JONES DAY | One Firm Worldwide®

Second in a Series

WHITE PAPER

April 2024

2023 False Claims Act Enforcement in Health Care and Life Sciences, Part II

In February 2024, the Department of Justice ("DOJ") announced the results of its 2023 False Claims Act ("FCA") enforcement efforts. Through those efforts, it obtained more than $2.6 billion in overall recoveries, and of that amount, $1.8 billion came from health care and life sciences ("HCLS") stakeholders alone.

Jones Day is issuing the second installment of its three-part *White Paper*: "2023 False Claims Act Enforcement in Health Care and Life Sciences." In Part I of the *White Paper*, Jones Day provides an overview of DOJ's FCA enforcement in the HCLS industry during 2023, how that enforcement differed from previous years in terms of monetary recoveries, DOJ's case mix, as well as the evolution of DOJ's priorities and judicial decisions impacting this area.

Now in Part II, we cover the major trends identified in Part I in more detail, discussing 2023 FCA matters involving the Anti-Kickback Statute and Stark Law, Medicare Advantage (Part C), cybersecurity, pandemic fraud, as well as the crescendo of public statements from federal regulators about private equity and corporate ownership in the health care and life sciences space. Part III, to be published later in April 2024, will provide in-depth discussions of key FCA developments from the bench.

FCA resolutions in the health care arena continued to dominate the overall FCA recoveries obtained by the DOJ in 2023, with 70% of the overall monetary recoveries coming from the health care sector. Unlike 2021, in which DOJ's recoveries reached more than $5 billion in large part due to outsize manufacturer settlements, health care resolutions in FY 2023 suggest a return to the FCA basics, for now.

As detailed below, the cases generally come from a familiar range of health care/life science stakeholders: namely, hospitals and health systems, large providers, manufacturers, electronic health records vendors, and, increasingly, health plans. In addition, the matters are based on fairly typical legal theories—violations of the Anti-Kickback Statute ("AKS") and/or the Stark Law, medically unnecessary services/devices, upcoding, underpayment of rebates, and inflation of diagnosis codes by Medicare Advantage Organizations ("MAOs").

As in past years, health care fraud remained a leading source of FCA settlements and judgments for 2023. Notable DOJ pronouncements and FCA resolutions for the year are discussed in detail below.

Anti-Kickback Statute/Stark Settlements

Recoveries in 2023 demonstrated DOJ's ongoing scrutiny of referral relationships between health care providers and manufacturers or hospitals. While neither the AKS nor the Stark Law was singled out as a 2023 enforcement priority, both statutes—particularly the AKS—have historically undergirded many of the largest DOJ recoveries in the health care space. 2023 was not an exception—and with a Stark Law settlement that occurred in calendar year 2023 (but after the 2023 fiscal year), 2024 is already primed to follow this historical trend. Highlights are below.

In *United States ex rel. Fesenmaier v. Cameron-Ehlen Grp.*, a distributor of ophthalmological supplies and its owner are facing a potential $487 million judgment—inclusive of a $43 million jury verdict, treble damages, and statutory penalties—for FCA/AKS violations related to offering trips, meals, and other items of value to dozens of ophthalmologists over a 10-year period. DOJ tried the case in early 2023, and it is currently on appeal.

DOJ entered into a number of other settlements with health care providers this year relating to alleged violations of both the Stark Law and the AKS. A selection of these matters include: (i) an $85 million settlement with an imaging provider for the alleged payment of above-market fees to physicians; and (ii) a $69 million settlement with a health system for allegedly improper financial arrangements with referring physicians (including medical directorships, non-arm's length equipment leases, and rent forgiveness); and (iii) a $36.5 million settlement with a hospital and its affiliated physician group for the hospital's alleged payment of physician bonuses tied to the volume or value of the physician group's referrals to the hospital system and causing the submission of false claims for services provided by such physicians.

DOJ also entered into two settlements with electronic health records ("EHR") vendors in fiscal year 2023. At the end of 2022 (near the beginning of DOJ's FY 2023), an EHR vendor agreed to pay $45 million for alleged acceptance of remuneration to recommend pathology lab services and alleged payment of remuneration to providers for recommending its EHR technology. That settlement also resolved allegations that the vendor had caused its users to report inaccurate information related to the "meaningful use" of EHR technology when claiming federal incentive payments. In addition, in July 2023, a different EHR vendor agreed to pay $31 million to resolve allegations that it misrepresented the functionalities of its technology and paid kickbacks (including $10,000 customer credits, sports tickets, and entertainment) to providers in exchange for recommending its software.

