13TH ANNUAL

HEALTHCARE FRAUD & ABUSE REVIEW

2024

BASS BERRY SIMS

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EXECUTIVE SUMMARY

Bass, Berry & Sims is pleased to bring you our 13th annual Healthcare Fraud & Abuse Review in which we cover significant civil and criminal enforcement issues for healthcare providers. This year's Review includes key enforcement initiatives, important case developments and documented fraud settlements, all presented in a readily digestible format. Here's what you can expect in this issue of our Review:

A LOOK BACK... A LOOK AHEAD

Where did the government focus its civil and criminal enforcement efforts last year? How did those results compare to prior years? What impact will the arrival of a new administration in Washington, D.C., have on enforcement efforts concerning the healthcare industry? Will we see priorities shift or approaches to enforcement change in any meaningful way? Our Review takes a look at these and other key questions and trends in predicting what the healthcare industry should expect in the coming year.

ISSUES TO WATCH

There are a number of key issues that will have a significant impact on how healthcare fraud matters are prosecuted and defended in the coming year. Continue reading to learn more about the future of the False Claims Act, the future of the administrative state, provider relief enforcement efforts, Controlled Substances Act & drug diversion enforcement trends, compliance guidance and cybersecurity issues confronting the healthcare industry.

NOTEWORTHY SETTLEMENTS

In FY 2024, healthcare fraud cases accounted for $1.67 billion (57%) of the $2.9 billion in FCA recoveries. This marks the 16th consecutive year that federal civil healthcare fraud recoveries have exceeded $1.5 billion. Continue reading to learn more about noteworthy settlements in the healthcare industry.

BY THE NUMBERS

$2.9 BILLION

Fourth Lowest Total Civil Fraud Recovery Since 2010

979

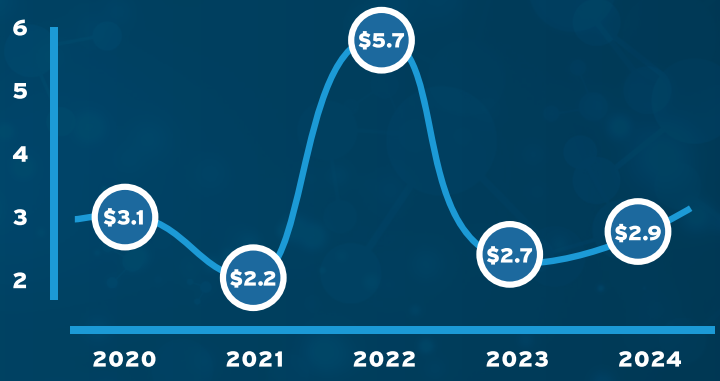
FCA *Qui Tam* Lawsuits Filed by Relators in FY 2024

82%

Civil Fraud Recoveries Associated with *Qui Tam* Lawsuits

Comparison of Recoveries FY 2024

Civil Fraud Recoveries FY 2020-2024 (Billions)



A LOOK BACK … A LOOK AHEAD

We are pleased to bring you our 13th annual Healthcare Fraud & Abuse Review. Our Review provides comprehensive coverage of the most significant civil and criminal enforcement issues facing healthcare providers. Each year, we endeavor to cover key enforcement initiatives, analyze important case developments and document healthcare fraud settlements across the industry and present these topics in a readily digestible format for our readers. We begin our review with a look back at last year's most notable developments and a look ahead to what we can expect in the coming year.

CIVIL HEALTHCARE FRAUD ENFORCEMENT

When looking back at last year's civil fraud recoveries, a few key points stand out.[1] The $2.9 billion in civil fraud recoveries reported by the U.S. Department of Justice (DOJ) is the fourth-lowest total recovery since 2010 and showed only a modest increase over fiscal year (FY) 2023's (adjusted) recovery of $2.78 billion. The annual total recoveries involving the healthcare industry were the lowest in more than a decade at $1.67 billion. This continues a significant trend in which four of the past five fiscal years (2020, 2022, 2023 and 2024) have seen recoveries under $1.9 billion. By comparison, from FY 2010 to FY 2019, total annual recoveries never fell below $2.1 billion.

False Claims Act (FCA) recoveries involving the healthcare industry amounted to approximately 57% of the total recoveries. The percentage of recoveries involving the healthcare industry typically has hovered over 80% in the past. While the dip in the percentage of recovery associated with the healthcare industry

1 https://www.justice.gov/opa/pr/false-claims-act-settlements-and-judgments-exceed-29b-fiscal-year-2024.

last year was attributable to a large FCA settlement involving the U.S. Department of Defense (DOD), that was not the case this year, as DOD FCA settlements accounted for only $93 million of the civil fraud settlement total. The declining percentage of recoveries involving the healthcare industry instead resulted from $1.15 billion in recoveries characterized by DOJ as "non-HHS [Department of Health and Human Services] and non-DOD."

For more than a decade, newly filed *qui tam* lawsuits brought by FCA relators hovered in the 600s—with a high of 757 new lawsuits filed in FY 2013 and a low of 598 new lawsuits filed in FY 2021. Newly filed *qui tam* lawsuits in FY 2024 significantly eclipsed FY 2013's prior record high, with 979 new lawsuits filed by relators last year. A staggering 609 of those lawsuits concerned matters outside of the healthcare industry.

Given the substantial number of *qui tam* lawsuits filed each fiscal year, it comes as no surprise that recoveries stemming from such lawsuits continue to drive overall civil fraud recoveries. Over 82% of the civil fraud recoveries, or nearly $2.2 billion of the $2.9 billion in total recoveries resulted from settlements and judgments associated with *qui tam* lawsuits. With 2,351 new *qui tam* lawsuits filed during the last three fiscal years, such lawsuits undoubtedly will remain the driving force for years to come.

Last year, we noted the declining number of *qui tam* lawsuits involving the healthcare industry. While that number ticked slightly upward in FY 2024 to 370 lawsuits (compared with 349 lawsuits in FY 2023), the percentage of *qui tam* lawsuits involving the healthcare industry declined sharply, dropping to only 38% and down from 49% in FY 2023. Whether that percentage dip continues to result in a declining percentage of total civil fraud recoveries involving the Department of Health and Human Services Office of Inspector General (HHS-OIG) remains to be seen.

Finally, it is worth noting that the total share of awards relators obtained from *qui tam* actions involving federal healthcare programs with respect to which DOJ declined to intervene ($189.5 million) was the lowest total since FY 2020.

CRIMINAL HEALTHCARE FRAUD ENFORCEMENT

DOJ continued its long-standing focus on criminal enforcement involving the healthcare industry. In June 2024, DOJ announced its annual healthcare fraud enforcement takedown involving more than $2.75 billion in intended fraud loss and 139 defendants charged across 32 federal judicial districts.[2] Traditional fraud schemes involving telemedicine ($1.1 billion of alleged fraud) and the prescribing and distribution of opioids (over $450 million of alleged fraud) remained a key focus.

Beyond those schemes, DOJ's takedown also included other notable results, including:

- **A $900 million fraud scheme involving amniotic wound graphs;**
- **The unlawful distribution of Adderall and other stimulants associated with a digital technology company;**
- **Over $90 million in fraud committed by executives distributing adulterated and misbranded HIV medication; and**
- **Over $146 million in fraudulent addiction treatment schemes.**

Beyond those schemes, DOJ's takedown also included other notable results, including: (1) a $900 million fraud scheme involving amniotic wound graphs; (2) the unlawful distribution of Adderall and other stimulants associated with a digital technology company; (3) over $90 million in fraud committed by executives distributing adulterated and misbranded HIV medication; and (4) over $146 million in fraudulent addiction treatment schemes.

Criminal enforcement efforts involving COVID-19 relief funds and related fraud schemes also remained a key focus. In April 2024, the COVID-19 Fraud Enforcement Task Force (CFETF) released its report detailing the efforts of the task force concerning "widespread fraud involving many COVID-19 relief programs targeted by fraudsters and other criminals who sought to exploit the government's relief efforts."[3] The report detailed that more than 3,500 defendants had been charged with COVID-19 relief-related crimes and more than $1.4 billion had been seized or forfeited to recover stolen Coronavirus Aid, Relief, and Economic Security (CARES) Act funds. DOJ also secured more than 400 settlements and judgments as part of its enforcement efforts.

2 https://www.justice.gov/opa/pr/national-health-care-fraud-enforcement-action-results-193-defendants-charged-and-over-275-0.

3 https://www.justice.gov/opa/pr/covid-19-fraud-enforcement-task-force-releases-2024-report.

The FCA and the Anti-Kickback Statute (AKS) are among the many laws with respect to which defendants have achieved recent success in limiting their reach, including a successful challenge to the constitutionality of the FCA's qui tam provision and court decisions adopting narrow interpretations of key AKS elements.

LOOKING AHEAD

With the arrival of a new administration in our nation's capital, there will be new leadership within DOJ, HHS-OIG and other federal agencies, and new policies and new (or renewed) approaches to civil, criminal and administrative enforcement. The second Trump administration promises a return to the same emphasis on deregulation that was a hallmark of the first Trump administration, and we will likely see a flurry of executive orders designed to pave the way for such an approach. From a practical standpoint, however, the manner in which the second Trump administration carries out its overall agenda may have limited impact on enforcement efforts relating to healthcare fraud. After all, civil fraud enforcement recoveries and the number of new *qui tam* lawsuits filed annually remained relatively consistent across the last several presidential administrations and criminal enforcement efforts have remained robust since DOJ and HHS-OIG leaders formed the Health Care Fraud Prevention and Enforcement Action Team (HEAT) strike force in 2009.[4]

Enforcement efforts in the coming year and beyond are far more likely to be impacted by court challenges resulting in the possible paring back of some of the more significant statutes and regulations upon which the federal government and whistleblowers rely in pursuing healthcare fraud recoveries. The FCA and the Anti-Kickback Statute (AKS) are among the many laws with respect to which defendants have achieved recent success in limiting their reach, including a successful challenge to the constitutionality of the FCA's *qui tam* provision and court decisions adopting narrow interpretations of key AKS elements. Deconstruction of the administrative state likely will result in roadblocks to enforcement efforts as litigants are beginning to spar about the consequences associated with the Supreme Court's decision to overturn the longstanding doctrine known as "*Chevron* deference" announced in ***Loper Bright Enterprises v. Raimondo.***

As has been the case for the last decade, healthcare providers will continue to face heightened enforcement scrutiny and the risk of *qui tam* lawsuits in the coming year amongst a rapidly changing landscape. We trust that our firm's annual **Healthcare Fraud & Abuse Review** will assist healthcare providers in better anticipating those challenges and understanding how best to navigate them in an ever-changing world.

4 https://www.justice.gov/opa/media/1384546/dl.

ISSUES TO WATCH

There are a number of key issues that will have a significant impact on how healthcare fraud matters are prosecuted and defended in the coming year.

THE FUTURE OF THE FALSE CLAIMS ACT

In recent years, there have been a number of important court opinions that we expected would have a significant impact on future litigation involving the FCA. We previously covered key cases decided by the Supreme Court, including the interpretation of the FCA's scienter element and the government's dismissal authority under the FCA over the objection of a *qui tam* relator. While we did not see any groundbreaking Supreme Court cases last year, the litigation of important issues involving the FCA in the lower courts sets the stage for future important cases likely to make their way to the Supreme Court.

