



Emerging Trends: With Health Care Reform a Reality, What's Next for Health Care Fraud Investigations?

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As part of the newly enacted health care reform package, Congress tightened rules and statutes relating to the prosecution of health care fraud offenses. In this month's Q&A, health care attorney Douglas Grimm, member of Pillsbury's multidisciplinary Health Care industry team, discusses modifications to the Anti-Kickback Statute under the Patient Protection and Affordable Care Act, the new trends in prosecution of such cases and the implications of the 2009 Physician Payments Sunshine Act. Prior to Grimm's arrival at Pillsbury in 2009, he served as Chief Operating Officer for several acute-care facilities throughout the United States.

Emerging Trends is a monthly feature from Pillsbury, highlighting key issues impacting energy, financial services, healthcare, technology, and other industries today.

Q: With the recent passage of the Patient Protection and Affordable Care Act, what changes have been made to existing health care fraud regulations?

Grimm: The Patient Protection and Affordable Care Act ("PPACA" or the "Act") signed into law by President Obama on March 23, 2010 includes many provisions that strengthen the government's ability to investigate and prosecute health care fraud. The Act allocates significant funds and resources to curb fraud and abuse in the health care and life sciences industries, including the expansion of enforcement tools and administrative penalties.

One of the most significant changes in PPACA relates to the Anti-Kickback Statute. Prior to the passage of PPACA, some courts (specifically the Ninth Circuit) had required the government to demonstrate that a defendant knew that the Anti-Kickback Statute prohibited offering or paying remuneration to induce referrals and that the defendant had the specific intent to violate the law. Under PPACA, while the government must still prove that the defendant intended to violate the law, it need not demonstrate they intended to violate the Anti-Kickback Statute specifically.

Q: What is the effect of the Patient Protection and Affordable Care Act on the Federal False Claims Act?

Grimm: PPACA also continues the expansion of the Federal False Claims Act (FCA) and provides that a violation of the Anti-Kickback Statute constitutes a "false or fraudulent claim" under the FCA. In essence, the federal government's burden is considerably lightened, as it can now prosecute violations of the Anti-Kickback Statute under the FCA, with no requirement to demonstrate a connection between the two.

The public disclosure bar under the FCA has also been dramatically modified. Previously, a whistleblower who was not a direct and independent source of the information could not pursue

a claim on behalf of the United States if that claim was publicly disclosed. PPACA changes this and allows whistleblowers who materially add to the publicly disclosed information to pursue claims. PPACA also limits the types of activities considered "public disclosure" to disclosures made in a federal setting – disclosures in state reports or state proceedings no longer qualify. Most importantly, PPACA permits the United States to waive application of the public disclosure bar at its discretion.

PPACA also contains a "report and return" requirement for overpayments. Providers must report and return overpayments within 60 days of discovering the overpayment or they will automatically be in violation of the FCA. This provision took effective immediately. Thus, any overpayments that are known by provider prior to March 23, 2010 must be reported and returned by May 22, 2010.

Q: Does the Patient Protection and Affordable Care Act provide for increased penalties?

Grimm: Yes, the PPACA provides for increased criminal and civil penalties. The Federal Sentencing Guidelines will be amended to increase sentences for defendants convicted of federal health care offenses, adding to this category of offense violations of the Anti-Kickback Statute. Administrative penalties have also been significantly expanded under the Act allowing the government, among other things, to impose civil monetary penalties on new grounds such as the knowing retention of an overpayment. For example, should a health care entity determine that it has been overpaid for the provision of a service to a Medicare beneficiary, and fails to return the overpayment, the entity would now be liable not only for the amount of the overpayment, but potentially also for a civil monetary penalty.

Q: What are the implications of the revisions to the Anti-Kickback Statute for the health care and life sciences industry?

Grimm: In the past, the government focused significant resources on investigations of pharmaceutical and medical device companies that promoted drugs and devices for "off-label" uses in violation of the Food, Drug and Cosmetic Act (FDCA). Violations of the Anti-Kickback Statute were often tacked on to the settlement, but rarely were the primary violation. Recently, however, there has been a trend at the Department of Justice to investigate violations of the Anti-Kickback Statute even in the absence of any "off-label" violations. Given that the Act loosens the standards for proving violations of the Anti-Kickback Statute, it is likely this trend will continue.

