§20.330 Introduction

Perhaps the most potent tool available to the government in enforcing federal fraud and abuse prohibitions, and one that can create major financial liabilities for health care providers is the civil False Claims Act (FCA). FCA claims against health care providers have risen dramatically in recent years and have resulted in some staggering monetary penalties. One example is a settlement in 2009 in which Eli Lilly and Company (Eli Lilly) agreed to pay a total of $1.4 billion to settle federal, state, and criminal charges in relation to the off-label use of Zyprexa. Of this sum, $800 million went to resolve FCA claims and related state claims by Medicaid and the other federal health care programs that claimed by marketing Zyprexa for unapproved uses Eli Lilly caused the submission of false claims for payment to federal insurance programs such as Medicare, TRICARE, and the Federal Employee Health Benefits Program, none of which provided coverage for such off-label uses.

In addition to authorizing the Attorney General to investigate and bring civil actions, the FCA allows a private person, often referred to as a qui tam relator, to bring a civil action in the name of the United States. The purpose of the qui tam provisions is to give an incentive to whistleblowers to come forward to help the government discover and prosecute fraudulent claims by awarding them a percentage of the amount recovered. There are many different types of health care fraud that can be the basis of qui tam lawsuits. These include: services not rendered/add-on services; upcoding and unbundling; kickbacks; false certification and information; lack of medical necessity; fraudulent cost reports; and grant or program fraud. The provisions are remedial rather than punitive, so a qui tam action brought under the FCA survives the death of the plaintiff. Since the 1986 amendments to the FCA, which served to enhance individual involvement in initiating false claims suits and to increase the number of qui tam law suits has rapidly increased. As defendants may be liable for treble damages in addition to penalties of $5,500 to $11,000 per false claim, the potential for recovery for a qui tam plaintiff can be substantial. For instance, qui tam relators collected roughly $78 million from the federal share as part of Eli Lilly's settlement.

Over the last five years, qui tam suits filed under the FCA have accounted for the majority of civil fraud cases pursued by the government. Recoveries under the FCA have topped $1 billion each year between 2005 and 2009. Of the more than $2.4 billion recovered for the 2009 fiscal year, almost $2 billion was derived from qui tam lawsuits.

In 2001, TAP Pharmaceuticals agreed to pay the United States government $559.5 million, state governments $25.5 million, and a $290 million criminal fine for allegations arising under the FCA. Initiated by whistleblowers and joined by the United States Department of Justice (DOJ), two civil FCA lawsuits charged TAP with paying illegal kickbacks to doctors who dispensed the company's high priced prostate cancer drug (Lupron). TAP also allegedly conspired with doctors to charge Medicare and Medicaid beneficiaries for free samples of Lupron.

In 2003, HCA, Inc. (formerly known as Columbia/HCA and HCA—The Healthcare Company) agreed to pay the United States $631 million in civil penalties and damages to resolve its civil liability. The government alleged that HCA submitted false hospital cost reports and paid kickbacks to physicians in exchange for their referral of Medicare and Medicaid beneficiaries. HCA routinely prepared two sets of cost reports, one that was submitted to the Medicare program, and a set of reserve cost reports reflecting how the filed cost reports might be adjusted downward if Medicare were to audit them. The government also alleged that HCA paid physicians illegal remuneration in the form of free rent, vacations, bonuses, payment for consulting work that was not performed, and phony partnership distributions.

HCA also entered into a settlement agreement with the government under which it paid an additional $250 million. Previously, in 2000, subsidiaries of HCA pleaded guilty to criminal conduct and paid more than $840 million in fines, civil restitution, and penalties for various acts, such as exaggerating the value of services and submitting separate bills for lab tests that should have been bundled. The case against HCA and its subsidiaries represents the most comprehensive health care fraud investigation ever undertaken with recoveries totaling $1.7 billion.