There were several significant developments that could reshape FCA enforcement. These developments include a growing dispute over the constitutionality of the FCA's *qui tam* provisions that may eventually reach the Supreme Court, as well as a case already before the Supreme Court with potentially important implications for the scope of FCA liability.

In September 2024, Judge Kathryn Mizelle of the U.S. District Court for the Middle District of Florida issued a landmark decision in ***U.S. ex rel. Zafirov v. Florida Medical Assocs., LLC***, becoming the first federal district court to hold that the FCA's *qui tam* provisions violate the Constitution—specifically, the

> ***While we did not see any groundbreaking Supreme Court cases last year, the litigation of important issues involving the FCA in the lower courts sets the stage for future important cases likely to make their way to the Supreme Court.***

Appointments Clause of Article II.[5] The district court's opinion concluded that *qui tam* relators qualify as "Officers of the United States" under the Appointments Clause because they exercise significant executive authority—including initiating enforcement actions, controlling litigation strategy and potentially binding the government through precedent—while occupying a continuing position established by law. Because relators are not properly appointed under the Constitution, the district court's opinion held that the *qui tam* claims must be dismissed. The district court was unpersuaded by arguments about the historical pedigree of *qui tam* actions, noting that many early analogues were rarely used or procedurally distinct and that FCA *qui tam* actions were uncommon before the 1986 FCA amendments.

Both the relator and DOJ have since appealed to the Eleventh Circuit, setting up what could be a watershed decision and paving the way for a possible circuit split. The constitutional status of *qui tam* relators has drawn increased attention since Justice Thomas's dissent in ***U.S. ex rel. Polansky v. Executive Health Resources***, which questioned whether the *qui tam* provisions comport with Article II and suggested the issue warranted the Court's review.[6] Justice Kavanaugh, joined by Justice Barrett, echoed these views in a concurrence.[7] While several circuits have previously rejected Article II challenges to the *qui tam* provisions, Justice Thomas's dissent—not to mention *Zafirov*'s reasoning—may lead courts to reevaluate those precedents. In particular, if the Eleventh Circuit in *Zafirov* were to affirm the district court's opinion, it would virtually guarantee that the Supreme Court would take up the issue itself. In the meantime, *Zafirov* at a minimum provides FCA defendants additional ammunition when it comes to defending *qui tam* lawsuits.[8]

The Supreme Court is also poised to address a significant question about the scope of FCA liability in ***Wisconsin Bell, Inc. v. United States***, which is currently pending before the Court.[9] The case presents the question of whether claims submitted to the Universal Service Fund (Fund)—an entity created by Congress that subsidizes telecommunications services for schools and libraries—qualify as claims for payment under the FCA. This issue has divided federal circuit courts, with the Fifth Circuit holding that such claims fall outside the FCA because the Fund's money comes from private telecommunications carriers rather than the U.S. Treasury, while the Seventh Circuit reached the opposite conclusion. The case has potentially broad implications because it could help define when funds administered through public-private partnerships trigger FCA liability.

At oral arguments in November 2024, the justices explored several key aspects of the program's structure, including the government's role in mandating carrier contributions, the Treasury Department's collection of delinquent payments and settlements and the Federal Communications Commission's oversight of distributions. The Court's eventual ruling could

affect FCA enforcement in several other contexts where federal programs rely on similar funding mechanisms, from Medicare Advantage to federal grant programs administered by private entities. A decision is expected before the end of the current Supreme Court term.

THE FUTURE OF THE ADMINISTRATIVE STATE

In June, the Supreme Court issued its landmark decision in ***Loper Bright Enterprises v. Raimondo***.[10] In its opinion, the Court overruled ***Chevron U.S.A. Inc. v. Nat. Res. Def. Council, Inc.***, which for 40 years required judicial deference to administrative agency interpretations of statutes in certain circumstances. Instead, *Loper Bright* directs courts reviewing agency interpretations pursuant to the Administrative Procedure Act to "exercise their independent judgment in deciding whether an agency has acted within its statutory authority" and provides that courts "may not defer to an agency interpretation of the law simply because a statute is ambiguous."

Much has been said about the potential implications of *Loper Bright* on the healthcare industry. The statutes governing that industry are the subject of extensive administrative agency interpretation. *Loper Bright*, therefore, injects real uncertainty into the legal landscape, but any clear assessment of the impact requires a case-by-case and statute-by-statute analysis.

In the context of the FCA, *Loper Bright* necessarily demands careful consideration. For example, can a claim be "false" if it is premised on an agency interpretation of an ambiguous statutory term and the agency interpretation does not reflect the "best reading" of the statute? Can a defendant act "knowingly" in such a case, where the agency's interpretation is no longer entitled to judicial deference? These questions and others will be front and center in many FCA actions moving forward.

5 2024 WL 4349242 (M.D. Fla. Sep. 30, 2024).
6 599 U.S. 419, 449 (2023) (Thomas, J. dissenting).
7 *Id.* at 442 (Kavanaugh, J. concurring).
8 Notably, however, at least two other recent district court decisions that have addressed the issue have upheld the FCA's *qui tam* provisions. *See United States v. Riverside Med. Grp., P.C.*, 2024 WL 4100372 (D.N.J. Sep. 6, 2024); *United States v. 24th St., Inc.*, 2024 WL 3272828 (D.N.J. June 30, 2024).
9 *U.S. ex rel. Heath v. Wisconsin Bell, Inc.*, 92 F.4th 654 (7th Cir.), cert. granted sub nom. *Wisconsin Bell, Inc. v. United States*, 144 S. Ct. 2657 (2024).

10 603 U.S. 369 (2024).

Other fraud and abuse statutes, like the Stark Law and the AKS, are comprised of extensive rulemaking atop relatively short, straightforward statutes. In many cases, these statutes expressly authorize the agencies to create additional regulatory requirements. Under *Loper Bright*, when Congress "expressly delegates" discretion to an agency to give meaning to a term or when it empowers an agency to issue rules to "'fill up the details' of a statutory scheme," agencies will be authorized to exercise that discretion. The role of a reviewing court involves "fix[ing] the boundaries of [the] delegated authority" and "ensuring the agency has engaged in 'reasoned decisionmaking' within those boundaries," not simply substituting its judgment.

However, there are cases where administrative agencies may have issued narrower regulatory interpretations in the absence of express delegation. Consider, for example, the AKS statutory exception for discounts in comparison to the regulatory safe harbor for discounts. Or consider the discrepancies between the Stark Law statutory exception for "payments by a physician" or "remuneration unrelated to designated health services" in comparison to the regulatory exceptions created by the Centers for Medicare & Medicaid Services (CMS). Or consider the concept of an "indirect compensation arrangement" in the Stark Law—a concept that is the subject of an extensive regulatory definition that has undergone numerous changes in recent years but with no definition in the statute itself.

The ultimate impact of *Loper Bright* on fraud and abuse laws, and more generally on the healthcare industry, remains to be seen. The landscape has changed and we expect more challenges to agency rulemaking, as well as changes in the ways laws are written and interpreted.

PROVIDER RELIEF ENFORCEMENT EFFORTS

The federal government continues to pursue pandemic relief-related enforcement efforts. During the prior year, the most detailed account of those efforts was set forth in the CFETF's 2024 Report, referenced above.[11] The Report indicated that the CFETF's member agencies have pursued "criminal charges against more than 3,500 defendants, civil enforcement actions resulting in more than 400 civil settlements and judgments and more than $1.4 billion in seizures and forfeitures."[12]

DOJ's criminal enforcement efforts related to pandemic relief included charges and convictions with respect to a number of schemes involving COVID-19 testing,[13] misappropriation of and false certifications associated with COVID-19 funds[14] and kickback schemes associated with laboratory testing.[15] In addition to those efforts, CFET established five strike forces to focus on the most complex and harmful fraud involving pandemic relief, which often involves violent actors and organized crime.

From a civil enforcement standpoint, the Report noted that DOJ has opened over 1,200 civil pandemic fraud matters, which included investigating the filing of more than 600 *qui tam* cases. Those efforts have resulted in more than 400 judgments or settlements totaling over $100 million and spanned numerous pandemic-relief programs. The Report highlighted the development and rollout of database tools designed to detect and investigate fraud, including analysis of more than 225 million claims paid by the Health Resources and Services Administration's (HRSA) COVID-19 Uninsured Program and approximately 15 million pandemic-relief program loans. Following the issuance of the Report, DOJ continued to announce significant FCA settlements, including a $6.3 million settlement against a California-based dental practice that allegedly received seven improper second-draw Paycheck Protection Program (PPP) loans and forgiveness of those loans based on false certifications and a $7 million settlement with respect to a California-based nursing home and two executives to settle alleged false claims that the nursing home submitted in connection with residents who did not have COVID-19 or any other acute illness or injury, but had merely been near other people who had COVID-19.[16]

Given the massive amounts of government spending associated with COVID-19 relief, it is certain that the government will remain focused on pursuing enforcement initiatives concerning these funds. As many of the more readily identifiable fraud schemes have been disrupted by regulators, we expect that regulators will sharpen their focus on data-driven detection of fraud and more complex and harder-to-spot schemes.

> ***"DOJ has opened over 1,200 civil pandemic fraud matters, which included investigating the filing of more than 600 qui tam cases. Those efforts have resulted in more than 400 judgments or settlements totaling over $100 million and spanned numerous pandemic-relief programs.***

11 https://www.justice.gov/opa/pr/covid-19-fraud-enforcement-task-force-releases-2024-report.
12 https://www.justice.gov/coronavirus/media/1347161/dl?inline.
13 https://www.justice.gov/usao-edmo/pr/testing-laboratory-co-owner-admits-38-million-fraudulent-billing https://www.justice.gov/usao-mdfl/pr/south-florida-resident-charged-receiving-millions-filing-fraudulent-covid-19-testing; https://www.justice.gov/opa/pr/laboratory-owner-pleads-guilty-30m-medicare-fraud-scheme; https://www.justice.gov/opa/pr/laboratory-owners-charged-36m-covid-19-testing-fraud-scheme; https://www.justice.gov/opa/pr/lab-owner-pleads-guilty-14m-covid-19-fraud-scheme.
14 https://www.justice.gov/opa/pr/woman-pleads-guilty-theft-and-misappropriation-covid-19-funds; https://www.justice.gov/usao-wdmi/pr/2024_0618_Kreykes_T_Indicted.
15 https://www.justice.gov/usao-edmo/pr/pair-accused-kickback-scheme-involving-lab-testing.
16 https://www.justice.gov/opa/pr/southern-california-dental-offices-and-former-owners-pay-63m-resolve-false-claims-act, https://www.justice.gov/opa/pr/california-based-nursing-home-chain-and-two-executives-pay-7m-settle-alleged-false-claims.

CONTROLLED SUBSTANCES ACT AND DRUG DIVERSION

The federal Controlled Substances Act (CSA) creates a "closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA."[17] Key provisions of the CSA and its implementing regulations focus on: (1) maintaining complete and accurate records of all controlled substance transactions; (2) ensuring adequate security measures to prevent theft and loss of controlled substances; and (3) mandatory reporting to the government of all transfers of controlled substances and any theft or significant loss of controlled substances.

