

## June 2023 FCA Settlement Wrap-Up: DOJ Continues to Crack Down on Health Care Fraud

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The U.S. Department of Justice (DOJ) announced several settlements related to False Claims Act (FCA) allegations this June. The settlements involved various types of health care entities, which shows the DOJ's continued interest in pursuing FCA allegations across the health care industry.

### CENCAL HEALTH SETTLEMENTS

On June 29, 2023, the DOJ announced four settlements that resolve allegations that Santa Barbara San Luis Obispo Regional Health Authority d/b/a CenCal Health (CenCal), Cottage Health System (Cottage), Sansum Clinic (Sansum), and Community Health Centers of the Central Coast (CHC) violated the federal FCA and the California False Claims Act by submitting or causing the submission of false claims to California's Medicaid Program (Medi-Cal) related to Medicaid Adult Expansion under the Patient Protection and Affordable Care Act (ACA).<sup>¶</sup> These organizations have agreed to pay a total of \$68 million to resolve these allegations.

CenCal is a county-organized health system (COHS) that contracts to arrange for the provision of health care services under Medi-Cal in Santa Barbara County and San Luis Obispo County, California. Cottage is a not-for-profit hospital network operating in Santa Barbara County. Sansum is a non-profit outpatient clinic operating in Santa Barbara County. CHC is a non-profit community health center operating in Santa Barbara and San Luis Obispo Counties.

Beginning in January 2014, Medi-Cal was expanded, pursuant to the ACA, to cover the previously uninsured "Adult Expansion" population—adults between the ages of 19 and 64 without dependent children with annual incomes up to 138% of the federal poverty level.<sup>¶</sup> Under contracts between California's Department of Health Care Services ("DHCS") and CenCal, if CenCal did not spend at least 85% of the funds it received for the Adult Expansion population on "allowed medical expenses," CenCal was required to pay back to the state the difference between 85% and what it actually spent. California, in turn, was required to return that amount to the federal government.

The United States and California alleged that the submissions by these organizations were not "allowed medical expenses" permissible under the contract between DHCS and CenCal; were pre-determined amounts that did not reflect the fair market value of any Enhanced Services provided; and/or the Enhanced Services were duplicative of

services already required to be rendered. The United States and California also alleged that the payments were unlawful gifts of public funds in violation of the California Constitution.

To settle allegations that it fraudulently submitted false claims to Medi-Cal for Enhanced Services to Adult Expansion Medi-Cal members: CenCal has agreed to pay the United States \$49.5 million; Cottage has agreed to pay the United States \$ 9 million; Sansum has agreed to pay the United States \$4.5 million; and CHC has agreed to pay the United States \$3.15 million.<sup>23</sup> Additionally, California will receive payments totaling \$1.85 million. The civil settlements resolve claims brought under the *qui tam* or whistleblower provisions of the FCA. The claims were brought by Julio Bordas, CenCal's former medical director.

### **SMART PHARMACY, INC. SETTLEMENT**

On June 15, 2023, the DOJ announced that two Jacksonville, Florida pharmacies—Smart Pharmacy, Inc. and SP2, LLC—along with owner Gregory Balotin (collectively, Smart Pharmacy) agreed to pay at least \$7.4 million to resolve civil claims that they violated the FCA by adding the antipsychotic drug aripiprazole to topical compounded pain creams and paying remuneration to patients to induce purchases of compounded drugs to increase profits from Medicare and TRICARE reimbursements.<sup>24</sup>

The claims against Smart Pharmacy were initiated through two whistleblower suits filed pursuant to the FCA's *qui tam* provisions in the United States District Court for the Middle District of Florida. Under the *qui tam* provisions of the FCA, a private party can file an action on behalf of the United States and receive a portion of any recovery. The Relators—Amy Sanchez and Ashok Kohli—were former employees of Smart Pharmacy and filed suit on December 2, 2014 and March 31, 2016 respectively.<sup>25</sup> On March 15, 2019, the United States filed notices to partially intervene in the Sanchez Civil Action and Kohli Civil Action. On June 6, 2019, the cases were consolidated.

