Eleven Things to Know About the False Claims Act

Scott Becker, Partner
312.750.6016 | sbecker@mcguirewoods.com

Julie Ann Sullivan, Associate
312.849.8116 | jsullivan@mcguirewoods.com

77 West Wacker Drive, Suite 4100
Chicago, Illinois 60601-1818

www.mcguirewoods.com

McGUIREWOODS
Relationships That Drive Results

1) Initial Development of the False Claims Act. The False Claims Act, also known as the "Lincoln Law" after its primary proponent, President Abraham Lincoln, was initially developed during the Civil War. The Act was a response to war profiteering by military contractors who attempted to defraud the government, for example, by sending boxes of sawdust instead of guns or selling the same cavalry horse to the armed forces multiple times. The Act remained in its original form from its initial passage in 1863 until 1943, at which point various amendments de-incentivizing qui tam actions made the statute nearly obsolete. In 1986, the Act was amended again with greater incentives for private citizens to report fraud on the government. The Act has become an increasingly active mechanism to combat fraud and false claims submitted to the federal government ever since. For additional background information, see http://www.all-about-qui-tam.org/fca_history.shtml.

2) Overview of Qui Tam Concepts. Qui Tam means in the name of the king. The concept of a Qui Tam action is similar to a whistleblower action and allows a private person, referred to as a "relator," to file suit on behalf of the United States against those who have falsely or fraudulently claimed federal funds. Incentives are built in so that the qui tam relator is able to receive a part of the proceeds of a victory on behalf of the government. Further, the portion of an award amount that the relator retains is greater if the government does not join in the suit and therefore he or she does not receive the help of the government. Alternatively, if the government joins or "intervenes" in the lawsuit, the relator retains a lesser portion of any judgment or settlement obtained.

False Claims Act qui tam actions run the gamut of federally funded programs, from Medicare and Medicaid to defense and other government procurement contracts, federally insured mortgage and other federal housing programs, disaster assistance loans, agricultural subsidies and more. Persons who knowingly make false claims for federal funds are liable for three times the government's loss plus a civil penalty of $5,500 to $11,000 for each claim. Relators recover 15 to 25 percent of the proceeds of a successful suit if the United States intervenes in the qui tam action, and up to 30 percent if the United States declines to intervene and the relator pursues the action alone. During fiscal year 2009 alone, relators were awarded $255 million. (This figure does not include relator shares awarded after Sept. 30, 2009.)

3) Top Hospital Recoveries. To see a list of the top 20 False Claims Recoveries to date, go to www.taf.org/top20. Several hospitals and hospital companies have paid massive settlements to resolve false claims actions against them, including St. Barnabas Hospitals, a non-profit hospital chain in New Jersey, which paid $265 million in 2006 to settle allegations related to improperly claiming "outlier" Medicare payments (additional payments for particularly difficult or complex procedures). Also in 2006, Tenet Healthcare, a national hospital system, agreed to pay the federal government $900 million for billing violations also involving manipulation of outlier payments, as well as kickbacks, upcoding, and bill padding. Similarly, in 2000, Columbia HCA, the largest for-profit hospital chain in the country paid more than $731 million to settlement False Claims Act allegations against it. Currently, Toumey Healthcare System in South Carolina is involved in a false claims litigation based on physician self-referral law violations that resulted in the submission of false claims, a legal theory that proved successful against a medical practice management company in the 2008 case U.S. v. Rogan in the Seventh Circuit Court of Appeals.

