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Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

Health Care Enforcement Review And 2017 Outlook: Part 4

By **attorneys at Mintz Levin Cohn Ferris Glovsky and Popeo PC**


Brian P. Dunphy


Karen S. Lovitch


Kevin M. McGinty

Law360, New York (January 19, 2017, 10:39 AM EST) -- In part 1 of our four-part health care enforcement review and 2017 outlook series, we examined the U.S. Food and Drug Administration's wide-ranging enforcement activities related to health care fraud. Part 2 addressed 2016's major case developments in health care enforcement and part 3 highlighted significant regulatory developments in this area.

In this final installment, we analyze health care enforcement trends gathered from 2016 civil settlements and criminal resolutions of health care fraud and abuse cases. Behind the headlines covering enormous recoveries in 2016, several themes are apparent.

FCA Continued to Generate Large Civil Settlements

Continuing the trend from recent years, the False Claims Act remained the primary civil enforcement tool against health care providers as well as pharmaceutical, life sciences and medical device companies, predominantly driven by qui tam FCA complaints filed by relators. In fiscal year 2016, the U.S. Department of Justice obtained more than $4.7 billion in settlements and judgments from FCA cases, $2.5 billion of which it obtained from the health care industry.

AKS Enforcement is Alive and Well

Olympus Corp. paid a criminal fine and a civil settlement for anti-kickback statute violations totaling $646 million. The government criminally charged Olympus, a medical device manufacturer, with conspiracy to violate the AKS by paying doctors and hospitals kickbacks, including consulting payments, travel, meals, grants and free endoscopes. Olympus paid a $312.4 million criminal penalty and entered into a three-year deferred prosecution agreement, allowing the company to avoid conviction by adhering to agreed-upon compliance requirements.

In addition to the criminal penalty, Olympus paid $310.8 million to settle civil claims under the federal FCA and various state FCAs. The civil FCA settlement resolved a qui tam FCA lawsuit filed by the company's former chief compliance officer. Increasingly, we have observed that compliance professionals have filed FCA claims against their former employers.

A large hospital chain, Tenet Healthcare Corporation, and two of its subsidiaries, paid over $513 million to resolve criminal charges and civil claims that the hospitals paid kickbacks to prenatal care clinics in return for the referral of patients for labor and delivery services at Tenet hospitals. The $513 million included both forfeiture of amounts reimbursed by Medicare and Medicaid and payments to the federal government and states to resolve a qui tam FCA lawsuit.

Failure to Report Rebates to Medicaid Resulted in 2016's Largest Settlement

In one of the highest-profile settlements of 2016, Pfizer Inc. and Wyeth (who Pfizer acquired) paid $784.6 million to resolve allegations that Wyeth knowingly reported to the government false prices on two of its proton pump inhibitor drugs. Two relators filed qui tam lawsuits, and the government intervened in the cases. The government alleged that Wyeth did not disclose to Medicaid bundled discounts that Wyeth gave to hospitals on the two drugs. Wyeth thus allegedly avoided paying hundreds of millions of dollars in rebates to Medicaid over a six-year period.

As my colleagues discussed in a recent client alert, in addition to rebates, two FCA cases have sparked a vigorous debate over the application of the frequently used discount exception and safe harbor under the AKS.

Use of Proactive Data Analysis to Identify Enforcement Actions Targets

In August, the DOJ announced a $7.4 million settlement of FCA allegations against a drug screening provider, Physicians Group Services PA, in which the initial trigger for the investigation was analysis of Medicare and TRICARE data to identify suspicious billing patterns.

Proactive data analysis is not a new concept, and government and private payors have disclosed their use of such analyses to identify potential fraud and abuse. For example, the CMS National Training Program module on fraud and abuse prevention indicated that the National Benefit Integrity Medicare Drug Integrity Contractor would "perform proactive data analyses" to identify fraud and abuse in the Medicare Part C and D programs.

The DOJ's explicit reference to proactive data analysis in the Physicians Group Services press release strongly suggests that growing experience with data mining has given enforcers greater confidence in their ability to identify potential fraud and abuse. As a result, proactive data analysis could lead to a greater number of FCA cases originating with government investigators instead of through qui tam FCA actions.

Brian P. Dunphy is an associate at Mintz Levin Cohn Ferris Glovsky and Popeo PC in Boston. Karen S. Lovitch is a member at Mintz Levin in Washington, D.C. She is practice leader of the firm's health law practice. Kevin M. McGinty is a member at Mintz Levin in Boston.