In its First Amended Complaint in Intervention,<sup>26</sup> which was filed on March 2, 2020, the United States alleged that from July 30, 2015 to December 31, 2016, Smart Pharmacy included crushed aripiprazole pills in topical compounded creams used for pain treatment to increase its profits on prescriptions for topical compounded pain drugs submitted to Medicare and TRICARE. Aripiprazole is approved for oral use, and the United States alleged that Smart Pharmacy included the crushed pills in topical compounded creams knowing that there was not an adequate clinical basis to justify doing so. The United States further alleged that from January 1, 2011 to May 31, 2016, Smart Pharmacy offered and paid remuneration to patients to induce patients to purchase compounded drugs reimbursed by Medicare and TRICARE by waiving or failing to collect copayments. According to the United States, Smart Pharmacy knowingly presented, or caused to be presented, false or fraudulent claims and used false records or statements material to false claims to Medicare and TRICARE as a result of this conduct, which violated the FCA.

Following these allegations, in 2022, Smart Pharmacy, Inc. and SP2 filed for voluntary dissolution with the Florida Department of State and agreed to resolve the claims. The settlement requires Smart Pharmacy to pay \$7.4 million, plus interest and additional potential contingency payments.<sup>27</sup> The United States will pay the Relators a total of \$2.2 million upon receipt of the initial payment. In addition to resolving the FCA claims, Gregory Balotin entered into a three-year Corporate Integrity Agreement with the Department of Health and Human Services Office of Inspector General (HHS-OIG), which includes an annual claims review by an independent review organization.

### **THE ALTA VISTA AND ROCKPORT SETTLEMENT**

On June 21, 2023, the DOJ announced that California-based skilled nursing facility, Alta Vista Healthcare & Wellness Centre, LLC (Alta Vista), and its management company, Rockport Healthcare Services ("Rockport"), agreed to a \$3.825 million settlement with the United States and California to resolve civil claims that it violated the federal FCA, California False Claims Act, and Anti-Kickback Statute ("AKS") by providing unlawful remuneration in exchange for referrals, causing the submission of false claims to Medicare and Medicaid.<sup>28</sup>

The AKS prohibits the exchange, or offer to exchange, anything of value in an effort to induce the referral of business covered by Medicare, Medicaid, and other federally funded programs. The claims against Alta Vista and Rockport were initiated on April 9, 2015 by a relator who filed suit pursuant to the FCA's whistleblower provisions. The Relator, a former accounting employee at Alta Vista, filed the action on behalf of the United States in the United

States District Court for the Middle District of Florida. It was later transferred to the Central District of California and amended.<sup>[9]</sup>

The United States and California contend that Alta Vista, under the direction and control of Rockport, gave certain physicians extravagant gifts and monthly stipends of \$2,500 to \$4,000. This conduct, which took place from January 1, 2009 through December 31, 2019, resulted in the submission of or caused the submission of false claims to Medicare and Medicaid.

The settlement requires Alta Vista and Rockport to pay a total of \$3.825 million to the United States and California,<sup>[10]</sup> of which \$3,228,300 is allocated to resolve the United States' claims and \$596,000 is allocated to the resolution of California's claims. The United States will pay the Relator \$581,094 upon receipt of the settlement amount. In connection with the settlement, Alta Vista and Rockport entered into a five-year Corporate Integrity Agreement with the HHS-OIG that requires, among other compliance obligations, an independent review organization to review Alta Vista's and Rockport's physician relationships.

## THE VITALAXIS INC. SETTLEMENT

On June 16, 2023, the DOJ announced that a Maryland-based billing company for diagnostic laboratories, VitalAxis Inc., agreed to a \$300,479.58 settlement with the United States to resolve allegations that it caused the submission of false claims to Medicare "for medically unnecessary respiratory pathogen panels run on seniors who received COVID-19 tests," which violated the FCA.<sup>[11]</sup>

VitalAxis provides billing services for diagnostic laboratories, among other services. VitalDX, a test-ordering platform, enables clients to view cloud-based medical test results and automates billing to health insurance programs. The DOJ alleged that between May 7, 2020 and November 26, 2020, VitalAxis performed billing services for a diagnostic laboratory in Atlanta, Georgia. This laboratory provided COVID-19 testing to residents of senior living services. For billing related to one senior community, a laboratory allegedly directed VitalAxis to bill Medicare for Respiratory Pathogen Panels ("RPPs") that, according to the laboratory, were ordered by a physician who did not order the tests and was ineligible to treat Medicare beneficiaries. VitalAxis, without authorization, found and used a different physician's National Provider Identifier ("NPI") number for claims submitted for RPPs billed with COVID-19 tests. Consequently, Medicare paid for medically unnecessary RPPs in violation of the FCA.