In recent years, federal and state regulators have increased enforcement of laws governing the handling of controlled substances, including the CSA. We have seen a steady uptick in enforcement actions against entities throughout the controlled substances supply chain, including pharmacies, hospitals and other healthcare facilities. That trend continued last year, with developments in several areas.

FCA Actions Based on Alleged Controlled Substances Act Violations

Typifying the government's increased interest in controlled substances enforcement, DOJ has begun to pursue FCA cases against U.S. Drug Enforcement Administration (DEA) registrants based on alleged violations of the CSA. In 2023, DOJ intervened in a *qui tam* FCA case against Rite Aid, alleging that Rite Aid defrauded federal healthcare programs by seeking reimbursement for opioids the pharmacy allegedly dispensed in violation of CSA.[18] In July 2024, DOJ announced a nearly $410 million settlement with Rite Aid to resolve the case.[19] Under the agreement, DOJ received a $7.5 million payment and obtained a $402 million claim in Rite Aid's pending bankruptcy.

In December 2024, DOJ intervened in a *qui tam* FCA case alleging that CVS pharmacies nationwide sought federal reimbursement for opioid prescriptions filled in violation of the CSA.[20] Also in December 2024, DOJ announced an $8 million settlement with grocery store chain Food City, resolving FCA allegations that Food City pharmacies dispensed opioids and other controlled substances in violation of the CSA.[21]

The government's theory of liability in all three cases is that the defendant pharmacies violated the FCA when they sought reimbursement from federal healthcare programs for prescriptions filled in violation of the CSA. DOJ alleged that the pharmacies violated their duty of corresponding responsibility when filling prescriptions for controlled substances. DEA regulations impose a "responsibility for the proper prescribing and dispensing of controlled substances" on "the prescribing practitioner." But, they also impose "a corresponding responsibility" on "the pharmacist who fills the prescription."[22] DOJ has asserted that the exercise of corresponding responsibility means that pharmacists must investigate and resolve all "red flags" before dispensing prescriptions for controlled substances.

In its cases against Rite Aid, CVS and Food City, DOJ alleged that the failure to exercise corresponding responsibility caused the pharmacies to fill invalid and unlawful prescriptions bearing the hallmarks of abuse and diversion. For example, DOJ alleged that Rite Aid pharmacies filled "trinity" prescriptions (a combination of an opioid, benzodiazepine and muscle relaxant), processed early fill requests for opioids and filled prescriptions from prescribers who had been flagged internally for writing prescriptions with no medical purpose.

DOJ likewise alleged that CVS ignored internal complaints about patient and employee safety, failed to adopt methods for its pharmacies to share information about concerning providers and implemented reduced staffing levels and bonus structures that incentivized pharmacists to fill prescriptions quickly and sacrifice the proper exercise of corresponding responsibility.

DOJ's use of the FCA to pursue alleged CSA violations represents a significant development for DEA registrants. Due to the substantial damages available to the government under the FCA (treble damages plus per-claim civil penalties), DEA registrants potentially face significantly higher monetary liability in an FCA case than under the CSA alone, as the $410 million Rite Aid settlement reflects.

17 *Gonzales v. Raich*, 545 U.S. 1, 13 (2005).
18 *U.S. ex rel. White v. Rite Aid Corp.*, Case No. 2:19-cv-04577 (E.D. Pa.).
19 https://www.justice.gov/opa/pr/rite-aid-corporation-and-affiliates-agree-settle-false-claims-act-and-controlled-substance.
20 *U.S. ex rel. Estright v. CVS Pharmacy, Inc.*, Case No. 1:22-cv-00222 (D.R.I.).
21 https://www.justice.gov/opa/pr/food-city-agrees-pay-over-8m-settle-false-claims-act-allegations-related-opioid-dispensing.
22 21 C.F.R. § 1306.04(a).

DOJ has not historically pursued many CSA-based FCA cases. However, its intervention in the foregoing cases shows its endorsement of that theory of liability. And, the multimillion-dollar recoveries against Rite Aid and Food City suggest DOJ and relators may see CSA-based FCA cases as promising high-dollar opportunities going forward.

Although the cases against Rite Aid, CVS and Food City focus primarily on the dispensing of opioids by retail pharmacies, moving forward the government and relators may also pursue CSA-based FCA cases related to the dispensing of other controlled substances or against other types of healthcare providers.

CSA Enforcement Actions Against Pharmacies

The government also continued to pursue liability against pharmacies under the CSA itself. There were several notable settlements relating to retail pharmacies, which again focused on allegations that the pharmacies violated their duty of corresponding responsibility. In February 2024, Kroger Pharmacy and Harris Teeter Pharmacy agreed to pay a total of $1.3 million to resolve allegations that they dispensed invalid prescriptions for opioids and benzodiazepines written by a physician acting outside the scope of his medical practice.[23] In June 2024, OptumRx Inc. agreed to pay $20 million to resolve allegations that one of its mail-order pharmacies improperly filled "trinity" prescriptions.[24] These settlements further demonstrate the role that corresponding responsibility plays for pharmacies dispensing controlled substances.

Telehealth Prosecutions

DOJ also pursued criminal liability against organizations and individuals related to telehealth prescribing of controlled substances. These cases are examples of the government pursuing liability related to non-opioid controlled substances.

For example, in June 2024, DOJ indicted the founder/CEO and clinical president of digital health company Done Global, Inc., alleging that these individuals conspired to commit healthcare fraud related to alleged improper telehealth prescriptions of Adderall.[25]

In November 2024, mental health provider Cerebral, Inc., entered into a non-prosecution agreement with DOJ and agreed to pay $3.6 million to resolve allegations that its practices encouraged providers to write invalid telehealth prescriptions for Attention-Deficit/Hyperactivity Disorder (ADHD) drugs.[26] These practices allegedly included implementing internal measures to increase the number of stimulant prescriptions, financially incentivizing providers to write controlled substances prescriptions and failing to maintain effective controls against diversion.

23 https://www.justice.gov/usao-wdva/pr/kroger-harris-teeter-pharmacies-charlottesville-pay-us-13-million.
24 https://www.justice.gov/opa/pr/optumrx-agrees-pay-20m-resolve-allegations-it-filled-certain-opioid-prescriptions-violation.
25 https://www.justice.gov/opa/pr/founderceo-and-clinical-president-digital-health-company-arrested-100m-adderall-distribution.
26 https://www.justice.gov/usao-edny/pr/telehealth-company-cerebral-agrees-pay-over-36-million-connection-business-practices.

CSA Enforcement Actions Against Healthcare Facilities

As addressed in previous years, we have seen a shift in the government's approach to the diversion of controlled substances. In the past, DOJ focused its enforcement efforts on the individuals involved in stealing controlled substances. In recent years, however, DOJ has increasingly sought to hold DEA registrants accountable for perceived shortcomings in their processes and controls that may have contributed to or permitted the diversion in recent years.

As an example of this increased scrutiny, DOJ announced a $1 million settlement with Sacred Heart Rehabilitation Center, a behavioral health and addiction treatment services network, along with its CEO and medical director, to resolve allegations that the facility violated dispensing and recordkeeping requirements under the CSA.[27] These alleged violations came to light during a DEA inspection. This settlement is notable because it shows DOJ's pursuit of liability against a behavioral health center and its individual officers.

Enforcement efforts involving Asante Rogue Medical Center (ARMC) exemplified the compounded liability faced by hospitals as a result of diversion. Under tragic circumstances, ARMC is facing nearly $500 million in private civil lawsuits after a nurse allegedly diverted fentanyl from patient IV bags and replaced it with contaminated tap water, leading to bacterial infections that caused numerous patient deaths. According to news reports, ARMC is also facing government investigations related to this incident.

Facility registrants—including hospitals, behavioral health centers, long-term care facilities and others—should be aware that they face the potential for significant and multi-faceted liability from the diversion of controlled substances at their locations.

KEY DOJ PRONOUNCEMENTS

Updates to DOJ Compliance Guidance

DOJ's Criminal Division continued to offer updates to its compliance guidance as set forth in its **Evaluation of Corporate Compliance Programs**.[28] As a point of reference, DOJ's June 2020 updated guidance set out the framework on which DOJ has been building ever since. By this point, most healthcare providers should be familiar with the government's expectations as outlined in this guidance.

In broad terms, DOJ's guidance highlights three fundamental questions regarding corporate compliance programs: (1) whether the compliance program is well designed; (2) whether the compliance program is applied earnestly and in good faith as evidenced by the fact that it is adequately resourced and empowered to function effectively; and (3) whether the compliance

27 https://www.justice.gov/usao-wdmi/pr/2024_0926_Sacred_Heart_Consent_Decree.
28 https://www.justice.gov/criminal-fraud/page/file/937501/download.

program works in practice. The guidance then proceeds to set forth considerations DOJ prosecutors should use in evaluating these questions, which healthcare providers should consider in evaluating their own programs.

In keynote remarks delivered to the American Bar Association's (ABA) National Institute on White Collar Crime in March 2024, then Deputy U.S. Attorney General Lisa Monaco announced her direction to DOJ's Criminal Division to incorporate assessment of disruptive technology risks into its compliance guidance. As a result, DOJ's Criminal Division updated its compliance guidance in September 2024 to include criteria that prosecutors should utilize in assessing the adequacy of a company's controls in reducing risk stemming from the use of artificial intelligence (AI).

DOJ's updated guidance incorporates previously announced compliance concepts to the many challenges posed by emerging technologies, including AI. By way of example, companies should evaluate processes for identifying and managing emerging internal and external risks associated with new technologies that may impact the ability to comply with the law. Companies must also consider whether the management of risks associated with new technologies, including AI, has been integrated into enterprise risk management strategies and whether companies have curbed any potential negative or unintended consequences resulting from the use of technologies, both in commercial business and in compliance programs. Additionally, companies must consider whether appropriate internal controls exist to ensure that emerging technologies are used for intended purposes and how accountability over the use of AI is monitored and enforced.

As AI and other new technologies continue to take center stage in the delivery of healthcare and the management of healthcare-related data, companies must redouble their efforts to ensure appropriate compliance measures are in place to address the associated challenges.

DOJ Whistleblower Program

During the same March 2024 ABA conference, Monaco announced DOJ's efforts to design a pilot program to pay monetary rewards to whistleblowers. DOJ then formally published its **Whistleblower Awards Pilot Program** (Program) on August 1, 2024. There are a significant number of criteria set forth by DOJ that will be used to evaluate whether any whistleblower may be eligible for an award under the Program.[29] In general terms, eligibility depends on whether the whistleblower provides DOJ with original information in writing and that information must lead to criminal or civil forfeiture exceeding $1 million in net proceeds in connection with a successful prosecution, corporate criminal resolution or civil forfeiture action related to corporate criminal conduct associated with particular subject matters. The whistleblower's information must be truthful and complete and must not conceal or mischaracterize the whistleblower's role in the misconduct. The information must not be publicly available or known to DOJ before the report; if such information is known to DOJ, the whistleblower may still be eligible to receive an award if the information materially adds to information in DOJ's possession. The whistleblower also must cooperate with DOJ in its investigation of the related conduct and criminal or civil actions.