4) 2009 Recoveries. In 2009, the U.S. government recovered $2.4 billion dollars under the False Claims Act. This was the second highest annual collection amount recorded in history, thanks in large part to an enormous settlement between the government and Pfizer Inc. The Department of Justice (DOJ) made the following statement regarding the Pfizer settlement in September 2009:

> American pharmaceutical giant Pfizer Inc. and its subsidiary Pharmacia & Upjohn Company Inc. hereinafter together "Pfizer") have agreed to pay $2.3 billion, the largest health care fraud settlement in the history of the Department of Justice, to resolve criminal and civil liability arising from the illegal promotion of certain pharmaceutical products, the Justice Department announced today.
>
> Pharmacia & Upjohn Company has agreed to plead guilty to a felony violation of the Food, Drug and Cosmetic Act for misbranding Bextra with the intent to defraud or mislead. Bextra is an anti-inflammatory drug that Pfizer pulled from the market in 2005. Under the provisions of the Food, Drug and Cosmetic Act, a company must specify the intended uses of a product in its new drug application to FDA. Once approved, the drug may not be marketed or promoted for so-called "off-label" uses – i.e., any use not specified in an application and approved by FDA. Pfizer promoted the sale of Bextra for several uses and dosages that the FDA specifically declined to approve due to safety concerns. The

company will pay a criminal fine of $1.195 billion, the largest criminal fine ever imposed in the United States for any matter. Pharmacia & Upjohn will also forfeit $105 million, for a total criminal resolution of $1.3 billion.

In addition, Pfizer has agreed to pay $1 billion to resolve allegations under the civil False Claims Act that the company illegally promoted four drugs – Bextra; Geodon, an anti-psychotic drug; Zyvox, an antibiotic; and Lyrica, an anti-epileptic drug – and caused false claims to be submitted to government health care programs for uses that were not medically accepted indications and therefore not covered by those programs.

5) Health Care Fraud – Top Industry for False Claims Recovery. Health care fraud represents the largest and most profitable industry for qui tam false claims collections. Health care fraud recoveries accounted for approximately $1.6 billion, more than two-thirds of the $2.4 billion dollars collected under the False Claims Act in total during 2009. Numerous federal agencies shared in these recoveries, including the Department of Health and Human Services, in connection with its Medicare and Medicaid programs); the Office of Personnel Management, which administers the Federal Employees Health Benefits Program; the Department of Defense for its TRICARE insurance program; and the Department of Veterans Affairs.

6) Pharmaceutical and Medical Device Companies – Main Targets. The largest qui tam settlements in 2009 came from pharmaceutical and medical device companies, including Pfizer, Sanofi-Aventis, Bayer HealthCare LLC, Quest Diagnostics and Eli Lilly, amongst others. The DOJ reported that pharmaceutical and device companies accounted for $866.7 million in settlements for federal recoveries, in addition to $402 million being returned to state Medicaid programs.

7) Retention of Overpayments Now Can Be Considered a False Claims Act Violation. In 2009, President Obama signed into law the Fraud Enforcement and Recovery Act of 2009 (FERA) which implemented significant changes to the False Claims Act, including the expansion of prohibited conduct under the False Claims Act to include not just the improper filing to collect monies, but also the known retention of overpayments by hospitals or other health care providers. The 2009 amendments also make clear that false claims submission to a state Medicaid program, although not directly submitted to the federal government, does constitute a violation of the False Claims Act.

8) Hospital Sample False Claims Policy. All health care providers and businesses submitting claims to the government for payment should have health care regulatory and false claims policies in place to educate its employees and agents and minimize the submission of false claims and the potential liability attached thereto. A good sample policy is available online at www.centralcommunityhospital.com. This sample policy is particularly designed to address a community hospital's approach to false claims and other policies, and may need to be modified depending on the size of the entity, breadth of practice, or type of industry or provider submitting the claims.

9) Plaintiff's Law Firms Focus on Qui Tam. Over the past several years, there has been a dramatic increase in the number of qui tam suits. As a result, there are now law firms that focus exclusively on qui tam actions. One such firm, Warren Benson Law Group, states on its website, www.warrenbensonlaw.com/medicare-fraud.com: .

"In recent years, Medicare fraud and Medicaid fraud have been the two most active areas of qui tam litigation, outnumbering qui tam cases involving defense contractor fraud. It is estimated that Medicare fraud and other fraud cost the federal government billions of dollars each year.

