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Government Investigations & White-Collar Alert

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False Claims Act enforcement in 2023

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The Justice Department's Civil Fraud Section reviewed 2023 False Claims Act recoveries in in its annual press release and offered a glimpse at what to expect in 2024.

What's the impact?

- The Fraud Section reported the "highest number of settlements and judgments in history," with the healthcare industry incurring the majority of the total liability.
- The department's fervour in pursuing claims underscores that anyone who benefits from a federal program must be constantly vigilant to ensure compliance with all applicable statutes, regulations, and rules.

The Justice Department's Civil Fraud Section took its annual victory lap last week, announcing False Claims Act recoveries of nearly $2.7 billion in fiscal year 2023.

The "Fraud Section," as it is known within the department, supervises FCA investigations and qui tam litigation across the country and, in larger matters, takes the lead role. Its annual press release reflects the department's fraud and abuse enforcement priorities and offers hints at what is to come in 2024 and beyond.

The press release touts the "highest number of settlements and judgments in history." As usual, recoveries from healthcare industry participants constituted the majority of the department's haul ($1.8 of $2.68 billion in total). The Fraud Section highlights recoveries with respect to the Medicare Advantage program, cases involving medically unnecessary services and substandard care, the opioid epidemic, and unlawful kickbacks, as well as certain procurement and pandemic fraud recoveries. It also emphasizes recent efforts to hold individuals accountable in the wake of the Yates Memo, and it continues to feature the department's "Cyber-Fraud Initiative," originally announced in 2021. To date, the Cyber-Fraud Initiative has seen few settlements, but accounts of sealed cases percolating through the system abound.

By and large, the press release speaks for itself. The False Claims Act remains the government's (and whistleblower's) most powerful civil anti-fraud statute, and anyone who benefits from a federal program must be constantly vigilant to ensure compliance with all applicable statutes, regulations, and rules. Rather than recount the specifics of the cases profiled, Nixon Peabody's False Claims Act team offers reflections on the press release's standout lines.

Dramatic increases in FCA investigations and lawsuits

"The number of lawsuits filed under the qui tam provisions of the act has grown significantly since 1986, with 712 qui tams filed this past year—an average of more than 13 new cases every week."

- There were more qui tams filed in 2023 than any year since 2014, in the wake of the Great Recession. The milestone underscores the continuing impact that private citizens have on government enforcement priorities and the importance of handling internal compliance complaints with extreme care.
- More striking, in 2023, the department opened a record 500 investigations without a qui tam—far eclipsing its previous highwater mark of 305.
- The large spike in government-initiated FCA investigations may be explained by the department's increasing reliance on "big data" analytics to identify trends that, to the government, may indicate fraud. Being an outlier in the data is increasingly perilous.

Medicaid and Medicare Advantage

The department takes credit for being "instrumental in recovering additional amounts from state Medicaid programs" and highlights a large settlement with a Medicare Advantage provider, noting "Medicare Part C is now the largest component of Medicare, both in terms of federal dollars spent and the number of beneficiaries."

- As it has done for the last three years, the department has used its annual FCA press release to specifically highlight recent recoveries in the Medicare Advantage space.

- A significant majority of Medicaid patients and close to half of Medicare patients now receive their benefits through Medicaid managed care organizations (MCOs) and Medicare Advantage (MA) insurers.
- MCOs and MA plans are private health insurance companies that receive billions of dollars from state Medicaid agencies and Centers for Medicare & Medicaid Services (CMS) based on annual or biannual bids. They are not obligated to use all of that money on patient care; some can be retained as profit or used for administrative costs. Nevertheless, the government has increasingly sought to include the full amount of MCO/MA-plan-paid claims in FCA settlements, in addition to payments by the "traditional" Medicaid and Medicare programs.
- Accounting for nuances like the medical loss ratio and the inability of private insurers to release conduct in FCA settlement agreements will take on heightened importance in 2024.
- Given the department's increasing scrutiny of the Medicare Advantage program, program participants must be conscious of critical developments with respect to compliance obligations and expectations. This includes the anticipated publication of the Department of Health & Human Services-Office of the Inspector General's (HHS-OIG's) first industry segment-specific compliance program guidance addressing Medicare Advantage, which HHS-OIG expects to publish in 2024.

Medically unnecessary and substandard services

"The provision of [medically unnecessary services and substandard care] not only wastes taxpayer funds but also can expose patients to harmful procedures and treatments or cause them to forego other potentially more effective treatments."