Stark Law–FCA enforcement is already having a material impact on DOJ's 2024 results. On December 19, 2023, after the close of the 2023 fiscal year, DOJ entered into "the largest False Claims Act settlement based on Stark Law violations in the history of the Department of Justice." The settlement, for $345 million, involved allegations that a health system had violated the FCA and Stark Law by paying compensation that was allegedly "well above fair market value" to cardiologists, cardiothoracic surgeons, vascular surgeons, neurosurgeons, and breast surgeons; and awarding bonuses to physicians that were tied to the number of their referrals.

Medicare Advantage Organizations

Without question, DOJ is devoting substantial resources to Medicare Advantage ("MA") matters. At the 2024 Federal Bar Association's Qui Tam Conference, Principal Deputy Assistant Attorney General Boynton, of DOJ's Civil Division, reaffirmed

DOJ's continued interest in MAOs. This enforcement coincides with other scrutiny from other governmental actors, including the Senate Finance Committee, CMS, and HHS-OIG.[1]

Over the past year, DOJ focused its enforcement efforts regarding MA plans on the purported submission of inaccurate diagnosis codes and/or failures to correct inaccurate codes to increase capitated payments. These efforts led to some of the largest FCA settlements of 2023:

- In July 2023, Martin's Point Health Care agreed to pay nearly $22.5 million to resolve FCA allegations that it engaged in chart reviews to submit diagnosis codes that were not properly supported by its beneficiaries' medical records.
- In September 2023, Cigna agreed to pay $172 million to resolve multiple FCA allegations, including that it relied on "one sided" chart reviews to submit additional diagnosis codes while failing to report overpayments. Cigna also entered into a corporate integrity agreement with HHS-OIG as a result of the FCA matters. In the context of Cigna's settlements, DOJ made clear that the government plans to keep its focus on MA insurers, stressing that more than half of the nation's Medicare beneficiaries are enrolled in MA plans, representing over $450 billion in annual health care spending.[2]

This past year, DOJ also continued to litigate a number of MA actions against UnitedHealth Group, Independent Health Corporation, Elevance Health (formerly Anthem), and the Kaiser Permanente consortium.

In parallel, OIG published a new toolkit at the end of 2023 to "help decrease improper payments in MA through the identification of high-risk diagnosis codes." MAOs, as well as coding consultants and providers, are expected to familiarize themselves with the new guidelines.

Pandemic Fraud

Pandemic fraud enforcement seems to be evolving from straightforward criminal matters (largely involving SBA loans) toward sprawling criminal and civil cases that, more and more, involve the health care sector. At this stage, FCA enforcement for health care-related pandemic fraud is still a relatively minor feature of the enforcement landscape. However, given the joint criminal and civil enforcement efforts targeting pandemic fraud, we can expect some cross-fertilization between the criminal and civil cases. Thus, we include discussion of criminal as well as COVID-FCA health care matters below.

DOJ's early COVID-19 cases focused largely on non-health care schemes, e.g., fraudulent claims made in connection with Small Business Administration ("SBA") programs—the Paycheck Protection Program ("PPP") and Economic Injury Disaster Loans ("EIDL"). These were primarily criminal matters and notably small-dollar FCA cases. By mid-2021 and through 2022, COVID criminal enforcement began to exhibit nationwide coordination and more focus on pandemic-related health care fraud—two trends that have only intensified. In terms of FCA matters, however, COVID enforcement through 2022 was limited, with DOJ announcing just 35 pandemic-related FCA cases and, of those few cases, virtually all focused on SBA loans.

In 2023, we saw larger numbers of both criminal and civil COVID-related cases, with an increased focus on the health care sector. On the criminal side, pandemic fraud matters increased in number and involved not only SBA loan fraud, but also showed a substantial focus on criminal misconduct in the health care space. DOJ announced two separate multidistrict sweeps—in April and August 2023—bringing criminal charges against hundreds of defendants, including medical professionals and owners of medical businesses, for more than $1.326 billion in alleged COVID-19 health care fraud. As part of this criminal crackdown, multiple defendants were accused of defrauding the Health Resources and Services Administration's ("HRSA") COVID-19 Uninsured Program and Provider Relief Fund—two areas that have been anticipated to be a focus of COVID-FCA enforcement for health care entities.[3]

In terms of FCA enforcement, 2023 saw a large increase in the number of pandemic-related resolutions, going from 35 matters in 2022 to 270 FCA matters in 2023, resulting in recoveries of more than $48.3 million. While the bulk of these resolutions consisted of non-health care cases (focusing on PPP-related claims), there was nonetheless a noticeable increase in the number and sophistication of COVID-FCA matters in the health care space, and at least one matter involving alleged double-billing in connection with the HRSA program. We detail those matters below.

