Health Care Enforcement: 2012 Trends

Quarterly Review — Part IV in a Continuing Series on Health Care Enforcement

BY HOPE S. FOSTER, TRACY A. MINER, BRIAN P. DUNPHY, SAMANTHA P. KINGSBURY, AND STEPHANIE D. WILLIS

Introduction

Mintz Levin's Health Care Fraud Enforcement Defense group has published a series of "Year in Review" articles discussing its observations about health care fraud enforcement trends in 2011 and its opinions as to what these trends might mean for 2012. This article, the next installment of our ongoing series, focuses on health care enforcement activities in the first quarter of 2012.

Federal and state enforcement authorities have committed significant resources to health care enforcement initiatives and strategies so far in 2012. For example, the Department of Justice (DOJ) and the Department of Health and Human Services (HHS) held a Health Care Fraud Prevention Summit in Chicago, Illinois, on April 4, 2012. Speaking at the summit, HHS Secretary Kathleen Sebelius reported on the federal government's successes in combating health care fraud since 2010:

> "[i]t's harder than ever to get into the system as a bad actor. Get in and it's harder still to submit a fraudulent claim. Find a way to submit a claim and you are more likely to get caught. And when you get caught, you're going to face a tougher punishment."[i]

She went on to describe the vigor with which the federal government is approaching its investigation and enforcement activities this year.

Civil Trends—The False Claims Act

Cases brought under the federal False Claims Act (FCA) have continued to drive substantial recoveries in 2012. Most of the cases that have settled so far this year were brought by *qui tam* whistleblowers, continuing a longstanding FCA enforcement trend. Cases alleging FCA violations have been brought against many types of health care providers and manufacturers. In addition, recent settlements and cases illustrate the breadth of alleged FCA violations and confirm that whistleblowers are increasingly suing under state false claims acts, reminding providers and manufacturers of the potency of these provisions.

State False Claims Acts: a Powerful Enforcement Tool

In a case brought under a state false claims act statute, Johnson & Johnson and a subsidiary, Ortho-McNeil-Janssen Pharmaceuticals (collectively, Janssen), were recently fined civilly more than $1.2 billion after a jury trial in Arkansas.[ii/] The case is noteworthy both for the size of the damages and because the defendants took the case to trial. Further, the state's case was not based on off-label marketing claims, but rather on the theory that the FDA package insert was deceptive.

In the Janssen case, the state alleged a violation of the Arkansas FCA and the Arkansas Deceptive Trade Practices Act, arising out of Risperdal's product insert. The relevant provision of the state FCA imposes civil penalties and requires restitution for knowingly making or causing any false statement or representation of a material fact "[w]ith respect to information required pursuant to applicable federal and state law, rules, regulations, and provider agreements."[iii/] The state (1) alleged that Janssen violated the Arkansas FCA by failing to disclose known safety information about Risperdal in its package insert; and (2) claimed that, therefore, the FDA-approved Risperdal product insert was misleading. Janssen argued that the state failed to show that (1) the package inserts were material to Arkansas Medicaid; (2) the package insert did not accompany each prescription; and (3) that any of the Risperdal prescriptions were fraudulent or improperly reimbursed.

After a trial, the jury found that Janssen downplayed and hid Risperdal's side effects. The judge found nearly 240,000 violations of the Arkansas FCA—one for each of the 240,000 Risperdal prescriptions reimbursed by the Arkansas Medicaid program over three and one-half years. Each violation carried a $5,000 civil fine, resulting in a total penalty of more than $1.2 billion. The judge also imposed an additional penalty under the Deceptive Trade Practices Act, notwithstanding the fact that, according to Janssen, Arkansas Medicaid paid a total of just ***$8.1 million*** for Risperdal prescriptions during the relevant time frame.

In another case brought under both state and federal FCAs, Mylan, Inc. agreed to pay $57 million to settle allegations that it caused California and the federal government to overpay for drugs prescribed for beneficiaries of California's Medicaid program. As a result of the settlement, the *qui tam* whistleblower in the case will receive $8.5 million, illustrating both the powerful financial incentives for *qui tam* whistleblowers to bring cases and the sophistication of whistleblowers and their counsel who file such suits. The whistleblower, Ven-a-Care, has, according to estimates, brought and settled more than two dozen *qui tam* lawsuits since 2000 and has collected more than $400 million from the settlement proceeds stemming from those cases.[iv/]