Assuming the Program requirements have been satisfied, the whistleblower may recover an award of up to 30% of the first $100 million in net proceeds recovered and up to 5% of any net proceeds forfeited between $100 million and $500 million.

The Program sets forth specific criteria that DOJ will use in exercising its discretion to determine the appropriate award percentage, which includes the following: (1) the significance of the information provided by the whistleblower; (2) the degree of assistance provided by the whistleblower; and (3) whether and the extent to which the whistleblower participated in internal compliance systems with regard to the matters at issue.

Within two months of the Program's rollout, DOJ announced its first acting director and assembled a team of prosecutors to handle tips made to the Program. In that time frame, DOJ publicized that it had received reports from more than 100 whistleblowers.[30] Given that the Program is in a "pilot" phase, we expect tweaks to the Program moving forward. Depending on its success, the Program may serve as a model for a future DOJ civil whistleblower program, particularly in the event that the FCA's *qui tam* provision does not survive judicial scrutiny in the future.

29 https://www.justice.gov/criminal/media/1362321/dl?inline.

30 https://www.wsj.com/articles/doj-sees-tips-flow-in-over-first-month-of-pilot-whistleblower-program-d2915104.

Cybersecurity

Three years ago, DOJ launched its **Civil Cyber Fraud Initiative** (CCFI) with the stated goal of holding entities accountable for knowingly misrepresenting cybersecurity practices or knowingly violating obligations to monitor and report cyber incidents to the federal government. Since then, the government's enforcement efforts under the CCFI have continued to increase, and 2024 was the government's most active year thus far, with DOJ announcing several multi-million dollar settlements under the CCFI. For example, DOJ announced that Insight Global LLC paid $2.7 million to resolve allegations that it failed to implement adequate cybersecurity measures to protect health information obtained during COVID-19 contact tracing.[31] As with the 2023 Verizon CCFI resolution, the Insight Global settlement also highlighted two things: the growing importance of the CCFI and DOJ's push for greater cooperation, remediation and/or self-disclosure from potential defendants.[32] Insight Global cooperated with the investigation and remediated the issue prior to learning of the investigation by issuing a public notice and offering identity protection services to those affected.

DOJ also announced a settlement with Guidehouse Inc., resolving allegations that Guidehouse failed to implement adequate cybersecurity measures to protect personal financial information obtained under the COVID-19 Emergency Rental Assistance Program.[33] As part of the settlement, the defendants admitted that they failed to perform the required pre-launch tests, which caused the enrollment site to be taken down just 12 hours after it went live. Together, they agreed to pay $11.3 million to resolve the allegations.

Notwithstanding DOJ's prioritization of self-disclosure and cooperation, all industries should expect to see increased enforcement in this area moving forward, evidenced by the government filing of its first complaint-in-intervention under the CCFI against the Georgia Institute of Technology and Georgia Tech Research Corp.[34] DOJ alleged that the defendants knowingly induced DOD to enter into and retain contracts under the false pretense that they would comply with applicable cybersecurity regulations and by providing accurate security assessment scores for the relevant laboratories, but that the defendants knowingly failed to meet those cybersecurity requirements in violation of the FCA. DOJ also announced a $1.25 million settlement with Pennsylvania State University resolving similar allegations that it failed to comply with cybersecurity requirements in 15 DOD and NASA contracts.[35]

As it relates to the healthcare industry in particular, the **Notice of Proposed Rulemaking** (Notice) for the **Cyber Incident Reporting for Critical Infrastructure Act** (CIRCIA) was published in April 2024. Under the CIRCIA, HHS will serve as the designated "Sector Risk Management Agency" for the "Healthcare and Public Health (HPH) Sector," which was identified as one of 16 critical infrastructure sectors covered by CIRCIA. Under CIRCIA, healthcare entities will have new cybersecurity and reporting obligations. The Notice provided additional information on how the Cybersecurity and Infrastructure Security Agency intends to implement CIRCIA, outlining how covered entities must report and retain information on substantial cyber incidents and ransom payments once CIRCIA's reporting and retention requirements take effect in 2026. If treated similarly to other federal security and reporting obligations, knowing failures to satisfy CIRCIA's requirements could likewise lead to FCA exposure.[36]

31 https://www.justice.gov/opa/pr/staffing-company-pay-27m-alleged-failure-provide-adequate-cybersecurity-covid-19-contact.
32 https://www.law360.co.uk/articles/1733442/lessons-from-verizon-s-cybersecurity-fca-self-disclosure.
33 https://www.justice.gov/opa/pr/consulting-companies-pay-113m-failing-comply-cybersecurity-requirements-federally-funded.
34 https://www.insidethefalseclaimsact.com/civil-cyber-fraud-initiative-first-complaint/.
35 https://www.justice.gov/opa/pr/pennsylvania-state-university-agrees-pay-125m-resolve-false-claims-act-allegations-relating.

36 https://www.bassberry.com/news/cisa-publishes-proposed-rule-for-cyber-reporting/.

NOTEWORTHY SETTLEMENTS

As in recent years, resolutions in healthcare fraud cases accounted for the vast majority of all FCA recoveries in FY 2024. Of the $2.9 billion total in settlements and judgments, recoveries from matters involving the healthcare industry amounted to $1.67 billion (57%).

Newly filed *qui tam* complaints accounted for the majority of the new civil fraud matters initiated in FY 2024, in line with past years, although the number of government-initiated and data-driven FCA actions continues to rise. Whistleblowers filed a record-breaking 979 *qui tam* lawsuits in FY 2024 and recoveries from these and earlier filed lawsuits accounted for $2.2 billion of the $2.9 billion recovered. Settlements associated with *qui tam* lawsuits where the government intervened or otherwise pursued the allegations comprised more than $1.3 billion of the recoveries from healthcare companies. The **Appendix** to our Healthcare Fraud & Abuse Review contains a detailed breakdown of key settlements from the past year, many of which are referenced within this section of the Review.

HOSPITALS & HEALTH SYSTEMS

Hospitals and health systems entered into a number of noteworthy settlements to resolve FCA allegations. Many of the cases involved alleged violations of the Stark Law and AKS, often in the context of financial relationships with physicians. Common themes in these cases included compensation in excess of fair market value (FMV), compensation structures that varied with referrals and the provision of items and services to physicians at reduced or no cost. Because Stark Law and AKS violations may taint large numbers of claims stemming from the alleged improper arrangements, these cases often result in significant FCA settlements.

There was no single, blockbuster settlement, as there was in late 2023 with the Community Health Network matter, which resulted in a record-breaking $345 million settlement and also yielded a separate $135 million settlement in early 2025.[37] There were, however, a handful of significant settlements, including a $42.5 million settlement with a Delaware health system related to allegations of providing free staffing services

37 https://www.justice.gov/usao-sdin/pr/community-health-network-agrees-pay-345-million-settle-alleged-false-claims-act.

to independent physicians.[38] There were also several other multi-million dollar settlements, including a $17.3 million settlement with a New York hospital[39] and a $10.8 million settlement with a Montana health system,[40] which resulted from voluntary self-disclosures to resolve liability related to physician payment arrangements.

Beyond Stark Law and AKS-based cases, there were numerous notable settlements in cases involving allegations of medical necessity, upcoding, non-covered services and inadequate oversight of personnel. In one case, a leading cancer center paid $19.5 million to resolve allegations that it improperly billed federal healthcare programs for items and services provided as part of clinical trial research that should have been billed to the clinical trial sponsors.[41] In another, a Colorado health system agreed to pay $23 million to resolve allegations that it automatically coded certain claims for emergency room visits at a higher level than was supported by the medical record.[42]

LONG-TERM CARE

There were notable shifts in the types of settlements announced involving home health, hospice, skilled nursing and nursing home providers. While the majority of settlements in 2023 involved allegations of medically unnecessary services and admissions, last year saw a rise in cases that alleged long-term care providers billed for services that were not rendered or were not rendered as billed. Those cases included a home healthcare agency that billed for nursing and personal care services when the provider was not present in the patients' homes,[43] another home healthcare agency that submitted claims for services that were purportedly provided by employees who were not in the area at the time of service[44] and a home healthcare and hospice provider that billed for home health services that were provided by untrained staff or not actually performed.[45]

There was also an uptick in settlements alleging that providers billed for services provided to patients who were ineligible for those services or did not satisfy all criteria for reimbursement of those services. Those cases included a nursing home operator, related consulting company and two of its executives who billed for services provided to residents who did not have any acute illness or injury, but who had merely been near other people who had COVID-19, during a period when CMS had waived the three-day hospital requirement for skilled nursing care eligibility.[46] They also included two separate settlements with hospice companies that billed for the care of patients who were ineligible for hospice care because they were not terminally ill.[47]

Long-term care providers continued to resolve allegations of AKS violations related to patient referrals. These settlements included a hospice company that paid monthly stipends and signing bonuses to medical directors in exchange for patient referrals,[48] and a group of related home health agencies that provided lease payments, wellness services and other items of value to assisted living facilities and physicians in exchange for patient referrals.[49]

In the largest long-term care settlement of FY 2024, a healthcare system and 12 of its skilled nursing facilities paid more than $21 million to resolve allegations that they billed for rehabilitation services that were unnecessary, unreasonable, unskilled or that did not occur or did not last as long as billed.[50] The settlement involved an admission, as part of the resolution, that management-level employees had implemented facility quotas that incentivized unnecessary services. In addition to the monetary settlement, the company entered into a five-year Corporate Integrity Agreement (CIA) with HHS-OIG.

And, in a notable departure from the most common FCA theories of liability involving healthcare organizations, two related home healthcare companies resolved allegations that they underpaid home health aides.[51] DOJ alleged that the companies' failure to pay aides the minimum wages required under state law rendered their claims for reimbursement to Medicaid false because they certified their compliance with the law when seeking that reimbursement from Medicaid. In addition to the FCA settlement, the companies agreed to pay $7.5 million to current and former aides who were entitled to compensation under the state law.

