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Blog Post

False Claims Act Enforcement Trends in Healthcare: FY 2024

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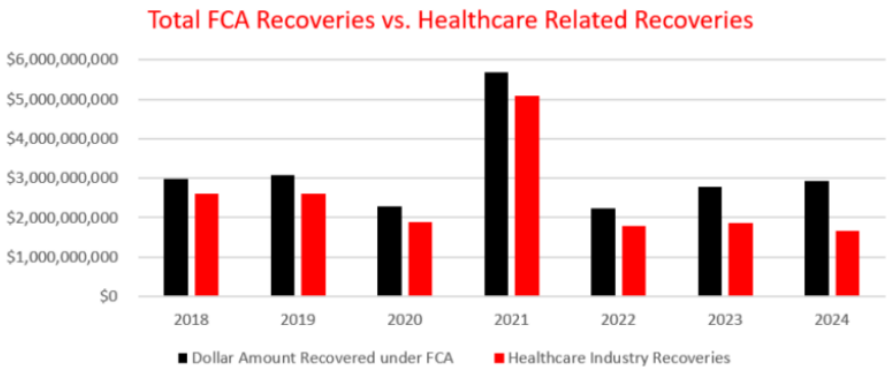
The Department of Justice (DOJ) released its annual False Claims Act (FCA) enforcement statistics on January 15, 2025, announcing that it had recovered in excess of $2.9 billion from FCA resolutions during Fiscal Year (FY) 2024 (ending September 30, 2024).

The $2.9 billion recovered in FY 2024 reflects a modest (approximately five percent) increase from the nearly $2.8 billion that the DOJ recovered under the FCA in FY 2023. FY 2024 is also the second-highest recovery since FY 2020, but still amounts to less than half of the highwater mark of $6.1 billion recovered in FY 2014. Since FY 2009, the government's FCA recovery has not dipped below $2.2 billion.



The healthcare industry once again played a disproportionate role in FCA recoveries, accounting for over $1.67 billion, or more than 57 percent, of the

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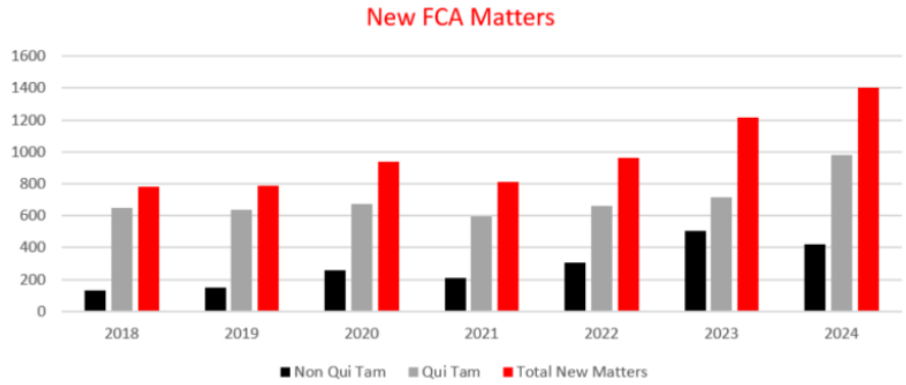
$2.9 billion in total FCA proceeds in FY 2024. Despite these numbers, this percentage marks the second consecutive year in which healthcare recoveries reflect a lower percentage of overall recoveries. Over the last decade, the portion of FCA recoveries attributable to the healthcare industry has typically been between 80 to 88 percent of total receipts. In 2023, the healthcare industry's share dropped to 66 percent. This year, that share has dropped further — FY 2024's 57% represents the lowest percentage of total FCA recoveries related to healthcare since FY 2017, when that number was just over 62 percent. However, healthcare has consistently been a primary target of FCA enforcement and represents 69 percent of overall recoveries since 1987 at $54 billion.

FCA enforcement of Department of Defense (DOD) contracts accounted for just over $93 million, only 3 percent of the total government recoveries. Matters outside of the healthcare and defense industries accounted for the remaining $1.1 billion, or more than 39 percent of total recoveries in FY 2024. More than $250 million of those receipts emanated from Paycheck Protection Program (PPP) fraud.



The overall number of new matters opened by the government and relator proxies in FY 2024 reached an all-time high of 1,402, topping the previous record from FY 2023 by 15 percent. Whistleblowers filed 979 of these lawsuits – the highest number in a fiscal year since the DOJ began keeping records in 1987. The DOJ opened 423 of these new matters, the second-highest on record following FY 2023 (505),

representing the DOJ's vigorous enforcement on its own initiative.

Overall, FY 2024 resolutions of *qui tam* lawsuits, whether or not the government intervened, yielded over $2.4 billion – 82 percent of total FCA recoveries. Whistleblowers received over $400 million, with more than $261 million going to whistleblowers in healthcare matters.

The DOJ also recorded the second-highest number of FCA-related case resolutions in 2024, with the government and whistleblowers being party to 558 settlements and judgments. This year's record is just shy of the number of recoveries in FY 2023, which continues to hold the record at 566 case resolutions.

