

## White-Collar Crime

WWW.NYLJ.COM

MONDAY, JULY 13, 2009

# Target Health Care Fraud

With the industry in government crosshairs, proactive internal measures can make a difference.

BY JOHN J. CARNEY  
AND ROBERT M. WOLIN

OVER THE PAST several years, the federal government has collected billions in fines and restitution from corporations accused of violating federal health care statutes and regulations. The targets of the government actions were not small, unknown companies, but major U.S. corporations including Eli Lilly, Pfizer and Abbott Laboratories. In addition to the staggering financial payments to the government, these corporations also incurred significant defense costs and unavoidable disruption of their businesses.

Considering these significant past actions, the newly enacted Fraud Enforcement and Recovery Act (FERA) and the growing "saber rattling" by the Department of Justice (DOJ) and the Department of Health and Human Services (HHS), the question arises: Can proactive internal investigative and compliance measures make a difference?

### Turning Up the 'HEAT'

On May 20, Attorney General Eric Holder and HHS Secretary Kathleen Sebelius issued a joint DOJ and HHS press release announcing the creation of the Health Care Fraud Prevention and Enforcement Action Team (HEAT). The creation of this cabinet level team composed of high-ranking DOJ and HHS officials follows on several years of increased government scrutiny of Medicare and Medicaid spending.

The creation of HEAT is in keeping with President Obama's increased focus on health care fraud as a key component of health care reform efforts. For example, the proposed Fiscal Year 2010 federal budget calls for spending \$311 million on fraud and abuse enforcement and prevention, a 50 percent increase, and spending \$1.7 billion over the next five years on fraud and abuse enforcement and prevention.

The joint statement of Holder and Sebelius shows that the current administration will continue previous

lines of enforcement and open new lines of attack.

In 2007, HHS and DOJ created a joint Medicare Fraud Strike Force in South Florida, adding another strike force in Los Angeles in 2008.<sup>1</sup> In South Florida, the strike force has already "convicted 146 defendants and secured \$186 million in criminal fines and civil recoveries."<sup>2</sup> The Los Angeles strike force has charged 37 defendants with criminal health care fraud offenses, with more than \$55 million ordered as restitution to the Medicare program.<sup>3</sup> Detroit and Houston will see the addition of Medicare fraud strike forces this year.

When health care reform budgetary requirements are combined with the creation of HEAT and the addition

Procedures to ensure that **allegations of improprieties are promptly and thoroughly investigated and corrected can minimize a provider's exposure to civil and criminal as well as administrative consequences.**

of state and local scrutiny, it is clear that the government aims to cut the costs of federal health care by not only increasing efficiency, but by aggressively pursuing those it suspects of fraud. "With this announcement," Attorney General Holder declared, "we raise the stakes on health care fraud...with increased tools, resources and a sustained focus by senior-level leadership."<sup>4</sup>

In late June, Holder, Sebelius and FBI Director Robert Mueller announced the indictment of 53 people for alleged schemes to submit more than \$50 million in false claims, citing the action as the third phase of a targeted criminal, civil and administrative effort against individuals and health care companies that fraudulently bill the Medicare program. According to Sebelius, "the Obama Administration is committed to turning up the heat on Medicare fraud and employing all the weapons in the federal government's arsenal to target those who are defrauding the American taxpayer...our joint efforts on HEAT don't just stop at the jailhouse door. Our Medicare program is working closely in partnership with our own and other law enforcement operations to prevent fraud from happening in the first place."<sup>5</sup>

While criminal prosecutions against individuals account for the high number of health care fraud indictments and convictions, the civil penalties levied on companies account for the greater part of the total dollars recovered. The HHS Office of the Inspector General reports that, from the first half of FY 2009 alone, HHS stands to recover over \$2.4 billion, with an additional

\$550 million going to states' shares in restitution. Many of these recoveries arise out of settlements brokered with well-known national companies.