FCA Cases Were Brought Against a Range of Health Care Providers

The government has continued to direct FCA enforcement efforts toward a broad spectrum of the health care industry, including pharmaceutical firms, managed care organizations, and medical supply companies. For example, in April 2012, a managed care organization, WellCare Health Plans, Inc. (WellCare), agreed to pay $137.5 million to settle four FCA cases brought by *qui tam* whistleblowers alleging that, among other things, WellCare: inflated the amount it claimed to spend on medical care; knowingly retained Medicare and Medicaid overpayments; and "cherry-picked" healthy patients to avoid the costs of treating sick patients.[v/]

In another *qui tam* case, fourteen hospitals in several states agreed in February 2012 to pay $12 million to resolve allegations under the FCA that the hospitals submitted false claims to Medicare by performing

kyphoplasty procedures (used to treat certain spinal fractures) on an inpatient basis when these procedures could have been performed safely, and at less cost, as an outpatient procedure. Including this settlement, DOJ reports that it has settled FCA claims relating to kyphoplasty procedures with more than 40 hospitals for a total of more than $39 million.[vi/]

In yet another FCA case, AmMed Direct, LLC (AmMed), a supplier of diabetes testing supplies, recently agreed to pay $18 million to settle a whistleblower suit premised on an illegal marketing scheme in which AmMed allegedly offered free cookbooks to induce Medicare beneficiaries to contact AmMed. When they did, AmMed allegedly tried to sell them diabetic supplies and then billed Medicare for those supplies. After the beneficiaries returned the supplies, AmMed allegedly failed to refund the Medicaid program for the funds it had received for delivering them.

In another settlement, an ambulatory cardiac telemetry (ACT) company, LifeWatch Services, Inc. (LifeWatch), agreed to pay the United States $18.5 million to resolve allegations brought in two *qui tam* lawsuits that LifeWatch billed Medicare for ACT monitoring services for patients who were not eligible for these services. In addition to the monetary settlement, LifeWatch entered into a five-year Corporate Integrity Agreement (CIA) with HHS's Office of Inspector General (OIG). CIAs generally require, among other things, a comprehensive compliance program and impose rigorous monitoring and reporting obligations on the settling defendant for a number of years.

FCA Settlements Pursuant to Self-Disclosures

As a result of a matter disclosed under a CIA, rather than filed by a *qui tam* whistleblower, Tenet Healthcare Corporation (Tenet) agreed to pay the United States $42.75 million to settle FCA allegations. In its self-disclosure to HHS, Tenet reported that it had overbilled the Medicare program for the treatment of patients at Tenet-owned inpatient rehabilitation facilities (IRF). IRFs are designated for patients who require an intense rehabilitation program, and Tenet disclosed that certain patients did not meet the standards for admission to an IRF.

Proposed Regulations for the FCA's 60-Day Repayment Obligations

In a significant regulatory development related to FCA enforcement, on February 16, 2012, the Centers for Medicare & Medicaid Services (CMS) released its proposed rule for the implementation of the 60-day deadline for returning Medicare and Medicaid overpayments, enacted as part of the Affordable Care Act (ACA) (Proposed Rule).[vii/] Under the ACA, the failure to report and return an overpayment within 60 days of identifying its existence can give rise to liability under the FCA and exclusion under the Civil Monetary Penalties Law.[viii/]

Since passage of the ACA, providers and suppliers have needed guidance about when an overpayment has been "identified" and thereby has triggered the ticking of the 60-day clock and the process for returning overpayments. Under the Proposed Rule, an overpayment is "identified" when a provider or supplier has actual knowledge of the existence of the overpayment or acts in reckless disregard or deliberate ignorance of the overpayment. This standard is consistent with the FCA's knowledge standard. Further, CMS proposed that providers should report overpayments that may have been received within a ten-year lookback period. Over 200 comments were submitted to CMS by the close of the comment period on April 16, 2012.[ix/]

The potential impact of the 60-day refund obligation on future FCA enforcement may be substantial as whistleblowers will likely bring claims under the "reverse" false claim provisions of the FCA, which impose liability for failing to pay money to the government that it allegedly should receive. In *United States ex rel. Matheny, et al. v. Medco Health Solutions, Inc., et al.*, the U.S. Eleventh Circuit Court of Appeals found that a *qui tam* whistleblower had sufficiently alleged that the defendant had violated the FCA by certifying compliance with its CIA when the defendant was not, in fact, in compliance with one of its provisions. The CIA required the defendant to refund overpayments within 30 days. The whistleblower alleged that defendant had concealed its receipt of overpayments and had not refunded them, despite the CIA's requirements.[x/] Although *Matheny* involves a provider's failure to refund overpayments under the contractual obligations of a CIA, it likely foreshadows *qui tam* whistleblower complaints under the "reverse" FCA provisions, alleging a failure to comply with statutory and regulatory requirements to return overpayments 60 days after they are identified.