In July 2023, DOJ filed a complaint against multiple laboratories, an affiliate, and their owner alleging FCA violations for submitting claims to Medicare for respiratory pathogen panel ("RPP") laboratory tests that were not ordered by health care providers, not medically necessary, and sometimes never performed.

DOJ also reached a number of FCA settlements in connection with COVID-19 tests and services. A few of the most noteworthy settlements are highlighted below:

- A network of walk-in urgent care clinics entered into a $9.1 million settlement to resolve FCA claims that it allegedly overbilled federal health care programs for COVID-19 tests and office visits, thereby artificially inflating reimbursements.
- A Texas hospital system entered into a $2 million settlement plus additional contingent payments to resolve allegations that it violated the FCA by double billing HRSA for COVID-19 tests and vaccines that were simultaneously billed to the State of Texas and City of Houston.
- A Maryland-based billing company for diagnostic laboratories agreed to pay $300,479.58 to resolve FCA allegations that it caused the submission of false claims for medically unnecessary RPP testing on seniors receiving COVID-19 tests. Notably, the company received cooperation credit for admitting liability and for disclosing the results of an internal investigation, including information on individuals involved in the conduct.
- A Georgia urgent care chain agreed to pay $1.6 million to resolve FCA allegations that, when testing and treating patients with suspected exposure to COVID-19, it submitted upcoded evaluation and management claims to Medicare.
- In December 2023, the government also brought suit against a network of Idaho-based health clinics, alleging that, in order to secure PPP loans (and loan forgiveness), the network falsely certified in federal loan applications that it was not engaged in illegal activity while purportedly running a kickback scheme. In a consent judgment entered in January 2024, the health care provider agreed to pay $2 million to resolve the allegations.

The federal government is focusing on COVID-19 enforcement for the long haul. In March 2023, President Biden introduced a $1.6 billion funding proposal, with $600 million of that amount to go toward the investigation and prosecution of "those engaged in major or systemic pandemic fraud."[4] (Recall that in August 2022, Congress extended the statute of limitations ("SOL") from five to 10 years for enforcement actions relating to PPP and EIDL programs.) In President Biden's 2023 proposal, his administration called for legislation applying this expanded SOL to all "serious, systemic pandemic fraud," including HRSA's Uninsured Program. Considering these initiatives, it seems likely that DOJ is prepared for sustained enforcement activity relating to COVID-19, which in turn could result in more complex and potentially larger-dollar FCA matters in both health care and non-health care arenas.

Cyber Fraud

In October 2021, Deputy Attorney General Monaco announced that DOJ would be launching a Civil Cyber-Fraud Initiative, which would "utilize the False Claims Act to pursue cybersecurity related fraud by government contractors and grant recipients." The initiative was intended to "hold accountable entities or individuals that put U.S. information or systems at risk by knowingly providing deficient cybersecurity products or services, knowingly misrepresenting their cybersecurity practices or protocols, or knowingly violating obligations to monitor and report cybersecurity incidents and breaches."

While not a health care-specific initiative, several actions taken thus far have occurred in a health care context. The first two DOJ resolutions occurred in 2022, with a third and fourth announced in 2023. In 2022, DOJ resolved one matter against a medical services contractor for $930,000 for failure to comply with contractual requirements relating to secure storage of medical records. A second matter, a declined *qui tam*, resulted in a $9 million settlement for allegedly misleading the government about the contractor's compliance with cybersecurity and privacy requirements.

In 2023, DOJ announced two more settlements under the initiative. On March 13, 2023, a contractor and its sole manager/50% owner agreed to pay $293,771 to resolve FCA allegations that they failed to secure personal information on a federally funded Florida children's health insurance website that the contractor created, hosted, and maintained. In particular, DOJ alleged that the website "failed to properly maintain, patch, and update the software systems underlying HealthyKids.org and its related websites" by, e.g., "running multiple outdated and vulnerable applications, including some software that [the company] had not updated or patched since November 2013." In addition DOJ alleged that more than

500,000 applications submitted on HealthyKids.org "were revealed to have been hacked, potentially exposing the applicants' personal identifying information and other data."