In 2009, Pfizer Inc. and its subsidiary Pharmacia & Upjohn Company Inc. (collectively Pfizer) agreed to pay $2.3 billion to resolve criminal and civil liability arising from the illegal promotion of certain pharmaceutical products, the largest health care fraud settlement in the history of the DOJ. Of the $2.3 billion, $1 billion was allocated to resolve allegations under the FCA that Pfizer (1) illegally promoted four drugs causing false claims to be submitted to government health care programs for off-label uses and, therefore, not covered by the terms of those programs and (2) paid kickbacks to health care providers to induce them to prescribe these four drugs as well as others. The $1 billion settlement with Pfizer is the largest civil fraud settlement under the FCA in history against a pharmaceutical company.

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The government has adopted a number of creative strategies for using the FCA in the context of national investigations and has been highly successful in obtaining settlements from providers that want to avoid the crippling consequences of astronomical civil and criminal monetary penalties and exclusion from Medicare, Medicaid, and other federal health care programs. Another noteworthy extension of the application of the FCA involves the government investigation and prosecution of nursing facilities for billing for inadequate patient care. Relying on its success in obtaining a settlement in a case against a nursing home where patients were allegedly undernourished, in 1997, the DOJ announced its intent to pursue similar claims under the FCA and has indeed continued to do so to this day. In 2009, Omnicare, Inc., the largest nursing home pharmacy, agreed to pay $98 million, and drug manufacturer IVAX Pharmaceuticals agreed to pay $14 million to settle allegations that Omnicare solicited or paid a variety of kickbacks to several parties including IVAX, Johnson & Johnson, and a number of nursing homes. In a related settlement in February 2010, Mariner Health Care Inc. and SavaSeniorCare Administrative Services LLC, as well as their principals, Leonard Grunstein, Murray Forman, and Rubin Schron, agreed to pay $14 million to the United States and several states resolving allegations that they solicited kickback payments totaling $50 million from Omnicare in exchange for agreements to continue using Omnicare's pharmacy services for 15 years.

The federal government also successfully prosecuted violations of the Anti-Kickback Statute under the civil FCA, arguing that illegal referrals are false claims under that statute. In 2005, Serono, S.A., its U.S. subsidiaries, and related entities (collectively Serono) agreed to pay $704 million to resolve criminal charges and civil allegations that it was engaged in illegal schemes to promote, market, and sell its drug, Serostim. In particular, the civil settlement settled allegations that Serono knowingly submitted false and fraudulent claims for Serostim that were not eligible for reimbursement because they were for unnecessary and/or off-label use and because the claims were for prescriptions induced by kickbacks to physicians. The arguments raised in this case also support a wider application of the FCA as a remedy for numerous statutory or regulatory violations by organizations that submit claims for payments to government programs.

The extent to which the government has relied on the civil FCA to enforce fraud and abuse prohibitions prompted the American Hospital Association to call for a six-month moratorium on Centers for Medicare and Medicaid Services (CMS), the Office of Inspector General (OIG), and DOJ false claims actions so that voluntary compliance programs and clear guidelines to distinguish simple error from genuine fraud could be established. These guidelines, first issued in 1998, known as the OIG Compliance Program Guidelines, are discussed and referred to throughout the Health Care Compliance Professional's Manual.

Footnotes

1 31 U.S.C. §§ 3729 through 3733.
4 United States v. NEC Corp., 11 F.3d 136 (11th Cir. 1993).
5 28 C.F.R. § 85.3(a)(9).
FBI Funding To Target Fraud and Abuse Increased by Health Insurance Reform Law, HEALTH CARE FRAUD REP., Jan. 15, 1997, at 9.


The False Claims Act (FCA) says that any person who knowingly presents, or causes to be presented, to the U.S. government 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; or conspires to defraud the government by getting a false or fraudulent claim allowed or paid violates the FCA. The Fraud Enforcement Recovery Act of 2009 (FERA) expands exposure under the FCA, making parties liable for any false claims paid with government funds and for the retention of money owed to the government. The Patient Protection and Affordable Care Act of 2010 (PPACA) states that FCA liability will arise if an actor does not repay any overpayment within sixty days.