Criminal Trends

During the first quarter of 2012, the government has sought, and courts have imposed, ever-increasing fines and prison sentences on defendants who are convicted of suspected health care fraud. The cases described below reflect some of the most severe penalties (both in terms of dollars fined and months of imprisonment imposed) in the past few months.

Pharmaceutical and Device Manufacturers

On April 19, 2012, Merck, Sharp & Dohme was sentenced to pay $321,636,000 in criminal fines after pleading guilty in December 2011 to violating the Food, Drug and Cosmetic Act for introducing a misbranded drug, Vioxx, into interstate commerce. Merck's guilty plea was part of a global resolution wherein Merck also entered a civil settlement agreement in November 2011. Under the civil settlement agreement, Merck agreed to pay $628,364,000 to resolve additional allegations regarding off-label marketing of Vioxx and false statements about the drug's cardiovascular safety. After imposing the criminal fine, Massachusetts U.S. District Court Judge Patti B. Saris expressed her hope that the size of the penalty will send a message to the industry, as she believes off-label marketing and promotion have become a big problem in the health care sector.[xi/]

In another federal case in Massachusetts, Stryker Biotech, and several of its salesmen, went to trial on charges of wire fraud, conspiracy to defraud the federal government, conspiracy to distribute misbranded medical devices, and making false statements related to off-label use of a combination of devices. Stryker faced thirteen felony charges. The government had specifically identified seven surgeons in its indictment who, it charged, had been deliberately misled by Stryker Biotech's sales team. During opening statements, the defense team revealed that federal prosecutors had failed to speak with any of these surgeons. Defense counsel told the jury that the defense team *had* spoken with the surgeons and that the surgeons were going to testify and tell the jury "three things: the defendants did not lie to them; the defendants did not deceive them; the defendants did not defraud them in any way."[xii/] After opening statements, prosecutors dropped charges against the individual salesmen. Stryker Biotech pleaded guilty to a misdemeanor crime of misbranding its product and agreed to pay a $15 million fine.

Individual Providers

On March 28, 2012, Dr. Joseph J. Kubacki, the Chair of the Ophthalmology Department of the Temple University School of Medicine and the Assistant Dean for Medical Affairs, was sentenced to 87 months in prison and ordered to pay restitution in the amount of $1,014,605.87 after being convicted by a federal jury on August 22, 2011, of 150 counts of health care fraud, wire fraud, and making false statements in health care matters. Dr. Kubacki's conviction resulted from a health care fraud scheme through which he submitted fraudulent claims and caused more than $1.8 million to be paid by Medicare and 31 other health insurers. Between 1996 and 2007, Dr. Kubacki caused thousands of false claims—totaling more than $4.5 million—to be submitted to health care benefit programs for services rendered to patients whom Dr. Kubacki did not personally see or evaluate.

To effect this scheme, Dr. Kubacki directed Ophthalmology Department staff employees to stack patient charts outside of his office door at the main campus of Temple University Hospital. Despite the fact that other physicians in the office had actually seen the patients, Dr. Kubacki falsified the charts by making notes indicating that he had personally seen and evaluated the patients. On several occasions, Dr. Kubacki was outside of Pennsylvania on days that he claimed to have treated patients. Dr. Kubacki also signed the patient charts and completed fee slips for the services that he falsely claimed to have provided. As a result of this scheme, health care benefit programs, including Medicare and private health insurers, paid $1.8 million in fraudulent claims.

Anti-Kickback Statute Enforcement

Since January 2012, there have been a number of charges filed, pleas entered, and convictions obtained under the federal Anti-Kickback Statute (AKS). A number of these cases arose in Texas and involve industries of historical enforcement focus, including durable medical equipment (DME) companies and patient recruiters. Some of the more noteworthy AKS cases in recent months are discussed below.