In September 2023, a telecommunications company agreed to pay approximately $4 million to resolve FCA allegations that it failed to fully comply with certain cybersecurity controls relating to secure connections to the public internet in connection with information technology services provided to federal agencies under General Services Administration contracts. The settlement documents demonstrated that the company had self-disclosed the matter, with DOJ acknowledging that the company had taken significant steps to both cooperate and remediate. As a result, the company received cooperation credit under Justice Manual § 4-4.112, DOJ's guidelines for taking disclosure, cooperation, and remediation into account in FCA cases. These guidelines are discussed in more detail in our overview of 2023 health care FCA trends, which appears in Part I of this *White Paper* on health care-FCA enforcement.

This trend shows no signs of slowing. In a recent speech, Principal Deputy Assistant Attorney General Boynton identified cybersecurity as an enforcement priority for the coming year and noted that DOJ is currently investigating "many more cases involving alleged violations of cybersecurity requirements" deriving from varied sources, including whistleblowers and voluntary disclosures.

Private Equity and Corporate Investment in Health Care

Although DOJ did not enter into notable health care FCA settlements involving private equity ("PE") or other corporate investors in 2023, the lack of settlements tells only a small part of the larger story, involving whistleblower activity, a crescendo of public statements from various federal components, and ongoing non-public investigations.

On the whistleblower side of the equation, there has been active litigation and a not-insubstantial resolution. In *U.S. ex rel. Ebu-Isaac v. Insys Therapeutics, Inc.*, 16 Civ. 7937-JLS (C.D. Cal.), after DOJ declined to intervene, the relator proceeded with certain claims alleging that a specialty pharmacy distributed controlled substances in violation of the Controlled Substances Act. The matter was resolved in 2023 after the pharmacies and their owner—a private equity fund—agreed to settle for $9 million.[5]

Over the last few years, DOJ has repeatedly called attention to the role of corporate investors (including PE) in health care, both in terms of alleged impacts on competition and patient care,[6] and in the last few months alone has issued public statements signaling ongoing and future scrutiny of corporate ownership. For instance:

- The Federal Trade Commission, which previously flagged that it was scrutinizing "private equity 'roll ups,'" filed a complaint in September 2023 against a PE fund and its portfolio company, alleging that the companies had engaged in anticompetitive conduct through a series of "roll up" acquisitions, among other allegations.
- HHS-OIG recently issued its Compliance Program Guidance, which has been covered separately by Jones Day here, and specifically calls out its concerns about ownership incentives against the backdrop of "[t]he growing prominence of private equity and other forms of private investment in health care."
- On December 7, 2023, the White House issued a Fact Sheet announcing that DOJ, FTC, and HHS will examine the role of PE and corporate ownership in connection with competitive considerations in the health care sector and coordinate to identify potentially anticompetitive roll up transactions involving health care entities.
- On December 6, 2023, Senate Budget Committee Ranking Member Chuck Grassley (R-Iowa) and Chair Sheldon Whitehouse (D-RI) announced a new bipartisan investigation into PE ownership in hospitals.

In addition to federal interest, scrutiny is growing on the state level as well, with various states adopting or considering legislation that would further scrutinize transactions and arrangements involving PE sponsors or affiliated management organizations.[7]

At both federal and state levels, regulators are clearly focused on the role of PE/corporate ownership in the health care space. Future public enforcement actions involving private investment in health care may be expected to involve diverse regulators and a range of overlapping theories of liability, such as alleged violations of the FCA, AKS, Stark Law, Controlled Substances Act, medical necessity, overutilization, substandard care, and worthless services, as well as antitrust and related claims.