PHARMACEUTICAL AND DEVICE

Pharmaceutical and medical device companies continued to remain important targets of DOJ enforcement actions, with several companies reaching significant settlements. As in recent years, many of the larger settlements in these sectors involved alleged AKS violations, including cases brought by DOJ alleging that a spinal device manufacturer paid excessive consulting fees, excessive IP acquisition and licensing fees, company performance shares

38 https://www.justice.gov/usao-de/pr/christianacare-pays-425-million-resolve-health-care-fraud-allegations-0.
39 https://www.justice.gov/usao-edny/pr/new-york-presbyterianbrooklyn-methodist-hospital-settles-health-care-fraud-claims-173.
40 https://www.justice.gov/usao-mt/pr/us-attorney-jesse-laslovich-announces-108-million-civil-settlement-st-peters-health-over.
41 https://www.justice.gov/opa/pr/florida-research-hospital-agrees-pay-more-195-million-resolve-liability-relating-self.
42 https://www.justice.gov/opa/pr/uchealth-agrees-pay-23m-resolve-allegations-fraudulent-billing-emergency-department-visits.
43 https://www.justice.gov/opa/pr/home-healthcare-company-agrees-pay-nearly-10-million-resolve-false-claims-act-allegations.
44 https://www.justice.gov/usao-wdnc/pr/north-carolina-home-health-care-agency-and-owner-agree-pay-600000-resolve-false-claims.
45 https://www.justice.gov/opa/pr/nationwide-home-healthcare-and-hospice-provider-pay-385m-resolve-false-claims-act.
46 https://www.justice.gov/usao-cdca/pr/san-gabriel-valley-based-nursing-home-chain-and-executives-pay-over-7-million-settle.
47 https://www.justice.gov/opa/pr/elara-caring-agrees-pay-42-million-settle-false-claims-act-allegations-it-billed-medicare; https://www.justice.gov/opa/pr/kindred-and-related-entities-agree-pay-19428m-settle-federal-and-state-false-claims-act.
48 https://www.justice.gov/usao-ndga/pr/tapestry-hospice-settles-healthcare-kickback-claims-14-million.
49 https://www.justice.gov/opa/pr/home-health-providers-pay-45m-resolve-alleged-false-claims-act-liability-providing-kickbacks.
50 https://www.justice.gov/opa/pr/grand-health-care-system-and-12-affiliated-skilled-nursing-facilities-pay-213m-allegedly.
51 https://www.justice.gov/usao-edny/pr/brooklyn-based-home-health-care-agencies-settle-fraud-claims-975-million-and-agree-pay.

and other extravagant benefits to surgeons;[52] an ophthalmic device company provided luxury travel and entertainment to surgeons;[53] and a specialty pharmaceutical company employed and made bonus payments to a physician's girlfriend.[54]

In one of the largest AKS settlements this year, a drug manufacturer paid $425 million to resolve allegations that it violated the AKS by conspiring with two co-pay assistance foundations to direct its charitable donations to patients taking its own multiple sclerosis drug.[55] In another significant settlement, a pharmaceutical company paid $47 million to resolve allegations that it offered free testing kits to providers in order to generate prescriptions for the drug it manufactures that treats the condition identified by the testing kits.[56] Two other sizable settlements involved generic pharmaceutical manufacturers who each paid $25 million to resolve allegations they paid and received compensation prohibited by the AKS through arrangements on price, supply and allocation of customers with other pharmaceutical manufacturers.[57]

Violations of program requirements also served as the basis for a number of enforcement actions, with durable medical equipment (DME) suppliers as a primary target. In January, a DME supplier and related entities resolved allegations that they submitted claims for used beds as if they were new and mischaracterized travel time as repair time to make it reimbursable.[58] Another DME supplier agreed to pay $25.5 million to resolve allegations that it billed for the rental of non-invasive ventilators to patients when the ventilator was either not being used or not needed by the patient.[59] And a third DME company agreed to pay $13.5 million to resolve allegations that it billed for custom wheelchairs and wheelchair parts based on patient evaluations that were not properly authored, completed or signed by qualified medical professionals.[60]

Pharmaceutical manufacturers were also targeted for violations of program requirements. In February, a drug manufacturer agreed to pay $475.6 million to resolve FCA allegations that the company engaged in a marketing scheme to target its opioid drug to providers

the company knew were prescribing it for non-medically accepted indications or at high volumes.[61] That resolution also included a corporate guilty plea with criminal restitution in excess of $1 billion.

And, late in the year, a compound ingredient supplier agreed to pay $21.75 million to resolve allegations that it overstated the average wholesale price (AWP) of two ingredients used in compound prescriptions, causing pharmacies to submit false claims because compounding pharmacies' reimbursement is based in part on listed AWP.[62]

LABORATORY AND DIAGNOSTIC SERVICES

Allegations of AKS violations continued to drive many of the settlements with laboratory and diagnostic providers. Several labs resolved allegations that they made commission payments to contract sales representatives or third-party marketers based on the volume of referrals, including a lab that paid $13.25 million,[63] a lab that paid $14.3 million[64] and a lab that paid $5.38 million.[65] Other labs resolved allegations that their arrangements with referring providers or practices constituted kickbacks, including a lab that paid an oncology practice for each biopsy the practice referred[66] and a radiology practice that engaged in an improper arrangement with physicians investing in their clinics to induce referrals to the clinics.[67] The year's largest laboratory and diagnostic settlements for kickback violations

52 https://www.justice.gov/opa/pr/medical-device-manufacturer-innovasis-inc-and-two-top-executives-agree-pay-12m-settle.
53 https://www.justice.gov/usao-mn/pr/precision-lens-agrees-pay-12-million-united-states-kickbacks-doctors-violation-false.
54 https://www.justice.gov/usao-nj/pr/california-pharmaceutical-company-pay-750000-resolve-false-claims-act-liability.
55 https://www.justice.gov/usao-ma/pr/teva-pharmaceuticals-agrees-pay-425-million-resolve-kickback-allegations.
56 https://www.justice.gov/opa/pr/pharmaceutical-company-qol-medical-and-ceo-agree-pay-47m-allegedly-paying-kickbacks-induce.
57 https://www.justice.gov/opa/pr/pharmaceutical-company-pays-25m-resolve-alleged-false-claims-act-liability-price-fixing; https://www.justice.gov/usao-edpa/pr/generic-pharmaceutical-company-pays-25-million-resolve-false-claims-act-liability.
58 https://www.justice.gov/usao-sc/pr/durable-medical-equipment-companies-pay-millions-false-claims-settlement.
59 https://www.justice.gov/usao-sdny/pr/us-attorney-announces-255-million-settlement-durable-medical-equipment-supplier.
60 https://www.justice.gov/usao-az/pr/united-seating-and-mobility-llc-dba-numotion-agrees-pay-13500000-resolve-alleged-false.

61 https://www.justice.gov/opa/pr/opioid-manufacturer-endo-health-solutions-inc-agrees-global-resolution-criminal-and-civil.
62 https://www.justice.gov/opa/pr/compound-ingredient-supplier-medisca-inc-pay-2175m-resolve-allegations-false-and-inflated.
63 https://www.justice.gov/opa/pr/new-jersey-laboratory-and-its-owner-and-ceo-agree-pay-over-13-million-settle-allegations.
64 https://www.justice.gov/opa/pr/georgia-laboratory-owner-pleads-guilty-felony-charge-and-pays-143-million-resolve-liability.
65 https://www.justice.gov/usao-edca/pr/admera-health-agrees-pay-over-5-million-settle-false-claims-act-allegations-kickbacks.
66 https://www.justice.gov/usao-wdtx/pr/oncology-practice-physicians-and-reference-laboratory-pay-over-4-million-settle-false.
67 https://www.justice.gov/usao-sdtx/pr/nirp-and-founder-pay-nearly-9m-resolve-alleged-kickback-referral-violations.

> ***DOJ continued to focus on individual actors including licensed and credentialed healthcare providers and executives, whom it views as important gatekeepers for federally funded healthcare programs.***

included a group of diagnostic companies that paid almost $28 million to resolve allegations that they billed for cancer genomic tests that were medically unnecessary and procured via illegal kickbacks[68] and a medical center and its lab that paid $15 million to resolve allegations that they, among other things, provided above-market rent, complimentary and discounted services and payment balance write-downs to third-party clinics in exchange for referrals.[69]

There were also several significant settlements with laboratory and diagnostic providers for unnecessary testing, including several with providers of urine drug tests. These included a lab that paid $10.45 million to resolve allegations that it billed for drug tests that were court-ordered or referred from organizations that did not provide medical treatments, such as faith-based centers and homeless shelters, and that they knew were not performed for any medical reasons;[70] a lab that paid $13.61 million to resolve allegations that it billed for PCR urinalysis lab tests that were medically unnecessary and not ordered by the patients' treating physician;[71] and two labs that paid $2.1 million and $6.5 million, respectively, to resolve allegations that they billed for definitive urine drug tests where the lab performed both presumptive and definitive urine drug tests on the same sample, at or near the same time.[72] In the year's largest lab settlement for unnecessary testing, a lab paid $27 million to resolve allegations that it billed for unnecessary urine drug tests, in part by promoting standing orders that caused physicians to order a significant number of tests without an individualized patient assessment.[73]

INDIVIDUAL PROVIDERS AND PHYSICIAN PRACTICE GROUPS

DOJ continued to focus on individual actors including licensed and credentialed healthcare providers and executives, whom it views as important gatekeepers for federally funded healthcare programs. In one notable case, the former CEO of a critical access hospital agreed to pay over $5.3 million to resolve allegations related to his role in a kickback scheme involving lab test referrals to the hospital.[74] The CEO also agreed to a 25-year exclusion from federal healthcare programs as part of the resolution.

DOJ also resolved several FCA cases with medical providers related to allegations that the providers had misrepresented services rendered in a manner that increased the reimbursement or permitted the providers to bill for services that were not reimbursable. These cases included multiple acupuncturists who allegedly billed for services not provided;[75] pain management clinicians and chiropractors who allegedly billed for medically unnecessary or more complex procedures than actually performed;[76] a preventive medicine physician who allegedly billed for upcoded evaluation and management (E&M) services and services never provided;[77] and an alternative clinician who allegedly billed Medicare and TRICARE for infusion and hormone supplement therapies that were not covered under either program.[78]

There were also a number of settlements by individuals relating to their role in alleged kickback schemes, including multiple settlements related to alleged schemes involving unnecessary DME[79] and several settlements related to lab test referrals.[80]

68 https://www.justice.gov/usao-sdfl/pr/florida-businessman-daniel-hurt-pay-over-27-million-medicare-fraud-connection-cancer.
69 https://www.justice.gov/usao-cdca/pr/southern-california-based-clinics-laboratory-and-owners-pay-15-million-false-claims.
70 https://www.justice.gov/usao-edky/pr/lexington-lab-agrees-104-million-civil-judgments-resolve-false-claims-act-allegations.
71 https://www.justice.gov/opa/pr/gamma-healthcare-and-three-its-owners-agree-pay-136-million-allegedly-billing-medicare-lab.
72 https://ncdoj.gov/attorney-general-josh-stein-reaches-2-1-million-medicaid-settlement-with-mako-medical/; https://www.justice.gov/usao-ma/pr/ethos-laboratories-agrees-pay-65-million-resolve-allegations-fraudulent-billing.
73 https://www.justice.gov/usao-co/pr/precision-toxicology-agrees-pay-27m-resolve-allegations-unnecessary-drug-testing-and.
74 https://www.justice.gov/opa/pr/texas-hospital-ceo-pay-over-53m-settle-kickback-allegations-involving-laboratory-testing.
75 https://www.justice.gov/usao-wdtx/pr/acupuncturist-and-acupuncture-clinic-ordered-pay-23-million-resolve-civil-false-claims; https://www.justice.gov/usao-edca/pr/us-attorneys-office-obtains-850000-settlement-fresno-acupuncturist-resolve-false.
76 https://www.justice.gov/usao-edmo/pr/united-states-reaches-12-million-civil-settlement-festus-pain-management-doctor-over; https://www.justice.gov/usao-edpa/pr/us-attorney-announces-two-additional-civil-settlements-part-national-effort-combat.
77 https://www.justice.gov/usao-nj/pr/doctor-pay-nearly-700000-resolve-false-claims-act-allegations.
78 https://www.justice.gov/usao-sdca/pr/san-diego-physician-and-medical-practice-pay-38-million-resolve-false-claims-act.
79 https://www.justice.gov/usao-edwa/pr/doctor-agrees-pay-95000-settle-allegations-health-care-fraud; https://www.justice.gov/usao-ndia/pr/iowa-nurse-practitioner-agrees-pay-over-50000-resolve-suit-alleging-fraudulent-durable; https://www.justice.gov/usao-edwa/pr/owner-spokane-valley-medical-supply-company-agrees-pay-224620-resolve-allegations.
80 https://www.justice.gov/opa/pr/marketers-and-physicians-five-states-agree-pay-over-15-million-settle-laboratory-kickback; https://www.justice.gov/opa/pr/laboratory-marketer-and-north-carolina-physicians-agree-pay-over-13m-settle-kickback; https://www.justice.gov/usao-edky/pr/hospital-laboratory-referring-physician-and-lab-employees-pay-more-72-million-resolve; https://www.justice.gov/opa/pr/north-carolina-physician-and-medical-practice-agree-pay-625000-settle-kickback-allegations-0.