Kickbacks to Patient Recruiters in Texas

- On February 29, 2012, Alicia Vasquez, the owner of a purported health care resource center in San Juan, Texas, pled guilty to one count of conspiracy for her involvement in a scheme to solicit and receive kickback payments in violation of the federal AKS. According to the indictment, from September 2009 through April 2011, Ms. Vasquez solicited numerous Medicare and Medicaid beneficiaries through her company in order to refer them to various health care providers, including DME companies, physicians, and home healthcare agencies. Ms. Vasquez allegedly received $70,000 in kickbacks from those providers, and they billed hundreds of thousands of dollars to the Medicare and Medicaid programs as a result of the referrals. Two such providers were Med-Quick Diagnostics and Go DME, Inc.

- On April 24, 2012, the owners of Med-Quick Diagnostics and Go DME, Inc., located in Weslaco and Pharr, Texas, respectively, each pled guilty to one count of conspiring to violate the AKS for paying kickbacks to Ms. Vasquez in exchange for referring Medicare and Medicaid patients for services provided by their companies. Each defendant could face up to five years in federal prison and a fine of $250,000.

- On April 19, 2012, Floyd Leslie Brooks and Gwendolyn Kay Frank, both of Houston, Texas, were charged with conspiracy to violate the AKS as a result of a scheme through which, between January 2007 and June 2009, they allegedly referred Medicare beneficiaries to City Nursing and received $13,700 and $24,500, respectively, from City Nursing in return for the referrals. City Nursing then billed Medicare and Medicaid more than $1 million for physical therapy provided to those beneficiaries and received approximately $790,460 in reimbursement.

Industries of Focus

In recent months, the government has continued its enforcement efforts in industries that traditionally have been the focus of its attention, including the home health and hospice industries, and has also begun to expand its scrutiny to cover others, such as providers of mental health care services and research grant recipients.

Traditional Industries of Focus

On March 23, 2012, the government unsealed an indictment against several individuals who worked for Home Care Hospice, Inc. (HCH), a hospice care provider in Philadelphia, Pennsylvania. The indictment charged five nurses in a health care fraud conspiracy which allegedly took place between 2005 and 2008 and resulted in over $9 million in fraudulent claims to Medicare. The indictment alleged that HCH's Director of Professional Services, Patricia McGill, authorized nursing staff and supervisors to fabricate and falsify documents either (1) in support of hospice care for patients who were not eligible for such care; or (2) in support of a higher, more costly level of care than was actually provided. The indictment also charged that other defendants created fraudulent nursing notes for approximately 150 patients, which stated that hospice services had been provided to patients when in fact they had not been.

Additionally, after HCH was notified in February 2007 that it was subject to a claims review audit, Ms. McGill is alleged to have assisted in a patient chart review, sanctioned false documentation by the nursing staff, and authorized the alteration of charts. Later, in September 2007, when HCH was notified that it had exceeded its cap for Medicare reimbursement and would have to repay $2,625,047, Ms. McGill and HCH's Hospice Director told staff to review patient files and discharge patients. This review resulted in a mass discharge of patients. In October 2007 alone, 79 hospice patients were discharged. By January 2008, a total of 128 patients had been discharged. Some of these patients had been ineligible for hospice or inappropriately maintained on hospice service for more than six months. If convicted of all charges against her, Ms. McGill could face between 108 and 135 months in federal prison and fines of $150,000.

Potential New Areas of Enforcement Focus

A few recent cases serve as good examples of the government's increased focus on mental health providers and could signal future enforcement priorities. In February, Mohammad Khan, an assistant administrator of Riverside General Hospital, pled guilty to (1) conspiracy to commit health care fraud; (2) conspiracy to defraud the United States and to pay and receive illegal health care kickbacks; and (3) paying or offering to pay health care kickbacks. From January 2008 until Mr. Khan's arrest (only two weeks prior to his plea), he caused the submission of $116,000,000 worth of fraudulent claims to Medicare for partial hospitalization program (PHP) services (a form of intensive outpatient treatment for several mental illnesses) that the

hospital purported to provide to patients. These PHP services were either medically unnecessary or never provided. Mr. Khan faces a maximum sentence of 40 years in federal prison.

In March, a federal grand jury indicted Joseph T. Hackett, owner and operator of Access Regional Taskforce (ART), a Richmond-based Medicaid contracted provider of Intensive In-Home Therapy Services for children and adolescents with severe mental health, behavioral, or emotional issues. The grand jury accused Mr. Hackett of health care fraud and conspiracy to pay health care kickbacks, alleging that Mr. Hackett (1) billed Medicaid for medically unnecessary services; (2) submitted Medicaid claims for services that were not reimbursable because they did not address a child's specific mental health issues or were not provided by qualified mental health workers; and (3) paid a marketing company $545,410 in illegal kickbacks for patient referrals. This scheme allegedly resulted in ART receiving at least $1,570,041 from Medicaid to which it was not entitled.