FCA Enforcement Trends in Healthcare

Within healthcare, the government's recoveries reveal at least four trends:

- A continued emphasis on allegations of billing for unnecessary healthcare services, substandard care, and improper billing, following a years-long trend.

- Pursuit of violations of the Anti-Kickback Statute (AKS) and the Physician Self-Referral Law (Stark Law), including by a healthcare system, skilled nursing facilities, and a clinical laboratory.

- An uptick, following the trend in FY 2023, of enforcement related to the Medicare Advantage (Medicare Part C) program, including a $60 million settlement and active litigation against at least three other entities.

- FCA enforcement related to the Opioid Epidemic and providers, pharmaceutical companies, and pharmacies that contributed to it, with two settlement agreements alone amounting to nearly $900 million in recoveries (involving general unsecured claims of entities in bankruptcy).

Substandard Care and Unnecessary and Improper Billing

A businessman paid over $27 million to resolve allegations that he and his companies conspired with others to submit false claims to and receive payments from Medicare for cancer genomic tests that were not medically necessary. This matter also involved allegations related to kickbacks in exchange for Medicare referrals. The scheme involved telemarketers soliciting Medicare beneficiaries for purportedly “free” cancer genomic tests that were then prescribed by telemedicine providers, with the billing laboratories and a hospital submitting claims for payments to the government. The whistleblower that brought the action received approximately $4.7 million.

Twelve affiliated skilled nursing facilities agreed to pay $21.3 million to resolve allegations that they knowingly billed for unreasonable, unnecessary, unskilled, or uncompleted therapy services, and that they falsified information in medical records. The company admitted that it implemented quotas for facilities, which led to some Medicare beneficiaries receiving therapy that was not based upon their individualized medical assessment and was provided for a period that was longer than medically necessary.

Six health facilities providing behavioral health services paid $16.6 million to resolve allegations that they knowingly billed for inpatient behavioral health services that were medically unnecessary or that otherwise did not comply with federal and state regulations. The government alleged the facilities kept patients in inpatient treatment longer than needed and that inadequate staffing, training, and supervision led to assaults, elopements, suicides, and other patient harm.

Stark Law and Anti-Kickback Statute

A healthcare network paid $345 million to resolve allegations that it submitted claims to Medicare for services referred in violation of the Stark Law, which requires, among other things, that a hospital employing a physician may not submit claims for certain designated health services that are referred by the physician unless the physician's compensation is consistent with fair market value. The government alleged that the network paid its employed physicians, including cardiologists, cardiothoracic surgeons, vascular surgeons, neurosurgeons, and breast surgeons, compensation that was well above fair market value. In addition, the network awarded the physicians bonuses that were tied to the number and value of their referrals. The government alleged that the network implemented a scheme to recruit physicians for the purpose of capturing their referrals.

A dialysis provider paid $34.5 million to resolve allegations it paid kickbacks to a competitor to induce referrals to the provider's former subsidiary that provided pharmacy services for dialysis patients. The government also alleged the provider paid kickbacks to nephrologists and vascular physicians to induce referrals to its clinics.

Six skilled nursing facilities and a management company and its owner entered into a $45.6 million consent judgment to resolve allegations that they paid kickbacks to physicians to induce patient referrals in the form of sham medical directorship agreements, which were ostensibly compensation for administrative services. The government alleged that the defendants hired physicians who promised a large number of referrals in advance and that physicians were paid in proportion to the number of their anticipated referrals.

A medical device manufacturer paid $12 million to resolve allegations that it paid kickbacks to spine surgeons to induce them to use the manufacturer's spinal devices. The improper remuneration to seventeen different physicians took the form of

consulting fees, intellectual property acquisition and licensing fees, registry payments and performance shares in the manufacturer, travel to a luxury ski resort, and lavish dinners and holiday parties for physicians' office staffs and family members. The whistleblower that brought the case received approximately $2.2 million.

A clinical laboratory and its CEO paid $10.3 million to resolve allegations that they paid five types of kickbacks, which they attempted to obscure, including commission-based kickbacks to marketers to recommend the laboratory to providers, and Management Services Organization (MSO) payments to physicians disguised as investment returns that were actually payments to induce referrals.

Medicare Advantage

A provider paid $60 million to resolve allegations that it paid kickbacks to insurance agents in exchange for recruiting seniors to its primary care clinics. The provider allegedly incentivized insurance agents to steer seniors towards MA plans that the provider contracted with, leading the agents to base their recommendations upon the provider's contracts rather than the best interests of seniors seeking to enroll in MA plans.

In addition, the government has intervened in an FCA lawsuit involving an insurance company allegedly mischarging the Medicare Advantage program, filed an FCA lawsuit against a separate insurance company for allegedly falsely certifying the accuracy of its diagnosis data to unlock millions of dollars in Medicare funds that it was not entitled to receive, and intervened in an FCA lawsuit against a health care consortium involving allegations that physicians were pressured into adding risk-adjusting diagnoses to patient medical records long after a patient encounter in order to increase Medicare reimbursement.