OTHER PROVIDERS

Multiple other types of providers resolved FCA allegations that they caused the submission of false claims as a result of alleged AKS violations. In one notable high-dollar settlement, a primary care center operator agreed to pay $60 million to resolve allegations that it paid kickbacks to third-party insurance agents in exchange for patient recruitment.[81] In another such settlement, a dialysis clinic provider agreed to pay $34.4 million to resolve allegations that it paid kickbacks to multiple constituencies, including uncollected management fees from physician owners of vascular access centers, to induce referrals to the company's dialysis centers and pharmacy subsidiaries.[82] In addition, 16 separate cardiology practices and associated physicians across 12 states agreed to pay over $17 million to resolve allegations that they violated the FCA by overbilling Medicare for diagnostic radiopharmaceuticals.[83]

Finally, multiple settlements involved healthcare grant funding,[84] and there were a number of others that involved the alleged failure to implement adequate cybersecurity measures to protect patient health information,[85] including self-disclosed allegations related to the same.[86]

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81 https://www.justice.gov/opa/pr/oak-street-health-agrees-pay-60m-resolve-alleged-false-claims-act-liability-paying-kickbacks.
82 https://www.justice.gov/opa/pr/davita-pay-over-34m-resolve-allegations-illegal-kickbacks.
83 https://www.justice.gov/usao-wdky/pr/sixteen-cardiology-practices-pay-total-177m-resolve-false-claims-act-allegations-0.
84 https://www.justice.gov/usao-ndny/pr/grant-administrator-pay-500000-resolve-false-claims-act-investigation-involving-misuse; https://www.justice.gov/usao-ndoh/pr/cleveland-clinic-pay-over-7-million-settle-allegations-undisclosed-foreign-sources.
85 https://www.justice.gov/opa/pr/staffing-company-pay-27m-alleged-failure-provide-adequate-cybersecurity-covid-19-contact.
86 https://www.justice.gov/usao-sc/pr/operator-south-carolina-medicaid-call-center-agrees-pay-113-million-resolve-false-claims.

FALSE CLAIMS ACT UPDATE

The FCA continues to be the federal government's primary civil enforcement tool for pursuing liability against healthcare providers that have allegedly defrauded federal healthcare programs. As in previous years, there have been a number of legal developments involving the FCA that will greatly impact the government's enforcement efforts and the manner in which *qui tam* relators pursue their FCA claims.

ESCOBAR'S "RIGOROUS" MATERIALITY REQUIREMENT

Courts continue to closely scrutinize the FCA's materiality element through the lens of the Supreme Court's 2016 decision in ***Universal Health Services v. U.S. ex rel. Escobar***. In *Escobar*, the Supreme Court described the materiality element as "rigorous" and "demanding," while identifying several non-dispositive factors that courts should consider. As in past years, courts provided guidance on the application of these factors, weighing in on the kinds of allegations and evidence that can establish materiality—and on those that do not suffice.

The Government's Payment History

Perhaps the most important materiality factor identified in *Escobar* is the government's reaction to alleged violations of regulatory or contractual requirements. Over the past year, several courts have grappled with the significance of evidence that the government either continued paying, or declined to pay, claims after being put on notice of such violations.

For example, in ***U.S. ex rel. Krahling v. Merck & Co.***, the Third Circuit affirmed summary judgment for a defendant vaccine manufacturer because, among other reasons, the relevant government agency had continued to purchase the vaccine at issue and "signaled no change in position," even after it gained "knowledge of the facts concerning the alleged misrepresentations and fraudulent acts as to testing, potency, shelf-life and the like."[87] As a result, the Third Circuit held that no reasonable jury could conclude that the alleged misrepresentations and fraudulent acts were material to the purchasing decision.

87 2024 WL 3664648 (3d Cir. Aug. 6, 2024).

Likewise, in ***U.S. ex rel. Stebbins v. Jefferson Cardiology Association***, the district court cited the fact that the government had continued to reimburse the defendants, "despite the public availability of information that would have put the government on notice of Defendants' alleged violations of a licensing law," among the reasons that supported dismissal of the relator's complaint at the pleading stage.[88] Notably, the district court found that fact to be significant for materiality purposes even though the government's *actual* knowledge of the alleged violations was "not evident from the record before the court."

By contrast, in ***U.S. ex rel. Ruggeri v. Magee-Womens Research Institute and Foundation***, the district court denied the defendant's motion to dismiss on materiality grounds where the government had reduced grant funding to the defendant research foundation after learning of allegations that it was using impermissible accounting practices.[89] The district court explained that the reduction in funding "underscored" the materiality of the alleged violations, describing the government's response as "perhaps the strongest evidence of materiality" in the case.[90]

"Essence of the Bargain"

Another factor that often drives the materiality analysis—but one that is perhaps more subjective—is whether the alleged violation goes to the "essence" of the government's bargain.

In ***U.S. ex rel. Depa v. Midland Orthopedic Associates***, for instance, the district court denied the defendant's motion to dismiss on materiality grounds largely because "common sense" dictated that the alleged violations of licensing and accreditation requirements were sufficiently "central to the bargain" between the government and the defendant.[91] Although the district court noted that further factual development might prove otherwise, the district court held that the inherent purpose of the relevant requirements sufficed to show materiality at the pleading stage because the requirements "help ensure that the government is paying for [services] performed by qualified, competent professionals, 'not charlatans' whose involvement is a waste of time and resources."[92]

The Eighth Circuit's decision in ***U.S. ex rel. Holt v. Medicare Medicaid Advisors*** illustrates the opposite conclusion.[93] There, the Eighth Circuit determined that the alleged fraud did not go to the "essence" of the government's bargain in part because the Medicare Advantage (MA) regulations at issue provided CMS with *discretionary*, rather than mandatory, authority to impose sanctions for violations, and the alleged violations did not affect CMS's or an insurance carrier's "ability to provide healthcare services."[94]

Sometimes courts also consider the magnitude of the alleged violations. For example, when granting summary judgment for the relator on the materiality element in ***United States v. SuperValu, Inc.***—a case involving allegations that a retail pharmacy failed to properly report its "price matching" practices to the government—the district court cited among other evidence of materiality both "how frequently" price matching took place and "the difference in the retail price SuperValu reported versus the price that was actually given to the government."[95]

Express Condition of Payment: Relevant But Not Dispositive

Finally, in analyzing materiality, at least some emphasis typically is placed on whether the relevant regulatory or contractual requirement was expressly designated as a condition of payment.

Among other such cases, two district court decisions declined to dismiss FCA claims premised on alleged "standing orders" for unnecessary urine drug tests (UDTs) in part because a federal statute requires, as a condition of payment under Medicare, that services be "reasonable and necessary," while a separate Medicare Local Coverage Determination specifically provides that routine standing orders are *not* reasonable and necessary.[96] In both cases, the district courts relied heavily on these conditions of payment when concluding that the relators had adequately pleaded materiality.

That said, consistent with *Escobar*'s guidance, the condition-of-payment factor is often treated as somewhat less important than other materiality factors, such as the government's reaction to the alleged violation and whether it goes to the essence of the bargain.

Accordingly, in ***U.S. ex rel. Heath v. Wisconsin Bell, Inc.***, the Seventh Circuit held that materiality was not a valid basis for affirming summary judgment for the defendant because, even though the relevant rule was not expressly labeled a condition of payment, such a label "should not have been necessary for a provider to understand that the rule [was] important to the program's functioning" and that "noncompliance could influence reimbursement decisions."[97] Meanwhile, in ***U.S. ex rel. Hartman v. Centra Health, Inc.***, the district court dismissed the relator's FCA claims regarding the alleged falsification of Joint Commission accreditation documents even though maintaining accreditation *was* an express condition of

88 2024 WL 3982318 (W.D. Pa. Aug. 29, 2024).
89 2024 WL 1767514 (W.D. Pa. Apr. 29, 2024).
90 *See also U.S. ex rel. Behnke v. CVS Caremark Corp.*, 2024 WL 1416499, at *38-39 (E.D. Pa. Apr. 2, 2024) (concluding that factual disputes precluded summary judgment where evidence regarding the government's knowledge of the alleged violations was "not conclusive" and where the government could have had other reasons for failing to act).
91 2024 WL 3797387 (N.D. Ill. Jan. 8, 2024).
92 *See also, e.g.*, *U.S. ex rel. Quaresma v. Journey to Hope Health & Healing, Inc.*, 728 F. Supp. 3d 251 (D.R.I. 2024) (citing the centrality of counseling requirements to regulations governing payment for methadone treatment while noting that "compliance with requirements that are repeatedly referenced in absolute language is 'the textbook example' of the type of representation that would be material to the Government's decision to pay claims").
93 115 F.4th 908 (8th Cir. 2024).
94 *See also U.S. ex rel. Zotos v. Town of Hingham*, 98 F.4th 339 (1st Cir. 2024) (alleged violations involving noncompliant highway signs did not go to the essence of the bargain because they "amount[ed] at best to the kind of ancillary violation for which 'the Government would be entitled to refuse payment were it aware'").
95 2024 WL 4351951 (C.D. Ill. Sep. 30, 2024); *see also Mazik v. Kaiser Permanente, Inc.*, 2024 WL 584162, at *9 (E.D. Cal. Feb. 13, 2024) (citing the magnitude of the alleged loss as supporting the materiality of the alleged fraud).
96 *See U.S. ex rel. Allstate Ins. Co. v. Phoenix Toxicology & Lab Servs., LLC*, 2024 WL 2785396 (D.N.J. May 30, 2024); *U.S. ex rel. Johnson v. Kelly*, 2024 WL 1862813 (W.D. Okla. Apr. 29, 2024).
97 92 F.4th 654 (7th Cir. 2023).

payment for the psychiatric services at issue.[98] Noting that such a label is not dispositive, the district court reasoned that the relators had not adequately alleged with particularity that the government would not have paid the defendant had it known of the allegedly fraudulent activity. Together, these decisions further highlight the "holistic" approach to materiality taken by most courts.