Q: Can you give examples of such recent prosecutions?

Grimm: In 2008, Biovail Pharmaceuticals, Inc. pled guilty to a kickback scheme where physicians were allegedly paid \$1,000 per patient, an amount alleged to be far above market-value, to enroll patients in the company's research program under the guise of performing valuable research. The government claimed that the purpose of the program was to increase the number of prescriptions written by the physicians participating in the program. Biovail paid a \$2,800 assessment, a \$22,243,590 criminal fine, and \$2,404,286 in restitution. (Judgment, *United States v. Biovail Pharmaceuticals, Inc.*, No. 1:08 CR 10124-NG-01 (D. Mass. May 6, 2008)).

In another case, without admitting any wrongdoing, Boston Scientific paid \$22 million in a civil settlement with the government. The company allegedly paid physicians between \$1,000 and \$1,500 to participate in post-market studies. DOJ alleged the studies were merely efforts to increase sales of pacemakers and defibrillators by targeting those doctors who traditionally used products from other companies.

Most recently, in March 2010, Alpharma, Inc. agreed to pay \$42.5 million as part of a civil settlement with the government and certain states to resolve allegations that the company paid kickbacks to physicians to induce them to write prescriptions. The alleged inducements included payments for sham consulting arrangements, lavish entertainment, and "educational" grants.

Q: With the passage of the health care reform package, what other legislation poses challenges for drug and medical device companies?

Grimm: The Physician Payments Sunshine Act, previously a stand-alone bill, was passed as part of President Obama's health care reform package. Beginning in 2012, drug and medical device companies will be required to disclose to the U.S. Department of Health and Human Services all payments to physicians over \$10. The new requirements aim to create a standard, nationwide reporting system to shed light on financial relationships and potential conflicts between physicians and companies. The Act seeks to address Congress's concern that such financial relationships could compromise the outcome of specific drug trials or research or compel a health care provider to prescribe one particular drug or device over another where it is not in the best interests of the patient.

Q: Does the Physician Payments Sunshine Act place limitations on payments?

Grimm: While the law requires reporting of all payments to physicians and teaching hospitals, it does not place any limits on the amounts that may be paid. Payments that must be disclosed include honoraria for speaking and consulting, funding for conferences, royalties and licensing, food, and gifts. Although some of the larger pharmaceutical companies have already started publicly releasing this information, very few of them offer the type of detail that would be required under the law.

Q: When should companies start preparing to comply with this law? What are the consequences for failing to comply?

Grimm: The law actually made compliance retroactive, requiring companies to start tracking their payments to health care providers as of January 1, 2010, with the first report to be submitted on March 31, 2013. The reports will be posted on a public website launched in September 2013, providing the public with an unprecedented level of detail about the recipients of payments, the amounts of the payments, and the nature of the transactions. For each failure to report, a company can be fined \$10,000, not to exceed \$150,000 annually. Where a company knowingly violates the requirements, civil penalties of up to \$100,000 can be imposed, not to exceed \$1 million annually.

Several states, including New York, Texas, and Connecticut, already have similar laws on the books. The new federal law preempts state law where the state law requires the reporting of the same type of information. With the exception of de minimis or threshold limits, states are allowed to require reporting of data that does not fall under the federal law, or is not specifically excluded by it. Therefore, companies need to be mindful of whether individual states require reporting of a broader range of relationships.

In preparation for meeting these reporting requirements, companies need to start developing internal procedures for documenting these transactions and keeping accurate databases. Any meaningful internal system needs to take into account both federal and state requirements.

Clients from all major sectors of the health care industry rely on Pillsbury's Life Sciences & Health Care team for legal advice and strategic counsel. Our lawyers are as diverse as the industry itself, combining backgrounds in medical science with public service at federal regulatory agencies. The team, nationally ranked by Chambers USA, is distinguished by its depth in the array of legal disciplines touching the health care industry—from intellectual property to tax; corporate governance to labor law; and fraud & abuse compliance to litigation.

For more information on issues concerning health care regulatory developments, please contact Katya Zelentsovskaya, Senior PR Coordinator, at 212.858.1866 or at katya.zelentsovskaya@pillsburylaw.com.