. Compliance programs should:
   A. Contain written standards of conduct.
   B. Utilize a regular, effective training program.
   C. Be drafted by, or in consultation with, a knowledgeable health law attorney.
   D. All of the above.

Correction

In the May 1999 issue, the CME Questions were numbered incorrectly. 30-33 should be number 1-4. We apologize for any confusion this may have caused.

In Future Issues: National Practitioner Data Bank