



Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE

Wednesday, July 13, 2022

Solera Specialty Pharmacy Agrees to Enter into Deferred Prosecution Agreement; Company and CEO to Pay \$1.31 Million for Submitting False Claims for Anti- Overdose Drug

Florida-based Solera Specialty Pharmacy has entered into a deferred prosecution agreement and agreed to pay a \$1.31 million civil settlement to resolve allegations that it submitted fraudulent claims to Medicare for Evzio, a high-priced drug used in rapid reversal of opioid overdoses.

According to Solera's admissions in the criminal and civil agreements, the pharmacy dispensed Evzio from January 2017 to May 2018. During that time, Evzio was the highest-priced version of naloxone on the market and insurers frequently required the submission of prior authorization requests before they would approve coverage for Evzio. Solera completed Evzio prior authorization forms in place of the prescribing physicians, including instances in which Solera staff signed the forms without the physician's authorization and listed Solera's contact information as if it were the physician's information. In addition, Solera submitted Evzio prior authorization requests that contained false clinical information to secure approval for the expensive drug. Finally, Solera waived Medicare beneficiary co-payment obligations for Evzio on numerous occasions without analyzing whether the patient had a genuine financial hardship.

"Pharmacies, like all Medicare providers, must submit accurate claims," said Principal Deputy Assistant Attorney General Brian M. Boynton, head of the Justice Department's Civil Division. "This settlement demonstrates the department's continuing commitment to preventing submissions of false claims by entities at all levels of the health care delivery chain."

"Taxpayers deserve honesty and integrity from those who profit from federal health care programs," said U.S. Attorney Rachael S. Rollins for the District of Massachusetts. "This resolution will provide oversight to correct behavior and prevent it from happening again."

Solera entered into a deferred prosecution agreement in connection with a criminal information charging the pharmacy with one count of health care fraud. Solera and its CEO, Nicholas Saraniti, also entered into a civil settlement agreement and will pay the government \$1.31 million to resolve claims under the False Claims Act.

In connection with the settlements, Solera and Saraniti entered into a three-year integrity agreement (IA) with the U.S. Department of Health and Human Services Office of Inspector General (HHS-OIG). The IA requires, among other things, Solera implement measures designed to ensure that its submission of claims for pharmaceutical products complies with applicable law relating to prior authorizations and collection of beneficiary co-payment obligations. In addition, the IA requires reviews by an independent review organization.

"The submission of truthful and accurate documentation by all parties involved in the delivery of health care goods or services is essential to the integrity of federal health care programs. This includes pharmacies that submit claims for pharmaceutical products," said Special Agent in Charge Phillip M. Coyne of the HHS-OIG. "Along with our law enforcement partners, HHS-OIG is committed to preventing fraud in Medicare and other taxpayer-funded health care programs."

“Today’s settlement resolves serious allegations that Solera submitted false and fraudulent claims to Medicare for their own financial gain, pilfering funds from a program intended to help those truly in need, while going behind the backs of prescribing physicians to secure approval for this expensive anti-overdose drug,” said Special Agent in Charge Joseph R. Bonavolonta of the FBI Boston Division. “This is not a victimless crime — health care fraud is a crime against all of us who contribute hard earned income and taxes into the system. The FBI will continue to work with our law enforcement partners to ensure those who willingly defraud the American people are held accountable.”

The civil settlement includes the resolution of claims brought under the *qui tam* or whistleblower provisions of the False Claims Act by Rebecca Socol, a former employee of kaléo Inc., the manufacturer of Evzio. Under those provisions, a private party can file an action on behalf of the United States and receive a portion of any recovery. As part of this resolution, Ms. Socol will receive \$262,000 of the settlement amount. The *qui tam* case is captioned *United States ex rel. Socol v. Solera Specialty Pharmacy LLC.*, 18-cv010050-RGS (D. Mass.) (under seal). In 2021, the department announced settlements with kaléo for \$12.7 million and with other pharmacies for \$1 million relating to the submission of false claims for Evzio.

The resolution obtained in this matter was the result of a coordinated effort between the Justice Department’s Civil Division, Commercial Litigation Branch, Fraud Section and the U.S. Attorney’s Office for the District of Massachusetts, with assistance from the HHS OIG; the Department of Defense Criminal Investigative Service; the Office of Personal Management, Office of Inspector General; the FBI; and the U.S. Postal Service Office of Inspector General.

The investigation and resolution of this matter illustrates the government’s emphasis on combating health care fraud. One of the most powerful tools in this effort is the False Claims Act. Tips and complaints from all sources about potential fraud, waste, abuse and mismanagement can be reported to the Department of Health and Human Services at 800-HHS-TIPS (800-447-8477).

The matter was handled by Senior Trial Counsel Sarah Arni of the Justice Department’s Civil Division and Assistant U.S. Attorneys David Derusha, Abraham George and Amanda P.M. Strachan for the District of Massachusetts.

The claims resolved by the settlement are allegations only and there has been no determination of liability.

Component(s):

Civil Division

USAO - Massachusetts

Press Release Number:

22-744

Updated July 13, 2022