by Scott R. Grubman, Esq

The top government enforcement priorities in healthcare: View from the trenches

» Fraud and abuse enforcement in the healthcare industry continues to be a top priority for the federal government.

» Both the federal and state governments have focused their resources to fight the opioid epidemic, including investigating potential fraud and abuse related to prescription opioids.

» Compounding pharmacies have remained a focus of the DOJ in both civil and criminal investigations and prosecutions.

» The DOJ and private whistleblowers continue to focus on hospice providers, leading to several large settlements in 2017.

» Large pharmaceutical companies are under scrutiny by federal authorities for violations of the False Claims Act.

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Although 2017 brought a change of Administration and with it, new leadership of federal agencies—including the United States Department of Justice (DOJ) and Health and Human Services (HHS)—government enforcement in healthcare remains at an all-time high. As in past years, the federal False Claims Act (FCA) continues to be the most powerful tool in the federal government's fraud-fighting toolkit, which is not surprising, considering Attorney General Jeff Session's public statements in support of the FCA, including during his Senate confirmation hearings. This article explores some of the current top government enforcement priorities in the healthcare industry.

Opioid fraud and abuse

Perhaps the central focus of the government's current enforcement activity in the healthcare industry relates to prescribing opioids and other narcotic drugs. The United States is in the midst of an opioid overdose epidemic and, according to the Centers for Disease Control and Prevention (CDC), nearly half of all opioid overdose deaths involve a prescription opioid.[1]

In July 2017, the DOJ announced the largest healthcare fraud takedown in history, which included charges against more than 412 individuals who were allegedly responsible for $1.3 billion in fraud losses.[2] The defendants included doctors, nurses, and other licensed medical professionals and, of those charged, more than 120 defendants were charged for their alleged roles in prescribing and distributing opioids and other dangerous narcotic drugs.

The following month, the DOJ announced the creation of the Opioid Fraud and Abuse Detection Unit, a new DOJ pilot program that will focus specifically on opioid-related healthcare fraud by using data to identify and prosecute individuals who contribute to the opioid epidemic.[3] The program includes funding 12 federal prosecutors who will spend

the next three years focusing exclusively on investigating and prosecuting healthcare fraud related to prescription opioids, including pill mills and pharmacies that unlawfully divert or dispense prescription opioids for unlawful purposes.

In September 2017, a coalition of 41 state Attorneys General announced a joint investigation focusing on manufacturers and distributors of prescription opioid drugs and whether those companies engaged in unlawful marketing or distribution practices.[4] The state investigation kicked off with subpoenas to pharmaceutical manufacturers Endo, Janssen, Teva, and Allergan, as well as distributors AmerisourceBergen, Cardinal Health, and McKesson.

Perhaps somewhat ironically, the DOJ is also cracking down on pain management specialists and other physicians who over utilize urine drug screening for opioid patients. A November 2017 *Bloomberg* article quoted both a federal prosecutor and an official from the Health & Human Services (HHS) Office of Inspector General (OIG), both of whom expressed concern over the amount of money that Medicare has paid doctors to conduct urine drug screening, much of which, according to the officials, may not meet medical necessity.[5]

Compounding pharmacy fraud

Another continuing focus area for the DOJ and its federal law enforcement partners is compounding pharmacy fraud. As reported as far back as February 2016 by *The Wall Street Journal*, the DOJ suspected over half a billion dollars in fraud related to compounding creams.[6] Since then, dozens of individuals have been prosecuted both criminally and civilly for compounding pharmacy fraud, and compounding pharmacies nationwide have become the focus of FCA investigations and administrative actions, such as payment suspensions and exclusion from federal healthcare programs.