The settlement requires VitalAxis to pay \$300,479.58 to the United States, but VitalAxis did receive cooperation credit for performing and disclosing the results of an internal investigation, disclosing relevant facts and materials to the DOJ (including information related to the misconduct of other individuals and entities), and admitting liability.

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## Key Takeaways

- The DOJ continues to tackle healthcare fraud by extracting substantial financial penalties, including against individuals and smaller entities that are less capable of paying larger settlements.
- The DOJ remains committed to creative settlements, including ongoing oversight of individuals and entities.
- The DOJ made a point to credit VitalAxis for its cooperation in the investigation, which may have impacted the value of the settlement or decision to prosecute.

If you have additional questions or need further assistance please reach out to Amandeep Sidhu (Partner, Government Investigations, Enforcement, and Compliance), Reed Stephens (Partner, Government Investigations, Enforcement, and Compliance), Amy Kearbey (Partner, Government Investigations, Enforcement, and Compliance), Christopher Parker (Associate, Government Investigations, Enforcement, and Compliance), Elayna Napoli (Associate, General Litigation) or your Winston & Strawn relationship attorney.

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<sup>[11]</sup> The DOJ press release is available here: <https://www.justice.gov/opa/pr/california-county-organized-health-system-and-three-health-care-providers-agree-pay-68>.

<sup>2</sup> Additional information on Medi-Cal expansion under the ACA can be found here: <https://www.dhcs.ca.gov/>

[individuals/Pages/AffordableCareActLinks.aspx#:~:text=The%20ACA's%20expansion%20of%20Medica%20healthier%2C%20more%20productive%20state.](#)

<sup>3</sup> The settlement agreement entered into by the United States, the State of California, the relator, and CenCal can be found here:

<https://www.justice.gov/media/1303366/dl?inline>. The settlement agreement entered into by the United States, the State of California, the relator, and Cottage can be found here: <https://www.justice.gov/media/1303381/dl?inline>. The settlement agreement entered into by the United States, the State of California, the relator, and Sansum can be found here: <https://www.justice.gov/media/1303376/dl?inline>. The settlement agreement entered into by the United States, the State of California, the relator, and CHC can be found here: <https://www.justice.gov/media/1303371/dl?inline>.

<sup>4</sup> The DOJ press release is available here: <https://www.justice.gov/opa/pr/two-jacksonville-compounding-pharmacies-and-their-owner-agree-pay-least-74-million-resolve>.

<sup>5</sup> *United States ex rel. Sanchez v. Smart Pharmacy, Inc., et al.*, No. 14-cv-1453 (M.D. Fla.); *United States ex rel. Kohli v. Smart Pharmacy, Inc., et al.*, No. 16-cv-387 (M.D. Fla.).

<sup>6</sup> The United States filed a Complaint in Intervention in the consolidated cases on June 13, 2019.

<sup>7</sup> The settlement amount was based on Smart Pharmacy's ability to pay in connection with the bankruptcy. See DOJ press release.

<sup>8</sup> The DOJ press release is available here: <https://www.justice.gov/opa/pr/california-skilled-nursing-facility-and-management-company-agree-pay-3825-million-settle>.

<sup>9</sup> *United States et al. ex rel. Orozco v. Rehnitz*, CV 15-6177 JVS (JEMx).

<sup>10</sup> The settlement amount was negotiated based on Alta Vista's and Rockport's ability to pay. See DOJ press release.

<sup>11</sup> The DOJ press release is available here: <https://www.justice.gov/opa/pr/lab-billing-company-settles-false-claims-act-allegations-relating-unnecessary-respiratory>.

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