Those who violate the FCA are liable to the government for a civil penalty of not less than $5,500 and not more than $11,000, plus treble damages sustained by the government, for each false claim filed. No proof of actual damages, such as payment or approval of the claim, is needed to prove a violation of the FCA.

One case starkly illustrates how the penalties and damages imposed under the civil FCA can dwarf the overpayment amount or amount unjustly received by an individual or business. In the 1991 case of United States v. Lorenzo, the court found that the U.S. government was entitled to a full recovery from the defendant. This case involved a dentist who performed dental exams on nursing home residents. The dentist's company billed Medicare for oral cancer examinations during the course of standard patient exams. The court found that the company had submitted 3,683 of these types of claims to Medicare over a five-year period and received reimbursement totaling $130,719.10. After finding that the company had filed false claims, the court ruled that the government was entitled to judgment of treble damages, three times the overpayment amount, and $5,000 per false claim. The recovery in this case totaled $18,807,157.30.

More recently, in the 2007 case of United States ex rel. Tyson v. Amerigroup Ill., Inc., the government proved that although defendants promised not to discriminate based on the need for health services to qualify for Medicaid managed care plan, defendants systematically avoided enrolling pregnant women. The jury found that each of the 18,130 enrollment forms that defendants filed constituted a false claim. The court imposed a $524 million penalty of which $476 million was based on civil penalties derived from the 18,130 claims.

Such dramatic results dissuade targets of FCA investigations from going to trial. Prosecutors generally indicate to targets that cooperation and settlement can lead to lower damage figures.

The statute defines knowing and knowingly as meaning that the person (1) has actual knowledge of the information, (2) acts in deliberate ignorance of the truth or falsity of the information, or (3) acts in reckless disregard of the truth or falsity of the information. The statute goes on to expressly state that no proof of specific intent to defraud is required. Thus, the government is not required to prove actual intent to submit false claims to establish liability under the FCA. Rather, the government can establish liability by simply proving deliberate ignorance or reckless disregard for the truth of the claims. Liability, however, cannot be established on the basis of innocent mistakes or negligence.

The Lorenzo case illustrates the broad reach of the civil FCA. Dr. Lorenzo and the other dentists employed by his company actually performed oral cancer screenings. Dr. Lorenzo, however, mistakenly relied on advice from an employee that this service could be billed to Medicare as a limited consultation. As it turns out, Medicare rules dictate that limited consultations are reimbursable only if requested by an attending physician and not when performed as part of routine screenings. The FCA charged the dentist and/or his billing staff with a reasonable degree of knowledge about Medicare billing rules and regulations. The court found Dr. Lorenzo liable under the FCA because he acted in reckless disregard of the truth or falsity of the claims submitted to Medicare.

The FCA's definition of knowingly was intended to establish liability of, for example, corporate officers who consciously avoid knowledge of false claims being filed by their subordinates. The definition also applies to corporate employees who follow the orders of superiors or even ignore the activities of coworkers. Thus, both corporate officers and lower level employees may be liable under the FCA for improper claims for which they are aware or should have been aware.

Liability is not reserved solely for actors who knowingly submit false claims. Under the FERA Amendments, parties are liable when they knowingly receive overpayments or conspire to conceal evidence that the government overpaid. The PPACA requires actors to report and return any overpayment within 60 days after the overpayment is identified, or the date any corresponding cost report is due (whichever is later). Thus, even if there is no overtly fraudulent act, courts and juries may find that actors violated the FCA.