Although it is too soon to tell, improper use of grant money may be another area of government focus this year. In February, a former Penn State University professor pled guilty to all counts in a case alleging that he committed a $3 million federal research grant fraud. Professor Craig Grimes's plea resulted from allegations that he defrauded the National Institutes of Health (NIH) of federal grant monies between June 30, 2006 and February 1, 2011, by misappropriating the funds for his own personal use instead of employing them for clinical research.

Conclusions

So far in 2012, we have continued to see substantial civil health care enforcement using the FCA. In criminal cases, the government is still targeting both companies and individuals for prosecution across many industries and is seeking, and often securing, substantial penalties.

One emerging trend that we are monitoring is the government's use of data analysis to identify health care fraud. Attorney General Eric Holder specifically addressed this area of focus at the Chicago Health Care Fraud Summit: "… the last three years have been characterized by significant—and, in many cases, record—progress, particularly in our ability to analyze claims and other data in order to rapidly identify emerging fraud patterns."[xiii] We will continue to monitor health care enforcement trends and issue further periodic reports during 2012.

ENDNOTES

i/ Kathleen Sebelius, Secretary, U.S. Dep't of Health and Human Services, Presentation at the Chicago Fraud Prevention Summit (Apr. 4, 2012), http://www.hhs.gov/secretary/about/speeches/sp20120404.html.

ii/ Katie Thomas, *J.&J. Fined $1.2 Billion in Drug Case*, N.Y. TIMES (Apr. 11, 2012), http://www.nytimes.com/2012/04/12/business/drug-giant-is-fined-1-2-billion-in-arkansas.html?_r=1.

iii/ Ark. Code Ann., § 20-77-902(8)(B).

iv/ Andrew Zajac, *Whistle-Blower Ven-A-Care Wins in Texas Case Against Drug Company*, L.A. TIMES, Feb. 2, 2011, http://articles.latimes.com/2011/feb/02/business/la-fi-whistle-blower-20110202.

v/ Press Release, Dep't of Justice, Florida-Based Wellcare Health Plans Agrees to Pay $137.5 Million to Resolve False Claims Act Allegations (Apr. 3, 2012), http://www.justice.gov/opa/pr/2012/April/12-civ-425.html.

vi/ Press Release, Dep't of Justice, Fourteen Hospitals to Pay U.S. More Than $12 Million to Resolve False Claims Act Allegations Related to Kyphoplasty (Feb. 7, 2012), http://www.justice.gov/opa/pr/2012/February/12-civ-173.html.

vii/ Medicare Program; Reporting and Returning Overpayments, 77 Fed. Reg. 9179 (proposed Feb. 16, 2012), *available at* http://www.gpo.gov/fdsys/pkg/FR-2012-02-16/pdf/2012-3642.pdf.

viii/ Section 6402(a) of the Patient Protection and Affordable Care Act, Pub. L. 111-148 (Mar. 23, 2010) (codified as Section 1128J(d) of the Social Security Act).

ix/ For more analysis of the proposed rule by Mintz Levin, see, Karen S. Lovitch and Stephanie D. Willis, *CMS Publishes Proposed Rule on Return of Medicare and Medicaid Overpayments* (Feb. 16, 2012), http://www.mintz.com/newsletter/2012/Advisories/1662-0212-NAT-HL/index.htm.

x/ No. 10-15406 (11th Cir. Feb. 22, 2012).

xi/ Press Release, Dep't of Justice, U.S. Pharmaceutical Company Merck Sharp & Dohme Sentenced in Connection with Unlawful Promotion of Vioxx® Judge Imposes Nearly $322 Million Fine For Illegal Marketing (Apr. 19, 2012), http://www.justice.gov/usao/ma/news/2012/April/MerckSentencingPR.html.

xii/ David E. Frank, *Defense Opening Upends Government Case*, MASS. LAWYERS WEEKLY, Jan. 30, 2012.

xiii/ Eric Holder, U.S. Attorney General, U.S. Dep't of Justice, Attorney General Eric Holder Speaks at the Chicago Health Care Fraud Prevention Summit (Apr. 4, 2012), http://www.justice.gov/iso/opa/ag/speeches/2012/ag-speech-120404.html.