- The pursuit of recoveries in connection with allegations of medically unnecessary or worthless services remains a department priority. Operators of skilled nursing facilities, long-term acute care facilities, hospice facilities, home health services providers, laboratories, telemedicine providers, and medical device suppliers, manufacturers, and distributors are frequent targets.
- As the health sector continues to emerge from the COVID-19 pandemic and stabilize, expect whistleblowers and others tasked with oversight of government healthcare programs to scrutinize processes implemented and actions taken during the COVID-19 pandemic, including motives and justifications, in pursuit of FCA claims.
- HHS-OIG has designated nursing facility compliance an agency priority and will be issuing its industry segment-specific compliance program guidance specific to nursing facilities in 2024. Facilities that do not prioritize the compliance function are at increased risk of FCA liability.

Bankruptcy filings

The Fraud Section highlights its "proofs of claim in the Chapter 11 bankruptcy" actions commenced by Endo Health Solutions Inc. and Kabbage Inc.

- Typically, if a defendant elects to resolve FCA allegations, the government will not put the defendant out of business, even if the defendant lacks the ability to pay. The Fraud Section's ability to pay process involves a detailed review of financials to determine a settlement amount that hurts but does not kill.
- Still, bankruptcy may be inevitable, and even bankruptcy may not discharge FCA liability. The Fraud Section takes the position that a "debt" arises upon a credible allegation of fraud, usually indicated by the department's intervention or filing of a complaint in intervention. If a defendant declares bankruptcy, the Fraud Section may file a proof of claim, as it did numerous times last year. Under various federal statutes, claims of the United States may rank ahead of claims of other creditors.
- The Fraud Section's willingness to partner with the department's corporate finance or "CorpFin" section and litigate in bankruptcy courts highlights the fervour with which the department continues to pursue alleged FCA violations.

Anti-kickback enforcement

"Kickbacks paid or received by healthcare providers undermine the integrity of federal healthcare programs by tainting medical decision-making."

- The department zealously maintains that it is not required to allege a causal connection between kickbacks and independent medical judgment and that all claims "tainted" by a kickback are false, not just those directly "resulting from" one.
- But those bedrock positions are under judicial attack, with the Sixth and Eight Circuits disagreeing with the Third Circuit and holding that the government must prove that, but for the alleged kickbacks, the alleged false claims would not have been submitted.
- The same issue is currently pending in the First Circuit. 2024 may be the year that the Circuit split makes its way to the Supreme Court. Regardless, the Anti-Kickback Statute will remain a key predicate to FCA investigations and litigation.
- The department demonstrated in 2023 that it is willing to support the trial of FCA cases based on illegal kickbacks, as demonstrated in *United States ex rel. Fesenmaier v. Cameron-Ehlen Group Inc. et al.*, No. 13-cv-3003, 2024 WL 489708 (D. Minn. Feb. 8, 2024), in which a jury issued a $487 million verdict against an ophthalmic supply company and its late co-founder based on gifts provided to ophthalmologists to induce the use of the company's products.
- Violations of the Physician Self-Referral Law, also known as the Stark Law, are often also

alleged in connection with allegations of illegal kickbacks. Although not highlighted in the 2023 statistics, as the department's fiscal year ends on September 30, in December 2023, the department announced the largest FCA settlement based on alleged Stark Law violations in history after an Indianapolis-based healthcare network agreed to pay $345 million.

Resolutions involving EHR

"The Justice Department announced two resolutions involving kickbacks relating to electronic health records (EHR)," one of which allegedly caused "certain of its users to submit false claims for incentive payments under the Department of Health and Human Services' EHR Incentive Programs."

- EHR incentive programs promote the expansion of EHR technology, which the government continues to view as positive for patient care.
- EHR incentive payments also continue to be used as a basis for FCA liability. If an EHR vendor or intermediary provides technology that does not meet all the government's criteria and a customer, often unaware of the deficiencies, claims entitlement to incentive payments, FCA liability may arise. That is, although EHR manufacturers and vendors do not bill government healthcare programs, they continue to face FCA exposure for causing others to seek EHR incentive payments under false pretenses.
- As EHR technology becomes more and more ubiquitous, expect to see increasing FCA activity in this space.

With the department's expanding use of data analytics and AI, 2024 may be the busiest year yet for the Fraud Section. And as relators' counsel continue to solicit whistleblowers from ever-expanding circles, we expect record numbers of qui tams in the coming years.

Nixon Peabody's False Claims Act team has decades of experience with the Department of Justice and HHS-OIG and has represented clients in False Claims Act investigations and litigation across nearly every sector. Our team actively monitors federal district court dockets for FCA activity and frequently counsels clients on the latest FCA developments.

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