A \$1.4 billion recovery comes from the settlement of federal and state suits against Eli Lilly for the False Claims Act (FCA) violations in its marketing of Zyprexa for off-label (non-FDA approved) uses. Lilly, as part of the settlement, agreed to a five-year corporate integrity agreement (CIA) that included provisions to increase the accountability of the company's board of directors and management.<sup>6</sup>

Bayer HealthCare agreed to pay \$97.5 million plus interest to settle allegations that it paid kickbacks to several durable medical equipment suppliers and distributors, leading them to submit false claims to Medicare. Bayer also agreed to a five-year CIA similar to that of Lilly's.<sup>7</sup>

Abbott Laboratories agreed to pay \$28 million to Texas and the federal government in a Medicaid fraud settlement to resolve its civil liabilities related to the false pricing of certain intravenous drugs and blood products.<sup>8</sup>

Walgreen Co. (Walgreens) agreed to pay the United States \$9.9 million to resolve allegations that it overcharged the Medicaid program in Minnesota, Michigan, Florida and Massachusetts for prescription drugs by charging Medicaid for the difference between the Medicaid negotiated amounts and the third-party primary insurer negotiated amounts for the drugs. Walgreens also agreed to enter into an amendment to its June 2008 CIA.<sup>9</sup>

SouthernCare Inc. (SCI), SouthernCare Holdings Inc., SouthernCare Carry, LLC, and SouthernCare's chairman, president and CEO Michael Parly agreed to pay the United States \$24.7 million and enter into a five-year CIA to resolve their FCA liability for allegedly submitting false claims to Medicare.<sup>10</sup>

Additionally, aside from adjudging monetary costs, the government can exclude individuals and corporations from participating in Medicare and Medicaid entirely. In January 2009, a Social Security Administration administrative law judge affirmed the determination to exclude the former CEO and COO, the chief science officer and the general counsel of drug-maker Purdue Frederick from participation in federal health care programs for a period of 15 years:

"The exclusions were based on the executives' convictions for their failure—as responsible corporate officers of Purdue Frederick—to 'prevent or correct' the fraudulent misbranding and distribution of OxyContin."<sup>11</sup>

JOHN J. CARNEY, a partner in Baker Hostetler's New York office and co-chair of the firm's white collar defense and investigations practice, previously served as the chief of the healthcare practice unit at the U.S. Attorney's Office in New Jersey. He can be reached at jcarney@bakerlaw.com. ROBERT M. WOLIN, a partner on the firm's national healthcare team, practices in the firm's Houston office and may be reached at rwolin@bakerlaw.com. PAUL-JON BENSON, a summer associate in the New York office, assisted in the preparation of this article.

## Fraud Enforcement and Recovery Act

On the same day that Holder and Sebelius announced HEAT, President Obama signed the Fraud Enforcement and Recovery Act into law. Although FERA, in the main, addresses the concerns arising from the use of economic recovery funds, the law also provides for more vigorous enforcement of the FCA.

Extending the government's intent to encourage qui tam actions, FERA provides for increased whistleblower protections allowing for damage awards to whistleblowers suffering retaliation. Under the new 31 U.S.C. §3730(h), a whistleblower is now "entitled to all relief necessary to make that employee, contractor, or agent whole" if he or she "is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment because of lawful acts done...in furtherance of other efforts to stop 1 or more violations" of the FCA.

In addition to reinstatement, the whistleblower statute provides an award of two times the amount of back pay, plus interest, and compensation for any special damages, as well as litigation costs and attorneys' fees. Similarly, FERA imposes additional costs on any company found liable under the FCA by assigning the costs of litigation and attorneys' fees to it.

FERA expands liability to any entity subcontracted by a company fraudulently claiming money, "any portion of which" the federal government provided. That is, while the subcontractor is not paid by and owes no obligation directly to the federal government, it can still be liable under the FCA if it has contracted under a company that receives some federal dollars. In practice, this also means that there can be federal violations for those third parties who indirectly receive income from state health funds as a portion of these derived from federal funds.

