WILLIAMS MULLEN
Where Every Client is a Partner®

August 2010

Long Term Care Industry Service Group

Alert

False Claims Act Demands Compliance

BY ADELE M. NEIBURG

One of the most powerful tools available to the government to combat health care fraud is the False Claims Act ("FCA"). Since January 2009, the Justice Department has used the FCA to recover approximately $2.2 billion in cases involving fraud against federal health care programs. It is shocking to note that the Justice Department's total recovery in FCA cases has topped $3 billion since January 2009. FCA violations can result in civil penalties, damage payments, criminal conviction and sentencing, and debarment from performing federal contracts.

Adele M. Neiburg

The FCA, 31 U.S.C. § 3729-3733, was enacted originally in 1863 after a series of Congressional inquiries disclosed several instances of fraud among defense contractors during the Civil War. It is a significant law for any employer who bills Medicare or Medicaid. The FCA protects the federal government against fraud and abuse. The FCA can be a very effective means to detect fraud. It encourages individuals, called "whistleblowers," to uncover and report fraud and to prevent fraud, by creating strong incentives for companies and individuals to be vigilant in their compliance efforts.

Maintaining a culture of compliance with the FCA is essential. The development and implementation of a compliance plan, described below, will greatly assist with prevention and early detection of FCA violations. An effective compliance plan also is an effective tool in negotiations with the Department of Justice in efforts to resolve allegations of FCA violations in both the civil and criminal context.

The FCA prohibits any individual or Company from knowingly submitting false or fraudulent claims, causing such claims to be submitted, making a false record or statement in order to secure payment from the federal government (Medicare and Medicaid) for such a claim, or conspiring to obtain the allowance or payment of such a claim. The FCA allows private citizens to sue on behalf of the government and to share in any recovery.

Common uses of the FCA include prohibiting (i) the presentation of false claims to the government and (ii) making false records to obtain the payment of a false claim. By far the most frequent cases involve situations in which a defendant —usually a corporation but on occasion an individual — overcharges the federal government for goods or services. This overcharging can take many forms. In addition to what might appear to be simple billing mistakes, charging the government for a product that does not meet the government's performance standards can be characterized as a false claim.

Two notable recent FCA cases illustrate the severity of the consequences of FCA violations. First, the U.S. Department of Justice announced that phar-

Long Term Care Team

Lawrence R. Siegel
Chair, Long Term Care Industry Service Group
757.473.5321
lsiegel@williamsmullen.com

Beth G. Hungate-Noland
Vice Chair, Long Term Care Industry Service Group
804.420.6913
bhungate@williamsmullen.com

Turner A. Broughton

Stephen W. Burke

Robert C. Dewar

Martin A. Donlan, Jr.

J. Conrad Garcia

G. Tayloe Gwathmey, III

Andrea J. Harlow

Marcus C. Hewitt

Travis G. Hill

Derek W.H. Kung

Jack W. Marin

Catherine M. Marriott

James V. Meath

Mark H. Miller

Douglas M. Nabhan

Adele M. Neiburg

Joel R. Nied

W. Benjamin Pace

Elizabeth Davenport Scott

Robert W. Shaw

continued from page 1

maceutical company AstraZeneca will pay $520 million to settle allegations of off-label marketing. Charges that the company illegally marketed the antipsychotic drug, Seroquel, were originally raised in a lawsuit brought under the *qui tam* provisions of the FCA, which allow a private individual who assists a prosecution to receive all or part of any penalty imposed. The civil settlement resolves allegations that, by marketing Seroquel for uses that had not been approved by the Food and Drug Administration ("FDA"), the company caused false claims for payment to be submitted to federal insurance programs. The federal government will receive $301,907,007 from the settlement, and state Medicaid programs and the District of Columbia will share up to $218,092,993.

Second, a federal judge in Boston has ordered two subsidiaries of pharmaceutical giant Johnson & Johnson to pay more than $81 million after pleading guilty to illegally promoting the epilepsy drug Topamax for psychiatric uses. Ortho-McNeil Pharmaceutical LLC will pay a $6.14 million criminal fine after pleading guilty to one count of misdemeanor violation of the Food, Drug and Cosmetic Act for promoting Topamax for unapproved uses. Its holding company will pay $75.37 million to resolve civil allegations under the FCA. Also as part of the settlement, Ortho-McNeil-Janssen Pharmaceuticals has agreed to enter into an expansive corporate integrity agreement with the Office of Inspector General of the Department of Health and Human Services. That agreement provides for the establishment of procedures and review processes to avoid and promptly detect similar conduct. The Justice Department's Civil Division and the U.S. Attorney's Office for the District of Massachusetts prosecuted the criminal case and handled the civil lawsuit, with assistance from the National Association of Medicaid Fraud Control Units and the officers of various state Attorneys General. The Office of Inspector General of the Department of Health and Human Services negotiated the Corporate Integrity Agreement.

To avoid this sort of negative press and monetary punishment, companies are encouraged to maintain an environment of honesty, integrity, and trust by proactively preventing fraud and abuse through education and training of staff, as well as developing and implementing a compliance plan, which should involve self-audits and the use of a hotline available to all employees. This culture of corporate compliance should extend to the creation of policies aimed at protecting against fraud, waste and abuse, and making those policies available for employee review in policy and procedure manuals or employee handbooks.

The following is sample language that can be incorporated into an employee handbook or general corporate policy manual to demonstrate an employer's commitment to preventing fraud and abuse, as part of the employer's overall compliance plan.

"It is our policy to strictly observe and enforce all state and federal regulations related to the operations of our facility. As an employer, we want to do what is right and to be fair and honest in the way we do business with everyone, including our employees. Our employees are also expected to act in this way and to do the right thing.

If you observe any incident(s) or action(s) that you believe may be a violation of state or federal laws or regulations, employer policies or procedures, including illegal or unethical behavior that violates the Code of Conduct, it is your duty to report these immediately. You may report these violations to your Supervisor, the Chief Executive Officer or Compliance Officer.

It is our policy that all employees are able to make good faith complaints and be heard by management without fear of retaliation or reprisal. This policy reiterates our commitment to comply with the standards of conduct established by (1) the False Claims Act and (2) Section 6032 (Employee Education About False Claims Recovery) of the Deficit Reduction Act of 2005 ("DRA"). The DRA requires certain types of health care providers to establish written policies that address the following: (1) the False Claims Act; (2) the whistleblower protections provided under both federal and state laws, and the role of these laws in preventing and detecting fraud, waste and abuse; (3) the administrative remedies found in the Program Fraud Civil Remedies Act; and (4) our policies and procedures for detecting and preventing fraud, waste, and abuse.

All employees will have access to written materials regarding compliance with the FCA and other relevant false claims laws. Summaries of these laws are located in: (1) the employee handbook; or (2) our policies and procedures."

Compliance assessment can reduce fraud, abuse, and innocuous billing errors that could result in considerable liability and negative press.

For more information about this topic please contact the author at 804.420.6530 or aneiburg@williamsmullen.com, or any member of the Williams Mullen Long Term Care Industry Service Group.