Civil actions for false claims can be brought by either the Attorney General or private persons. An action may not be brought more than six years after the date on which the violation was committed or more than three years after the date when facts material to the right of action are known or reasonably should have been known by the government official.
charged with responsibility to act in the circumstances (but in no event more than 10 years after the date on which the violation was committed), whichever occurs last. 35 An action may be brought in any judicial district in which the defendant or, in the case of multiple defendants, any one defendant resides or transacts business or in which any act prohibited by the statute has occurred. 36 A case under the FCA must be proven by a preponderance of the evidence. 37

Footnotes

18 The Patient Protection and Affordable Care Act § 6402(d) (PubL.No 111-148) (2010).
19 28 C.F.R. § 85.3(a)(9).
22 United States v. Lorenzo, 768 F. Supp. 1127 (E.D. Pa. 1991); see also United States ex rel. Tyson v. Amerigroup Ill. Inc., 488 F.Supp.2d 719 (N.D. Ill. 2007) (calculating a maximum of $524 million in civil claims of which $476 million were based on civil penalties derived from 18,130 in false claims).
24 31 U.S.C. § 3729(b). These broad definitions were made a part of the 1986 amendments to clarify prior law and to avoid decisions such as United States v. Ueber, 299 F.2d 310, 314 (6th Cir. 1962), which required actual knowledge. See False Claims Reform Act of 1985, S. Rep. No. 345, at 7 (1986); see also United States ex rel. McCready v. Columbia/HCA Healthcare Corp., 251 F.Supp.2d 114, 120 (D.D.C. 2003).
27 Hagood v. Sonoma County Water Agency, 929 F.2d 1416 (9th Cir. 1991).
28 Wang v. FMC Corp., 975 F.2d 1412 (9th Cir. 1992).
33 The Patient Protection and Affordable Care Act § 6402 (PubL.No. 111-148) (2010).
34 31 U.S.C. § 3730(a) through (b).
37 31 U.S.C. § 3731(d). This clarifies the standard, which had sometimes been held to be clear and convincing. See United States v. Ueber, 299 F.2d 310 (6th Cir. 1962).
\section*{\textbf{\textsection{20.340 Qui Tam Provisions of the False Claims Act}}}

The language of the False Claims Act (FCA) indicates that virtually anyone can be a \textit{qui tam} relator and expresses Congress's intent to allow \textit{qui tam} cases to be brought by a wide variety of people and entities. In spite of the broad statutory language, however, a number of cases have arisen with respect to the identity of \textit{qui tam} plaintiffs.

To prevent parasitic suits, the law bars actions based upon public disclosure of allegations in a criminal, civil, or administrative hearing, in a government report, hearing, audit, or investigation, or from the news media unless the action is brought by the Attorney General or the \textit{qui tam} relator is an original source of the information.\textsuperscript{38} Under the Patient Protection and Affordable Care Act (PPACA), effective March 23, 2010, to qualify as an original source, the relator must provide independent and material information to the government before such information has been publicly disclosed.\textsuperscript{39} Previously, a relator had to have direct knowledge of the claim to satisfy the original source requirement.

If the \textit{qui tam} relator brings an action based on information of which he or she is not the original source, the federal court does not have jurisdiction to hear the case. For instance, a \textit{qui tam} action brought under the FCA was dismissed for lack of subject matter jurisdiction when the court found that a government audit had first revealed the fraudulent Medicare billing practices alleged by a former employee of a mental health facility.\textsuperscript{40} The court noted that the threshold issue is whether the action is based on the public disclosure of transactions in an administrative hearing, report, audit, or investigation. An action is based on public disclosure if the action is based on allegations, transactions, or information that is part of the public record or that has been disclosed to nonparticipants. The court found that the plaintiff's action was based in part on a government audit—which was part of the public record—and, thus, was barred because the plaintiff was not the original source of the information.\textsuperscript{41}