DEVELOPMENTS IN PLEADING STANDARDS

Because FCA complaints contain allegations of fraud, they are subject to the heightened pleading standard of Federal Rule of Civil Procedure 9(b), which requires allegations to be pleaded with particularity. In applying Rule 9(b) to FCA complaints, courts typically demand specific allegations of a fraudulent "scheme" carried out by the defendant, but they continue to disagree as to how detailed the allegations must be to connect that scheme to actual claims submitted to the government for payment.

Pleading the Details of a Fraudulent Scheme

Rule 9(b) does not require plaintiffs to prove their case in a complaint, but in order to survive a motion to dismiss, all courts agree that Rule 9(b) requires some level of factual specificity regarding the alleged fraud scheme, including the "who, what, when, where, and how" of the alleged wrongful conduct.

Multiple decisions considering whether FCA allegations satisfied Rule 9(b) turned on whether the complaints sufficiently described "who" was involved in the alleged fraud scheme and the details of their role in it. In ***U.S. ex rel. Kyer v. Thomas Health Sys., Inc.***, the district court dismissed an amended complaint alleging a hospital and its subsidiaries engaged in an unlawful compensation scheme in violation of the AKS and the Stark Law.[99] The district court held the complaint failed to distinguish between the conduct of the four defendants and thus failed to satisfy Rule 9(b)'s requirement that "an FCA Relator, must identify, with particularly, *each individual's culpable conduct*."

Conversely, in ***United States v. Peters***, the district court concluded that the government adequately alleged FCA violations, where it alleged that the defendants engaged in a kickback scheme offering high-volume doctors valuable shares of management companies in exchange for sending prescriptions to the defendant pharmacies.[100] The defendants challenged the allegations under Rule 9(b), arguing that the complaint failed to distinguish between the individual defendants. The district court held that "[b]ecause the pharmacies all played the 'same role' in the centrally operated scheme, the government may collectively plead the allegations against the pharmacies."

98 724 F. Supp. 3d 549 (W.D. Va. 2024).
99 2024 WL 4707811 (S.D.W. Va. Nov. 7, 2024).
100 2024 WL 3378034 (E.D. Cal. July 11, 2024).

> ***"In applying Rule 9(b) to FCA complaints, courts typically demand specific allegations of a fraudulent "scheme" carried out by the defendant, but they continue to disagree as to how detailed the allegations must be to connect that scheme to actual claims submitted to the government for payment.***

In ***U.S. ex rel. Olsen v. Tenet Healthcare Corp.***, the district court dismissed an amended complaint alleging fraudulent billing for services billed as in-patient that were performed in the emergency room in part because the complaint did not plead sufficient details of the named defendants' involvement.[101] The relators provided details of six exemplar patients purportedly harmed by this practice and highlighted a "protocol" that the defendants allegedly employed to bill for these services. The district court granted dismissal under Rule 9(b) finding the factual allegations in the complaint did not support a plausible inference that the defendants directed their subsidiary hospitals to submit false claims. The district court explained that "[e]ven assuming *arguendo* that Defendants had a general policy and were generally aware of severe staffing issues and excessive boarding times, the factual allegations do not suggest that, with respect to each of the six individual patients, Defendants billed government healthcare programs despite knowing that their subsidiaries had failed to render care in compliance with regulations at the respective times in question." The district court further held that various emails and tracking systems that allegedly alerted the parent defendants did not sufficiently connect the parent corporations to any fraud scheme.

Other decisions analyzed whether the complaint's allegations were sufficient to plead a far-reaching fraud scheme. In ***U.S. ex rel. Pepe v. Fresenius Medical Care Holdings***, the district court dismissed the relators' claims alleging a nationwide self-referral scheme from the defendants' dialysis centers to their vascular care centers.[102] The district court held that generalized presentations, financial policies and information on the defendants' website did not infer an illicit billing scheme under Rule 9(b), nor did the six patient examples pleaded with particularity: "[p]atient examples from such a limited geographic scope, without more, cannot reasonably support the Court's extrapolation as to nationwide practices." The relators also pointed to aggregated data that allegedly showed that defendant physicians performed many vascular interventions and received "extraordinarily high" Medicare payments for the same, but the district court held that the relators failed to adduce facts specifying that any of the payments reflected in the data were the product of any false claims submitted to the government.

101 2024 WL 3926474 (E.D. Mich. Aug. 23, 2024).
102 2024 WL 4635236 (E.D.N.Y. Oct. 31, 2024).

Similarly, in ***U.S. ex rel. Hunter v. Fillmore Cap. Partners, LLC***, the district court dismissed a complaint alleging the defendants engaged in a scheme to routinely overbill for substandard care provided over a years-long period at 273 nursing homes.[103] The complaint relied on, among other things: computer models quantifying the relator's impossible day theory; affidavits from nurses in other lawsuits describing understaffing and overbilling at certain defendant facilities; and the relator's own resignation letter and other patient and employee complaints. The district court held the complaint did not sufficiently plead the details of any fraud scheme. The complaint "generally and repeatedly allege[d] that due to understaffing, claims were 'routinely falsified,' but [] provid[ed no] factual details that would support the submission of false claims."

Other decisions turned on whether the "what" and "how" were adequately pleaded under Rule 9(b). In ***U.S. ex rel. Senters v. Quest Diagnostics, Inc.***, the district court dismissed a complaint that alleged that Quest Diagnostics created custom, multi-test lab panels without clear instructions regarding which tests were on which panels.[104] Doctors were allegedly encouraged to use the custom panels under the belief that they were billed at bundled rates, but then Quest would complete and bill each test on each panel, resulting in alleged medically unnecessary tests being submitted to the government. The district court dismissed the relator's allegations, in part, because the relator provided no facts to show that any test completed and billed by Quest was, in fact, medically unnecessary or not actually ordered by a physician. The district court noted that other cases alleging medically unnecessary lab tests had survived dismissal by relying on specific facts and scientific information to show that the tests were not medically unnecessary. The relator claimed only that Quest did not know or confirm that each test was medically necessary before certifying that they were on their claim forms. The relator also failed to plead that any medically unnecessary tests were ever submitted to the government. While the relator provided exemplar patients, none connected all the dots in the district court's view.

By contrast, the district court in ***U.S. ex rel. Shiloh v. Philadelphia Vascular Inst. LLC***, held that the government adequately alleged that the defendants submitted false claims for medically unnecessary procedures.[105] The defendant moved to dismiss, arguing that the government had failed to meet the heightened pleading standard of Rule 9(b) for falsity because the government had not alleged how any particular procedure was "outside a particular medical standard of care." The district court disagreed, finding that the government had cited "well-established medical standards of care" for the relevant treatment, specifically alleged that the defendants regularly failed to adhere to those standards and further alleged that the defendants were outliers compared to other providers in terms of procedures performed, reimbursement submitted and amounts billed for the relevant CPT codes. Taken together, this was enough to allege that the claims were medically unnecessary, and therefore, "false."

Likewise, in ***U.S. ex rel. Quaresma v. Journey to Hope, Health and Healing, Inc.***, the government alleged that the defendants, a substance use disorder treatment provider and its CEO, submitted Medicaid claims for methadone treatment including counseling services and treatment plans that were required under Rhode Island law, but never provided, resulting in the submission of false claims to Medicaid.[106] The district court denied the defendants' motion to dismiss, finding that the government had sufficiently pleaded its claims under Rule 9(b) by providing specific examples of false claims submitted for patients without updated treatment plans or counseling records. The district court found that the allegations were specific as to time, place and content, and were supported by extensive testimony from former employees, meeting the heightened pleading standard required for fraud claims under Rule 9(b).

In ***U.S. ex rel. Askari v. PharMerica Corp.***, the Second Circuit affirmed dismissal of a complaint alleging various pharmacies and their executives engaged in a series of schemes that resulted in the submission of false claims for prescription drugs.[107] Specifically, the complaint alleged that the defendants violated various out-of-state pharmacy licensing laws, and in turn federal laws, that require compliance with state licensing laws. The district court dismissed the complaint without leave to amend for failure to plead allegations supporting materiality with the particularity required by Rule 9(b) and the Second Circuit affirmed. On appeal, the relator pointed to a purportedly similar action brought by DOJ and general CMS handbook guidance related to fraudulent billing. The district court held these allegations were insufficient to plead materiality.

In ***U.S. ex rel. Dunn v. Procarent, Inc.***, the district court dismissed allegations of fraudulent billing for medically unnecessary and upcoded non-emergency ambulance transports.[108] Since the complaint did not contain specific examples of false claims, the district court performed a careful analysis of whether the relators had alleged facts demonstrating specific personal knowledge that supported a strong inference of the submission of false claims and found, although it was a "close call," they had not. Although the relators alleged to have personal knowledge of the defendant's billing practices and were involved in billing procedures, their third amended complaint still failed to provide any details about the *submission* of allegedly fraudulent claims. Conversely, certain of the relators' false statement claims partially survived dismissal against the defendant's Rule 9(b) challenge because the complaint provided documentary support in addition to alleging personal knowledge of the false statements in forms that were a prerequisite to payment.

In ***U.S. ex rel. Daron Street, M.D. v. Genentech, Inc.***, the district court found the complaint contained sufficient detail to support a reasonable inference that false claims were submitted as to one of two false drug-labeling schemes.[109] As to the first, the district court found allegations that approximately 90% of the lots of the subject drug were underfilled and that the government entered multiple contracts to purchase the drug between 2004-2016 were an adequate basis for a reasonable inference that false claims were submitted as part

103 2024 WL 1051971 (E.D. Pa. Mar. 11, 2024).
104 2024 WL 4297469 (N.D. Ga. Aug. 23, 2024).
105 2024 WL 1355135 (E.D. Pa. Mar. 29, 2024).
106 2024 WL 1340920 (D.R.I. Mar. 29, 2024).
107 2024 WL 1132191 (2d Cir. Mar. 15, 2024).
108 2024 WL 993310 (W.D. Ky. Mar. 7, 2024).
109 2024 WL 1143513 (N.D. Okla. Mar. 14, 2024).

> ***The Second Circuit this year found that relators were not entitled to rely on a relaxed Rule 9(b) pleading standard where their allegations suggested that the billing information was not peculiarly within the defendant's control.***

of the scheme. As to the second scheme, the complaint relied on a "single email, written in very technical language" that the district court held was insufficient to put the defendant on notice of all of the relevant details of the alleged fraud scheme and dismissed those claims pursuant to Rule 9(b).

Pleading the Presentment of False Claims

Pleading the submission of false claims with the requisite particularity is no easy hurdle, and courts continued to hold relators to a stringent pleading standard for presentment under Rule 9(b). District courts dismissed a number of *qui tam* lawsuits on presentment grounds, even when applying various formulations of a more relaxed pleading standard—for instance, permitting a relator to plead reliable indicia that support a strong inference that a party submitted false claims for payment in lieu of pleading specific false claims.