Opioid Epidemic

A pharmaceutical company entered a $469 million settlement to resolve allegations that it used a marketing scheme targeting healthcare providers that the company knew were prescribing its opioid medication for non-medically accepted indications. The providers that it targeted represented less than 10% of providers prescribing the company's medications but wrote more than half of all prescriptions for the drug. The company also admitted in a criminal plea that it misbranded its drug in violation of the Food Drugs and Cosmetics Act (FDCA) by touting its opioid drug's supposed abuse deterrence, tamper resistance, and crush resistance despite the lack of clinical data supporting those claims. According to a separate criminal plea, the company's sales representatives used demonstrations, including hitting a demonstration pill pack with a hammer, to convey these messages to healthcare providers.

A pharmacy chain agreed to a settlement worth more than $408 million to settle allegations it knowingly dispensed hundreds of thousands of unlawful prescriptions that lacked a legitimate medical purpose and that were not valid prescriptions, including for dangerous combinations of drugs known as "the trinity" (involving an opioid, a benzodiazepine, and carisoprodol). The government alleged that the chain filled these prescriptions despite clear red flags, ignored substantial evidence that this was occurring after pharmacists raised concerns, and even intentionally deleted internal notes written by its pharmacists about suspicious prescribers. The company also violated the Controlled Substances Act (CSA) by filling prescriptions by prescribers who did not have the proper controlled substance prescribing authority. In addition, the company entered into a memorandum of agreement (MOA) with the Drug Enforcement Agency and a corporate integrity agreement (CIA) with Health and Human Services Office of Inspector General to address its obligations moving forward.

An Ohio physician entered into a consent judgment to settle allegations that he unlawfully issued opioids and other controlled substances prescriptions without a legitimate basis in violation of the CSA and FCA. According to the government complaint, at least one patient died from an overdose of Fentanyl patches the physician prescribed. The physician is prohibited from prescribing opioids and other controlled substances, was ordered to pay $4.7 million, and was sentenced to 42 months in prison and 1 year of home confinement in a related criminal case.

Other Key FCA Takeaways From FY 2024

- *Qui Tam* Constitutionality

As we discussed in our blogs on October 17, 2024 and January 16, 2025, *U.S. ex rel. Zafirov v. Florida Medical Associates, LLC, et al.* was the first case to hold that the *qui tam* provision of the federal False Claims Act violates the Appointments Clause of the Constitution. An ultimate invalidation of the *qui tam* provision on constitutional grounds would change the landscape of fraud, waste, and abuse enforcement nationwide. The case is currently up on Appeal before the Eleventh Circuit.

- DOJ FCA Cooperation Credits

In our FY 2023 blog, we noted that the DOJ had begun, for the first time, acknowledging cooperation credits provided to defendants that are cooperative in FCA investigations. That trend continued this year, with the DOJ noting that cooperative measures in FY 2024 included "self-disclosures, assistance with the determination of government losses, disclosures of internal investigations and facts not known to the government, and remedial measures such as implementing tracking system enhancements or terminating or separating employees."

- Private Equity and Venture Capital

Last year, we noted that Principal Deputy Assistant Attorney General Brian M. Boynton expressed concern with firm-set revenue targets in healthcare and noted that the DOJ had pursued cases involving private equity firms in recent years. The FY 2024 press release makes no mention of or reference to private equity and venture capital in healthcare. While this may be a sign that the DOJ has not yet reached any notable case resolutions with private equity sponsors, *qui tam* relators continue to name investors as defendants in FCA cases. In the meantime, healthcare investors should continue to conduct robust due diligence, pre- or post-closing, to assess potential FCA exposure.

Conclusion

FY 2024 continued the DOJ's decades-long reliance on the FCA to combat fraud and to recoup funds paid to providers based on knowingly false claims or statements. FCA recoveries for improper billing, substandard care, unnecessary services, and Stark and AKS violations demonstrate that healthcare entities remain the perennial favorite target of FCA actions.

In a sign of the times, the DOJ also saw three key recoveries related to the Opioid Epidemic spanning different levels in the healthcare industry — a pharmaceutical company, a national pharmacy chain, and an individual physician. The DOJ also focused on Medicare Advantage for a second year in a row, including active litigation that will continue into FY 2025.

Recoveries based on PPP fraud saw an uptick this year compared to FY 2023, representing the DOJ's relentless pursuit of fraud long after the fact. Supreme Court precedent allows relators, in some instances, to recover damages for FCA violations that occurred up to ten years prior.

Recoveries based on military contractors allegedly defrauding the DOD were lower this year, representing only three percent of overall recoveries, compared to more than 20 percent in FY 2023.

FY 2025 will see continued high-stakes litigation in *Zafirov* involving the constitutionality of the FCA's *qui tam* provision. Akerman will be closely monitoring these developments and other trends in FCA enforcement throughout the year.

Any organization conducting itself in the American healthcare system is acutely aware that it is perhaps the most heavily regulated industry in the world. Akerman has a specialized team of attorneys dedicated to advising and guiding clients with healthcare compliance as well as FCA, Anti-Kickback, and Stark Law investigations and litigation.