Finally, FERA rolls back the knowledge requirement in cases of fraud under the FCA by requiring only a finding of recklessness or deliberate ignorance without any specific intent to defraud, further expanding the net of liability for companies and individuals dealing with federal health care funds. These expansions, in principle, allow a number of federal charges, and the concomitant costs, for those who, though not health care providers themselves, contract with any such providers receiving "any portion of" their profits from Medicaid or Medicare.

## Proactive Compliance, Investigations

Health care providers, like others in heavily regulated industries, face a daunting challenge to remain abreast of changing legal requirements and to assure that their operations are administered in a consistent compliant manner, particularly when many of the requirements are subjective in nature and involve hundreds of one-on-one, human-to-human interactions.

Compliance efforts must be organized and should focus on the risk areas that are relatively well understood in the industry and on evolving risks in order to develop effective internal controls. Companies should also develop procedures to ensure that allegations of improprieties are promptly and thoroughly investigated and corrected to minimize the provider's exposure to civil litigation damages and penalties, criminal sanctions, and administrative agency remedies.

The most critical aspect is the development of a comprehensive compliance program. Such programs help companies to:

- (i) identify weaknesses in internal systems and management to help assure early detection and reporting of improper actions;
- (ii) establish an organizational culture that resists

improper practices;

(iii) identify and prevent criminal and unethical conduct;

(iv) improve the quality of their services;

(v) create a system for distributing information on relevant statutes, regulations and other program directives; and

(vi) develop a methodology that encourages employees to report potential problems before they become significant legal and economic risks.

## It Can Make a Difference

Compliance efforts will reduce the likelihood and duration of government audits and investigations and will be considered to be a mitigating factor under the Federal Sentencing Guidelines, in the event of a government audit or investigation.

For example, Eli Lilly could have avoided the \$1.4 billion settlement and criminal charge in connection with the marketing of Zyprexa if it had adopted and implemented standards of conduct throughout the organization and routinely audited and evaluated its compliance with FDA requirements.

In its Information, the government contended that Eli Lilly's "management created marketing materials, [and]... trained its sales force to disregard the law" in order to promote Zyprexa for off-label uses in markets where "there was virtually no on-label use for Zyprexa." Effective, routine audits likely would have detected the abnormal sales patterns and allowed Lilly to investigate and correct the problem before incurring a massive liability.

Likewise, the proactive use of compliance monitoring and analytical auditing procedures could have helped Bayer Healthcare and Abbott Laboratories detect payment patterns that suggested the existence of possible improper kickback or false pricing activity. Having identified a potential issue early on, targeted investigations and prompt remedial measures might have enabled counsel to better position the company in settlement negotiations with the government.

## The Top Ten for Effective Programs

Effective compliance and investigative programs should assure that:

(1) written standards of conduct are developed and implemented, as well as written policies and procedures that promote the organization's commitment to compliance;

(2) individuals are appointed to administer and monitor the compliance efforts in a clear manner and assure that they report directly to the CEO and the governing body;

(3) regular and effective education and training programs are provided to all affected employees and contractors;

(4) a process is put in place to receive complaints, such as a hotline, and that procedures are adopted to protect the anonymity of complainants and to assure whistleblowers are protected from retaliation;

(5) the organization implements a system to respond to allegations of improper or illegal activities;

(6) the organization utilizes appropriate disciplinary actions against employees who have violated internal compliance policies, applicable statutes, regulations or federal health care program requirements;

(7) the organization routinely audits and evaluates its compliance;

(8) the organization identifies and remediates identified systemic problems;

(9) investigations into the cause of suspected compliance failures are launched quickly and are designed to probe in sufficient depth in order to be

effective; and

(10) strict policies are implemented to preclude employing individuals who have been sanctioned for fraud and abuse activities.

## Conclusion

The government's interest in promoting the fair and efficient distribution of health care to those who need it clearly coincides with its interest in the country's financial well-being.