AUTHORS

Rebecca C. Martin
New York
+1.212.326.3410
rcmartin@jonesday.com

Laura F. Laemmle-Weidenfeld
Washington
+1.202.879.3496
lweidenfeld@jonesday.com

ADDITIONAL CONTACTS

Randi C. Lesnick
Practice Leader
New York
+1.212.326.3452
rclesnick@jonesday.com

Andrew M. Levine
Practice Leader
New York
+1.212.326.8319
amlevine@jonesday.com

Heather M. O'Shea
Practice Leader
Chicago
+1.312.269.4009
hoshea@jonesday.com

B. Kurt Copper
Dallas
+1.214.969.5163
bkcopper@jonesday.com

James T. Kitchen
Pittsburgh
+1.412.394.7272
jkitchen@jonesday.com

Shireen Matthews
San Diego
+1.858.314.1184
shireenmatthews@jonesday.com

Kristen Pollock McDonald
Atlanta
+1.404.581.8498
kmcdonald@jonesday.com

Rajeev Muttreja
New York
+1.212.326.8367
rmuttreja@jonesday.com

Jeff Rabkin
San Francisco/Silicon Valley
+1.415.875.5850/+1.650.739.3954
jrabkin@jonesday.com

Tina M. Tabacchi
Chicago
+1.312.269.4081
tmtabacchi@jonesday.com

Kerianne N. Tobitsch
New York
+1.212.326.8321
ktobitsch@jonesday.com

Associates Rachel E. Page, Marielle C. Coutrix, Mary Katherine Hickey, and Sophie Leff contributed to this White Paper.

ENDNOTES

1 On October 18, 2023, the Senate Finance Committee held a hearing in which senators discussed setting more rigid limits on broker compensation and criticized Medicare Advantage marketing and enrollment practices. Policymakers pointed to misaligned broker incentives, who receive "administrative fees" that fall outside the current regulatory framework/CMS oversight. Following the hearing, CMS issued a proposed rule on November 15, 2023, which would place a cap on Medicare Advantage broker compensation, prohibit plans from paying brokers administrative fees, and redefine total compensation to prevent Medicare Advantage Organizations from circumventing maximum compensation rates. "Medicare Advantage Annual Enrollment: Cracking Down on Deceptive Practices and Improving Senior Experiences," United States Senate Committee on Finance (Oct. 18, 2023).

2 In October 2023, DOJ announced criminal charges against the former director of HealthSun Health Plans, Inc. for allegedly falsifying risk-adjustment data. The former director is accused of tampering with electronic health records to support higher diagnosis codes. DOJ declined to prosecute HealthSun Health Plans, Inc., citing the company's "voluntary self-disclosure, cooperation, and remediation," including its agreement to disgorge $53 million in overpayments. "Former Executive at Medicare Advantage Organization Charged for Multimillion-Dollar Medicare Fraud Scheme," U.S. Department of Justice (Oct. 26, 2023).

3 These programs were respectively designed to expand coverage for COVID-19 treatment and support providers who experienced lost revenues and increased expenses during the pandemic. Also of note was the scope of the August sweep, which involved 718 enforcement actions against 371 defendants and 117 civil matters with more than "$10.4 million in judgments." *See* "Justice Department Announces Results of Nationwide COVID-19 Fraud Enforcement Action," U.S. Department of Justice (Aug. 23, 2023). It is not clear whether those 117 civil matters involved the FCA or other theories, *e.g.*, civil forfeiture. But it is notable that the overall monetary impact ($10.4 million) of the civil cases was a small fraction of the overall enforcement action.

4 DOJ's 2023 budget included funds for the hiring of an additional 120 attorneys to handle pandemic fraud. Attorney General Merrick B. Garland Delivers Remarks to the ABA Institute on White Collar Crime, U.S. Department of Justice (March 3, 2022).

5 Other FCA cases involving settlements with private equity in the recent past include: *U.S. ex rel. Martino-Fleming v. South Bay Mental Health Ctr.*, No. 15-13065 (D. Mass. May 19, 2021) (resolved with PE firm and former mental health center executives for $25 million); *U.S. ex rel. Medrano v. Diabetic Care Rx, LLC d/b/a Patient Care Am., et al.*, No. 15-CV-62617 (S.D. Fla. Mar. 6, 2019) (resolved with pharmacy, two executives, and PE firm for $21.36 million); *U.S. ex rel. Mandalapu, et al. v. Alliance Family of Companies, and Ancor Holdings, L.P., et al.*, No. 4:17-cv 00740 (S.D. TX 2021) (resolved in July 2021 with EEG testing company and PE owner for $15.3 million).

6 *See, e.g.*, "U.S. Antitrust Agencies Take Aim at Private Equity," The M&A Lawyer (July/August 2022); "Federal Agencies Launch Joint Inquiry Into Private Investment in Health Care," Jones Day *Alert* (March 2024).

7 *See*, *e.g.*, Required Reporting of Material Transactions, New York State Department of Health (March 2024).