In November 2017, for example, the owner of a Florida compounding pharmacy pleaded guilty to a $100 million fraud scheme, admitting that he manipulated billing codes and paid kickbacks and bribes in exchange for prescriptions billed to federal healthcare programs, including TRICARE.[7] The DOJ has also gone after individuals who committed fraud against private insurance companies related to compounding creams. For instance, in October 2017, the DOJ charged a compounding pharmacy sales representative in a prescription fraud conspiracy related to compounding pharmacy claims to various private payers, including Blue Cross Blue Shield of Alabama.[8]

Hospice fraud

Hospice providers have long been a favorite target of the DOJ and private whistleblowers, a trend that has continued. Most hospice fraud cases involve allegations of providing services to Medicare beneficiaries who are not terminally ill, and many involve alleged kickbacks to referring physicians, often times in the form of medical directorship fees.

In October 2017, for example, the nation's largest for-profit hospice chain—VITAS Healthcare—agreed to pay more than $75 million to resolve FCA allegations related to the submission of claims to Medicare for services to hospice patients who were not terminally ill.[9] Similarly, in June 2017, Genesis HealthCare agreed to pay over $50 million to resolve FCA allegations related to, among other things, medically unnecessary hospice services.[10]

Pharmaceutical fraud

Large pharmaceutical companies have also paid their fair share of recent FCA settlements. For example, in August 2017, Mylan agreed to pay $465 million to resolve allegations that it

violated the FCA by knowingly misclassifying EpiPen as a generic drug to avoid paying rebates owed to Medicaid. According to the DOJ, Mylan erroneously reported EpiPen as a generic drug to Medicaid despite the absence of any therapeutically equivalent drugs and, by doing so, was able to demand price increases in the private market while avoiding corresponding rebate obligations to Medicaid.[11]

The following month, another drug manufacturer—Aegerion Pharmaceuticals—agreed to pay more than $35 million to resolve criminal charges and FCA allegations that it introduced a misbranded drug into interstate commerce and then caused false claims to be submitted to federal healthcare programs for that drug. The DOJ alleged that Aegerion filed a misleading Risk Evaluation and Mitigation Strategy (REMS) report with the U.S. Food and Drug Administration (FDA) and failed to give healthcare providers complete and accurate information about the condition for which the drug in question was prescribed and how to properly diagnose that condition.[12]

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Electronic health record incentive payments

Electronic Health Record (EHR) incentive payments have also made their way to the top of the government enforcement list. Both EHR vendors and healthcare providers that use EHR software have become the focus of government fraud investigations, particularly related to the receipt of Meaningful Use incentive payments from Medicare.

In May 2017, EHR software giant eClinical Works (ECW) agreed to pay $155 million to settle an FCA investigation wherein the government alleged that ECW misrepresented the capabilities of its software and paid kickbacks to certain customers in exchange for promoting its product. Specifically, the DOJ alleged that ECW falsely obtained certification from HHS for its EHR software by concealing that the software did not comply with the requirements for certification. As a result, according to the DOJ, ECW caused the submission of false claims for federal Meaningful Use incentive payments.[13]

The federal government has also begun to focus on healthcare providers that have received potentially improper EHR Meaningful Use incentive payments. In June 2017, the OIG issued a report estimating that Medicare paid over $729 million in improper EHR incentive payments to healthcare providers who did not meet Meaningful Use requirements.[14] Not only has this led to administrative recoupment actions by the Centers for Medicare and Medicaid Services (CMS) and its contractors, but because providers are required to submit certain attestations in order to receive Meaningful Use incentive payments, the DOJ has begun using the FCA to investigate providers that submitted attestations that they knew—or should have known—contained false information.

Conclusion

These are just some of the recent top government enforcement priorities in the healthcare industry. As has been the case for the last decade or more, many other types of healthcare providers, including hospitals,

laboratories, ambulatory surgery centers, nursing homes, and physician groups have also found themselves in the crosshairs of government enforcement, a trend that is bound to continue for many years to come.

The author will present on this topic at the 2018 Compliance Institute, April 15-18, 2018 at the ARIA in Las Vegas.

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