Prior to the passing of the PPACA, a relator had to exercise great care in how he or she filed suit. For example, in \textit{United States ex rel. Federal Recovery Services, Inc. v. Crescent City E.M.S., Inc.},\textsuperscript{42} an individual who uncovered alleged false claims made by an ambulance service informed the government and the news media of the allegations. After the information was made public, the individual and his attorney formed a corporation to act as the \textit{qui tam} plaintiff. The court concluded that the corporation was not a proper plaintiff because all of the relevant information was publicly disclosed before the corporation even came into existence. The court further found that the individual who uncovered the information could not be added as a \textit{qui tam} plaintiff even though he was the original source of the information because the FCA prohibits intervention by any person other than the U.S. government. Although both the individual and Federal Recovery Services were dismissed as relators, the case continued with the United States as the plaintiff.

While the Fraud Enforcement Recovery Act (FERA) and the PPACA remained silent on the issue of government relators, several courts have addressed the issue of whether current or former government employees may be \textit{qui tam} plaintiffs. Most courts have looked at the broad congressional purpose and have found such parties to be proper relators.\textsuperscript{43} At least one court has concluded that, because government employees have a duty to uncover and report fraud, the disclosure of such information could not be considered voluntary. Also, any information that was known to a government employee could be deemed to have been publicly disclosed.\textsuperscript{44} Conversely, a federal employee who acquired his knowledge of alleged Medicare fraud through years of his own claims processing, research, and correspondence with government officials was found to be the original source of the information and, thus, could bring a \textit{qui tam} action under the FCA, even though the information had been publicly disclosed five weeks earlier.\textsuperscript{45}

Competitors of the defendant are another potential source of \textit{qui tam} plaintiffs. A relator who collected a $15 million share of a FCA settlement was a salesman employed by a competing laboratory.\textsuperscript{46} To initiate a \textit{qui tam} action, not only must a complaint be served upon the defendant, but a copy of the complaint and written disclosure of substantially all material evidence and information in the possession of the relator also must be served on the U.S. government.\textsuperscript{47} The complaint must be filed in camera, must remain under seal for at least 60 days, and may not be served on the defendant until the court orders that it be done.\textsuperscript{48} Within the 60 days (or within a court-approved extension), the government must either proceed with its own action—in which case the government takes over for the relator—or notify the court that it is declining to take the action. If the government declines to take the action, the relator is free to proceed on his or her own.\textsuperscript{49} If the government takes over the action, the relator may continue as a party, but the government and/or the defendant may seek to limit the relator's participation in the action.\textsuperscript{50} Moreover, the government may dismiss the action notwithstanding any objections from the relator so long as the relator is given the opportunity to be heard, or it may settle the action notwithstanding the relator's objections so long as a court determines, after a hearing, that the settlement is fair, adequate, and reasonable.\textsuperscript{51}

If the government allows the relator to proceed but discovery in the case may interfere with a civil or criminal

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investigation or prosecution arising out of the same facts, the government can seek a stay of discovery upon an in camera showing to this effect.\textsuperscript{52} The government also may elect to pursue its claim through alternate means such as an administrative hearing. Though this would preclude the relator from pursuing a court action, the relator has the same rights in an administrative proceeding as in a court proceeding. Moreover, the relator—like all parties to the action—is bound by any findings of fact or conclusion of law reached in any proceeding brought under the FCA.\textsuperscript{53}

If the government proceeds with an action initiated by a \textit{qui tam} relator, the party initiating the action is entitled to recover at least 15 percent but not more than 25 percent of the proceeds of the action.\textsuperscript{54} The amount of the relator's award depends upon the extent to which the relator contributed to the action.\textsuperscript{55} If the court finds that the relator's action was based primarily upon information from other sources (a congressional hearing, another civil, criminal or administrative hearing, the news media, etc.), the court may award the relator up to 10 percent of the proceeds depending upon the significance of the information and the role of the person bringing the action in advancing the case to litigation.\textsuperscript{56} In addition, the party initiating the action is entitled to recover reasonable costs plus reasonable attorneys' fees.\textsuperscript{57}

