DOJ Announces Agreement With Rite Aid to Settle Allegations of Violating the FCA and CSA in Relation to Opioid Dispensing

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Headlines that Matter for Companies and Executives in Regulated Industries

DOJ Announces Agreement With Rite Aid to Settle Allegations of Violating the FCA and CSA in Relation to Opioid Dispensing

On July 10, the US Department of Justice (DOJ) announced that Rite Aid Corporation and 10 of its subsidiaries agreed to settle the DOJ's allegations under the False Claims Act (FCA) and Controlled Substances Act (CSA) by paying $7.5 million and having an allowed claim of $401.8 million in the company's pending bankruptcy case.

According to the government's complaint, from May 2014 until June 2019, Rite Aid allegedly knowingly dispensed hundreds of thousands of unlawful prescriptions for controlled substances that lacked a medical purpose and/or were not valid prescriptions. The allegedly unlawful prescriptions were for dangerous drugs containing excessive quantities of opioids such as oxycodone and fentanyl. The government alleged that Rite Aid filled these prescriptions despite clear "red flags" and ignored substantial evidence that its stores were dispensing unlawful prescriptions.

The settlement also resolves claims that certain Rite Aid pharmacies in Washington State violated the CSA by filling prescriptions written by prescribers who lacked proper controlled substance prescribing authority and *qui tam* claims brought under the FCA by former Rite Aid pharmacy employees. In addition to the civil settlement, Rite Aid has entered into agreements with the Drug Enforcement Administration and the US Department of Health and Human Services Office of Inspector General to address its obligations going forward. These include increased communication, additional training for employees, and the creation of an anonymous hotline for reporting suspected illegal dispensing of controlled substances.

The case is *United States ex rel. White et al. v. Rite Aid Corp.*, No. 1:21-cv-1239 (N.D. Ohio).

The DOJ press release can be found here.

Home Health Providers to Pay $4.5 Million to Resolve Alleged FCA Violation for Providing Kickbacks to Assisted Living Facilities and Doctors

On June 28, home health agencies Guardian Health Care Inc., Gem City Home Care LLC, and Care Connection of Cincinnati LLC, along with their owner Evolution Health LLC, agreed to pay $4.496 million to settle allegations of violating the FCA.

The companies were accused of providing illegal kickbacks to assisted living facilities and physicians in exchange for Medicare referrals between 2013 and 2022. The kickbacks allegedly included lease payments, wellness health services, sports tickets, and meals. The government further alleges that the companies then billed Medicare for the services provided to the referred patients.

In response to the settlement, the DOJ emphasized the importance of ensuring that improper financial incentives do not influence patient care decisions and affirmed its commitment to protecting the integrity of federal health care programs. Notably, the companies received credit under the DOJ's guidelines for disclosing the conduct, identifying the individuals involved, and assisting in determining the losses caused to Medicare.

The DOJ press can be found here.

Pharmaceutical Subsidiary Pleads Guilty to False Prescription Scheme

On July 8, a subsidiary of DMK Pharmaceuticals Corp., US Compounding Inc., pleaded guilty to a scheme involving the shipment of drugs using false prescriptions, resulting in a $16.9 million criminal fine. The company will also forfeit approximately $4.2 million. The alleged scheme involved distributing a drug meant for horses across the United States, generating significant revenue. The company's former vice president of sales, Sam Glover, was also arrested and charged with drug adulteration and misbranding conspiracy in violation of the Food, Drug, and Cosmetic Act.

According to court documents, in exchange for a 10% sales commission, US Compounding allegedly engaged a veterinarian to illegally use their veterinary license to generate fake prescriptions and ship the drugs to consumers without legitimate prescriptions. Despite multiple pharmacists' objections and resignations, Glover and an unnamed sales representative continued to submit false prescriptions, generating millions of dollars of revenue.

According to the US Attorney's Office for the Southern District of New York, the "corporate resolution entered into today, and the indictment of Sam Glover, an executive who oversaw and allegedly perpetuated that scheme, reflects this office's commitment to holding accountable those who seek to violate laws designed to ensure that the drugs distributed across the United States are safe, necessary and legal." In reaching its resolution with US Compounding, the DOJ measured the nature, seriousness, and pervasiveness of the conduct, in addition to the company's willingness to cooperate with the investigation and make widespread remedial efforts.

The DOJ press release can be found here.

LA Drug Testing Lab to Pay $1 Million to Settle FCA Case Arising From Medicare Double-Billing Claims

According to July 1 settlement documents, Pacific Toxicology Laboratories, a Los Angeles-based drug testing lab, will pay at least $1 million to settle claims of double-billing Medicare for toxicology tests related to opioid use disorder treatments. The company admitted to billing Medicare through a bundled payment rate and separately invoicing the government insurer for the same tests using different medical billing codes. The settlement also includes a provision for the company to pay a quarter of its ordinary business income to federal authorities for five years.

According to court filings, Pacific Toxicology allegedly double-billed claims from January 2020 through March 2023. In the settlement agreement, the company admitted to separately billing Medicare for urine drug testing (UDT) even though UDT was included in the bundled payment rate made applicable by Medicare regulations. The claims were brough under the *qui tam* provisions of the FCA.

The DOJ press release can be found here.

Former Defense Department Employee Pleads Guilty to Defrauding Government in Fake Invoices Scheme

On July 2, Zelene Charles, a former civilian employee of the US Department of Defense at the Defense Language Institute in Monterey, California, pleaded guilty to defrauding the US government through a multi-year scheme involving fake invoices for non-existent supplies. The fraudulent activities, which occurred between December 2016 and April 2020 and involved approximately 185 fraudulent charges, resulted in a total loss of $624,250 to the government.

According to court documents, the fraudulent scheme involved creating fake purchase requests and invoices from both fictitious and legitimate businesses. The items listed were never purchased or received by the government. To hide her activities, Charles frequently changed the business names associated with intermediary accounts, using at least 78 different account names.

Charles faces a maximum penalty of 20 years in prison for the wire fraud charge and 10 years for the theft charge. She has also agreed to pay $624,500 in restitution and forfeit stolen government equipment.

The DOJ's press release can be found here.

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