There are numerous frauds Medicare and other healthcare providers and companies have devised to cheat the Government…[such as:]

- Services not rendered
- Upcoding schemes and Unbundling
- Kickbacks and Self Referrals

- Falsely Certifying and Giving False Information
- Lack of Medical Necessity
- Fraudulent Cost Reports
- Grant or Research Fraud

These firms generally take qui tam cases on a contingency fee basis, making it enticing for potential relators to come forward and initiate litigation against the alleged wrong-doers.

10) Broad Provider Responsibility – Scope of Liability. In the face of the increasing scrutiny of claims and the relatively new era of Recovery Audit Contractors, parties should understand the broad scope of what can be considered a false claim and their obligations to properly bill for services. A good discussion of the breadth of the provider's responsibility is set forth in an article by Charlie Artz, a well-regarded health care attorney. See False Claims Act Implications in Physician's News Digest www.physiciansnews.com/law/805artz.html. A few of the key concepts discussed by Mr. Artz are excerpted below:

> In Re: Cardiac Devices Qui Tam Litigation, the U.S. District Court in Connecticut refused to dismiss a whistleblower's case against health care providers who submitted claims for services that were not covered by Medicare, held that the health care providers had a duty to familiarize themselves with all requirements for reimbursement, and allowed the False Claims Act case to proceed exposing the health care providers to millions of dollars in refunds and civil fines.
>
> Although the opinion was close to 100 pages in length, the key facts can be summarized as follows. Then-HCFA published a manual over 1,000 pages in length containing literally hundreds of reimbursement rules and requirements. These billing guidelines were not statutes passed by Congress after the people had an opportunity to debate them. These were not regulations published with notice and comment by the general public or the health care community to make improvements or to object to certain clauses. These were purely interpretive guidelines published by the federal government. One of those several hundred billing guidelines contained a provision prohibiting reimbursement for any non-FDA approved device or service. The 40 hospital defendants in this massive federal court litigation submitted claims to Medicare and received payment for services provided to patients who participated in clinical trials involving several different investigational cardiac devices that had not been approved for marketing by the FDA.
>
> One clause in the hospital payment manual stated that medical devices not approved for marketing by FDA are considered investigational by Medicare and are not reasonable and necessary for the diagnosis and treatment of illness or injury under the Medicare statutory definition of medical necessity. Apparently, the hospitals billed these services by mistake, believing that since the clinical trial was approved, the provider was allowed to bill Medicare for the device and related services.
>
> A whistleblower realized many hospitals were billing Medicare for non-FDA approved cardiac devices and filed a civil false claims case in federal court. The federal government intervened and is now prosecuting the False Claims Act case against hospitals. The hospitals asked the federal court to dismiss the case for several reasons. One of the key defenses is that a simple violation of a statute or regulation does not, by itself, trigger False Claims Act liability. The federal court rejected that analysis and made the following key points that should guide your compliance efforts.

11) Heightened Regulatory and Enforcement Environment – False Claims Act and Anti-kickback Statute. The government has looked to regulatory mechanisms like the False Claims Act to recover money spent improperly as a politically palatable way to attack health care providers and health care costs. Given the demonstrated success of

this strategy, we expect more, not less, recovery of claims of this sort. As William Corr, Deputy Secretary of the U.S. Department of Health and Human Services, stated on October 28, 2009:

> As a result of the priority given to combating health care fraud by President Obama, the government has been able to achieve a more rapid response to fraudulent schemes and increase its recovery of more funds lost to fraud than in previous years. For example, HHS Office of Inspector General investigations have resulted in $4.0 billion in receivables for FY 2009, increase from $3.2 billion in DIG investigative receivables in FY2008. Strike force cases typically are indicted and litigated faster than traditional criminal health care fraud cases.
>
> Since March 2007 strike force cases that included HHS agents have obtained 189 convictions, 443 indictments, and total an estimated $227 million in expected recoveries. During this time, the Department of Justice also secured the largest health care fraud settlement in history against a pharmaceutical company for Medicare and Medicaid fraud and for violating the Food, Drug and Cosmetic Act. I refer to the $2.3 billion settlement with Pfizer to resolve criminal and civil liability arising from the illegal promotion of certain pharmaceutical products.