"By a wide margin," President Obama said in March, "the biggest threat to our nation's balance sheet is the skyrocketing cost of health care. It's not even close."<sup>12</sup>

The government attributes part of this cost to fraud and has steadily increased the financial, technological and human resources available to pursue and prosecute for these lost funds. "[E]very year," Holder said when announcing HEAT, "we lose tens of billions of dollars in Medicare and Medicaid funds to fraud. Those billions represent health care dollars that could be spent on medicine, elder care or emergency room visits, but instead are wasted on greed."<sup>13</sup>

While the specifics of this administration's health care reform are still changing, companies can be assured that increasing enforcement initiatives against waste, fraud and abuse will be a significant component of the effort.

Investing now in upgrading internal compliance and investigative programs could make all the difference in avoiding becoming the target of the next government crackdown. More than just a good legal idea, it's simply good business.

.....●●●.....

1. Less formal health care fraud task forces have been organized locally in many other areas of the country. See e.g., <http://www.usdoj.gov/usofo/ohs/HCFCA.html> (Southern District of Ohio) and [http://www.uspsoig.gov/press\\_releases/Arabatzis.pdf](http://www.uspsoig.gov/press_releases/Arabatzis.pdf) (Western New York Health Care Fraud Task Force).

2. U.S. Dept. of Health & Human Services. "Attorney General Holder and HHS Secretary Sebelius Announce New Interagency Health Care Fraud Prevention and Enforcement Action Team." (May 20, 2009), <http://www.hhs.gov/news/press/2009pres/05/20090520a.html>

3. Id.

4. Id.

5. U.S. Dept. of Health and Human Services. "Medicare Fraud Strike Force Operations Lead to Charges Against 53 Doctors, Health Care Executives and Beneficiaries for More Than \$50 Million in Alleged False Billing in Detroit." (June 24, 2009), <http://www.hhs.gov/news/press/2009pres/06/20090624a.html>.

6. HHS Office of Inspector General. "Department of Health and Human Services Semiannual Report to Congress, Oct. 1, 2008-March 31, 2009" (Spring 2009), [http://oig.hhs.gov/publications/docs/semiannual/2009/semiannual\\_spring2009.pdf](http://oig.hhs.gov/publications/docs/semiannual/2009/semiannual_spring2009.pdf).

7. Id.

8. Id at 38.

9. Id.

10. Id. at 39.

11. HHS Office of Inspector General. "Administrative Law Judge Upholds HHS-OIG Exclusions Imposed Against Responsible Corporate Officers in OxyContin Case." (Jan. 23, 2009), [http://oig.hhs.gov/publications/docs/press/2009/hhs\\_oig\\_press\\_01232009.pdf](http://oig.hhs.gov/publications/docs/press/2009/hhs_oig_press_01232009.pdf).

12. President Barack Obama, Remarks at the Opening of the White House Forum on Health Reform (March 5, 2009) (transcript available at [http://www.whitehouse.gov/the\\_press\\_office/Remarks-by-the-President-at-the-Opening-of-the-White-House-Forum-on-Health-Reform](http://www.whitehouse.gov/the_press_office/Remarks-by-the-President-at-the-Opening-of-the-White-House-Forum-on-Health-Reform)).

13. Department of Justice. "Remarks as Prepared for Delivery by Attorney General Holder on New Medicare Fraud Initiative at a Press Conference with HHS Secretary Sebelius." (May 20, 2009), [www.usdoj.gov/ag/speeches/2009/ag-speech-090520.html](http://www.usdoj.gov/ag/speeches/2009/ag-speech-090520.html).

Reprinted with permission from the July 13, 2009 edition of the NEW YORK LAW JOURNAL© 2009 Incisive US Properties, LLC. All rights reserved. Further duplication without permission is prohibited. For information, contact 877-257-3382 or [reprints@incisivemedia.com](mailto:reprints@incisivemedia.com). # 070-07-09-25