If the government elects not to proceed with an action initiated by a \textit{qui tam} relator and the relator wins or settles the case, the court may award the relator not less than 25 percent and no more than 30 percent of the proceeds, plus reasonable costs and attorneys' fees.\textsuperscript{58} Regardless of whether the case is advanced by the government or the relator, the court may reduce the relator's share if the court finds that the relator planned and initiated the false claim that is the basis of the action.\textsuperscript{59} If the person bringing the action is convicted of criminal conduct arising from his or her role in the false claim, that person must be dismissed from the civil action and shall not receive any share of the proceeds of the action.\textsuperscript{60} Finally, if the government does not proceed with the action but the relator proceeds and the defendant prevails, the court may award to the defendant its reasonable attorneys' fees and expenses if it finds that the relator's action was clearly frivolous, clearly vexatious, or brought primarily for the purposes of harassment.\textsuperscript{61}

To encourage employees to come forward against their employers, the FCA protects any employees who are discharged, demoted, harassed, or in any manner discriminated against by their employer because of their participation in or furtherance of an FCA action.\textsuperscript{62} Section 3730(h) of FERA extends this protection to contractors and agents.\textsuperscript{63} The statute entitles all such employees, contractors, and agents to all necessary relief to make them whole. This includes reinstatement with the same seniority status they would have had but for the discrimination, twice the amount of back pay, interest on back pay, and compensation for any special damages sustained as a result of the discrimination, including litigation costs and reasonable attorneys' fees.\textsuperscript{64}

In \textit{Cook County v. United States ex rel. Chandler}, the U.S. Supreme Court addressed the issue of whether counties and municipalities can be considered persons under the FCA and, therefore, be sued by individuals in \textit{qui tam} actions.\textsuperscript{65} In this case, the Cook County Hospital received a $5 million grant from the National Institute of Drug Abuse to study a treatment regimen for pregnant drug addicts. The administration of the grant was later transferred to the Hektoen Institute for Medical Research, a private nonprofit research organization affiliated with the hospital. Dr. Janet Chandler conducted the study from September 1993 until the Institute fired her in January 1995. In 1997, Dr. Chandler filed a \textit{qui tam} action, claiming that the County and the Institute had submitted false claims to obtain grant funds in violation of the FCA.

Cook County moved to dismiss the claims against it, making the argument that it was not a person subject to liability under the FCA. In a unanimous decision, the U.S. Supreme Court concluded that a person, as that term has been used in the FCA since 1863, does include municipalities. Accordingly, these governmental units may be subject to the penalties and treble damages imposed under the FCA. Health care providers that can be considered to be a unit of government need to be aware of the reasoning and conclusions reached by the Court in this case.

\begin{footnotes}
\item [38] 31 U.S.C. § 3730(e)(4)(A).
\item [43] \textit{See United States ex rel. Holmes v. Consumer Ins. Group}, 318 F.3d 1199, 1212 (10th Cir. 2003) (en banc), citing
\end{footnotes}

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United States ex rel. Marcus v. Hess, 317 U.S. 537, 546 (1943) ("Thus, we believe that Marcus, to the extent it construed the qui tam provisions as allowing a government official to file suit as a relator based upon information obtained in the course of his or her official duties, remains valid"); United States ex rel. Fine v. Chevron, U.S.A., 39 F.3d 957 (9th Cir. 1994) (former Inspector General auditor); United States ex rel. Williams v. NEC Corp., 931 F.2d 1493 (11th Cir. 1991) (Air Force attorney who conducted investigation); United States ex rel. Hagood v. Sonoma County Water Agency, 929 F.2d 1416 (9th Cir. 1991) (government attorney).


Cooper v. Blue Cross and Blue Shield of Fla., Inc., 19 F.3d 562 (11th Cir. 1994).


31 U.S.C. § 3730(c)(5).