Early in 2024, the Second Circuit analyzed when a relator is entitled to a more relaxed pleading standard. In ***Pilat v. Amedisys, Inc.***, former employees of a home health and hospice care company brought FCA claims alleging that the company falsely certified unqualified patients for home health care, provided unnecessary and improper treatment, falsified time records and manipulated patient records.[110] The district court dismissed the complaint, holding that the relators had not satisfied either prong of the Second Circuit's standard for pleading presentment upon information and belief. That standard allows a relator to satisfy Rule 9(b) by: (1) showing that billing information is peculiarly within the defendant's knowledge; and (2) making plausible allegations that create a strong inference that specific false claims were submitted to the government. On appeal, as to the second prong, the Second Circuit held that the relators had plausibly alleged sufficient facts to create a strong inference that the defendant had submitted false claims. The relators identified multiple instances in which a clinician was instructed to document patient information falsely or to recommend unnecessary courses of treatment, and the relators alleged that 80 percent of the defendant's revenue came from government funded healthcare. But, the Second Circuit affirmed the district court's ruling that the complaint fell short of satisfying the first prong, finding that the relators had alleged some instances in which they reviewed forms used for submitting bills to the Government and noted some changes to those forms to increase revenue, which suggested that the billing information was not peculiarly within the defendant's control. As a result, the relators were not entitled to rely on a relaxed pleading standard.

In ***U.S. ex rel. Stephens v. Malik***, the district court required the relator to identify particular false claims to satisfy Rule 9(b).[111] The relator alleged that physicians submitted false claims for myocardial stress tests and/or nuclear imaging services that were allegedly part of a self-referral scheme to the co-defendant cardiology practice in which the physicians held ownership interests. The district court found that the relator failed to allege a specific, representative example of a false claim as required by Seventh Circuit precedent and instead relied on conclusory allegations with no factual support regarding specific patients or services improperly billed or referred. The district court stressed that the relator also failed to allege any rationale as to why he would not have access to the billing records in order to meet his pleading standard. In doing so, the district court rejected the relator's arguments that allegations related to the amounts of physicians' Medicare reimbursement should suffice.

Numerous district courts dismissed *qui tam* claims for failure to plead facts sufficient to satisfy the FCA's presentment element, even under some form of a relaxed pleading standard. For example, in ***U.S. ex rel. Powell v. Medtronic, Inc.***, the relator alleged that the defendant had engaged in a fraudulent scheme to encourage customers to reuse a component of a glucose monitoring system on multiple patients, contrary to its U.S. Food and Drug Administration (FDA) label, and thereby causing providers to submit false claims for reimbursement.[112] The district court granted the defendant's motion to dismiss, finding that the relator had failed to plead presentment with respect to the counts alleging violations of the FCA based on the defendant's failing to disclose that the device was only approved by the FDA for single use and its making false or misleading statements about reuse of the device on multiple patients. The district court noted that the relator failed to identify any actual false claims submitted, and that even under a more relaxed pleading standard requiring a "strong inference" that false claims were submitted, the relator failed to allege a link between the alleged misconduct and specific fraudulent claims. The district court emphasized that even though the relator

> ***Numerous district courts dismissed qui tam claims for failure to plead facts sufficient to satisfy the FCA's presentment element, even under some form of a relaxed pleading standard.***

110 2024 WL 177990 (2d Cir. Jan. 17, 2024).

111 2024 WL 4590838 (N.D. Ind. Oct. 28, 2024).
112 2024 WL 4165522 (S.D.N.Y. Sept. 12, 2024).

alleged that the defendant trained individuals on how to reuse the component on multiple patients, the relator had made no effort to plead that those individuals then prescribed or sought reimbursement for reuse of the device.

Likewise, in ***U.S. ex rel. Switzer v. Wood***, the district court held that the relators failed to satisfy Rule 9(b)'s particularity requirement as to the submission of false claims. The relators alleged that the defendants were engaged in a kickback arrangement related to a physician-owned distributorship and the use of spinal devices in surgeries performed at a defendant's hospital, while disguising payments as consulting fees or distributions provided pursuant to an allegedly sham consulting agreement.[113] The district court concluded that although the relator relied on an implant log providing a record of surgeries from 2012 to 2020, the log failed to show whether a false claim was actually submitted, and instead only provided an inference that false claims *may* have been submitted. The district court likewise held that the relator did not allege, in the alternative, that the relator possessed "direct knowledge" of the submission of false claims under the Eleventh Circuit's "more tolerant" approach, where the allegations must provide sufficient indicia of reliability that false claims were submitted.

In ***U.S. ex rel. Siegel v. Novo Nordisk, Inc.***, the relator, a former physician employee, alleged that Novo Nordisk was engaged in a nationwide marketing and promotion scheme to have its hemophilia drug prescribed for off-label and medically unnecessary use and provided kickbacks to physicians and patients to prescribe and use the drug instead of a competitor's drug.[114] The district court found that the relator's allegations regarding her own experiences as an employee at Novo Nordisk failed to show that a false claim was actually submitted, given that her work was unrelated to any interactions with hemophilia patients or individuals who were prescribed the drug in question. Arguing that she had sufficiently pled the submission of a false claim by describing a scheme in great detail and establishing a strong inference that a claim was submitted, the relator explained that Novo Nordisk had been successful in its nationwide marketing campaign by the virtue of the fact that the campaign endured over time. The district court granted Novo Nordisk's motion to dismiss, concluding that the relator had not established reliable indicia that claims were submitted as required for pleading presentment under Rule 9(b), highlighting that the drug at issue was largely not covered by Medicare or Medicaid and only 15 percent of the drug's revenue stream was for off-label use.

Finally, district courts dismissed claims where the relators may have pleaded a fraudulent scheme but failed to connect that scheme to any false claims. In ***U.S. ex rel. Kyer v. Thomas Health Sys., Inc.***, the relator alleged that a health system, hospital subsidiaries and their affiliated physician group violated the FCA, the Stark Law and the AKS.[115] The district court held that the complaint failed to connect any claim for payment to the allegedly unlawful compensation scheme, either by alleging specific false claims actually presented to the government or by alleging a "pattern of conduct" that "necessarily leads to the submission of false claims" for payment. Although the relator included 32 pages of alleged claims within appendices to her complaint, the district court found that those claims were not sufficiently particular to satisfy Rule 9(b), and the complaint failed to explain how the appendices show false claims or "connect the dots" between alleged false claims and government payment.

In ***U.S. ex rel. Hunter v. Fillmore Cap. Partners, LLC***, the district court engaged in a similar analysis. There, the relator alleged that the defendants had engaged in a scheme to overbill Medicare and Medicaid at hundreds of nursing homes by admitting high-acuity residents in order to increase reimbursements, limiting staffing, and consequently billing for services that the relator alleged would have been impossible to provide appropriately with such staff limitations and acuity levels.[116] To support these allegations, the relator cited: (1) computer models quantifying his impossible day theory; (2) affidavits from nurses in other lawsuits describing understaffing and overbilling; and (3) his own resignation letter and other patient and employee complaints. The district court held that while the relator sufficiently pleaded the details of a scheme, the relator had failed to plead reliable indicia that lead to a strong inference that claims were actually submitted for payment. The district court noted that it would not require a relator to identify particular false claims, but here there was "no accompanying factual explanation of how and whether any false claims were actually submitted."

DEVELOPMENTS REGARDING FALSITY

FCA plaintiffs must plead and prove that claims were actually false in order to successfully state a claim for relief. As a result, the defendants facing FCA claims often challenge the legal viability of any number of theories of what renders a claim false asserted by the government or *qui tam* relators.

Express and Implied False Certification

It is well-settled that FCA liability attaches to claims that are either factually false or legally false. Factually false claims involve billing for goods or services that are incorrectly described or were not provided at all. Defendants also can be held liable under the FCA for submitting "legally false" claims that either expressly or impliedly certify compliance with applicable statutes, regulations or contractual provisions.

As for implied false certification, the Supreme Court in *Escobar* held that defendants can be liable if: (1) "the claim does not merely request payment, but also makes specific representations about the goods or services provided;" and (2) "the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths."[117]

During the past year, courts analyzed the bounds of false certification liability.

113 2024 WL 3742713 (S.D. Ga. Aug. 9, 2024).
114 2024 WL 3582417 (W.D. Wash. July 30, 2024).
115 2024 WL 4707811 (S.D.W. Va. Nov. 7, 2024).
116 2024 WL 1051971 (E.D. Pa. Mar. 11, 2024).
117 579 U.S. at 180.

In ***U.S. ex rel. Stenson v. Radiology Ltd., LLC***, the Ninth Circuit reversed in part the district court's dismissal of FCA claims for failure to plead falsity.[118] The relator alleged that the defendant radiology facility submitted claims that violated the FCA under two theories of falsity. The relator alleged that the defendant falsely billed government healthcare programs because the defendants performed diagnostic readings on non-medical grade Dell computer monitors. While the defendants expressly and impliedly certified compliance with applicable Medicare rules, regulations and policies, none of the foregoing required radiologists to use FDA-approved devices outside of performing mammography. As such, the Ninth Circuit affirmed the district court's dismissal of this theory of falsity. The Ninth Circuit, however, reversed the district court's dismissal of the relator's other theory of falsity regarding the defendants' implied certification that the diagnostic readings were reasonable and necessary because it was sufficient for the relator to plead that the defendants had an obligation to use appropriate technology with respect to the claims submitted for diagnostic services and that they allegedly failed to do so.

In ***U.S. ex rel. Hunter v. Fillmore Cap. Partners, LLC***, the district court concluded that the relator failed to plead falsity with respect to the relator's theory that the defendant nursing homes submitted false claims to government healthcare programs.[119] The relator's theory of falsity turned on allegations that the nursing homes performed grossly substandard services stemming from understaffing and then submitted false claims based on fraudulently inflated or non-existent medical records, which allegedly were a consequence of the alleged understaffing. The district court characterized the relator's allegations as conclusory and explained that the relator failed to put forth any facts alleging that claims were falsified.

The relator in ***U.S. ex rel. O'Laughlin v. Radiation Therapy Servs., P.S.C.***,[120] alleged that the defendants billed for chemotherapy services as if they were provided by a physician when they were allegedly neither provided nor supervised by a physician. The district court granted summary judgment in favor of the defendant because the relator failed to produce evidence of any actual false claims and referenced only vague descriptions of schemes without evidentiary support. The relator's allegations of insufficient staffing relied on a master schedule, but those allegations were contradicted by staff testimony that established these schedules were created for the sole purpose of tracking patients after checkout, not to track physician presence. In sum, the district court concluded that the record failed to support a finding of falsity on any particular day with respect to the relator's theory of FCA liability.

Courts also continued to consider whether violations of particular laws and regulations may satisfy the FCA's falsity element. For instance, in ***U.S. ex rel. Powell v. Medtronic, Inc.***,[121] the relator alleged that Medtronic encouraged physician customers to reuse a component part of a glucose monitoring system on multiple patients, contrary to the device's FDA label. The relator asserted that this recommended reuse of the component raised such a risk of infection to render the service medically unnecessary or to adulterate the device, resulting in false reimbursement claims. The district court rejected the relator's implied false certification theory because any potential harm from the alleged misuse was considered too speculative. The district court cited to the lack of any authoritative evidence such as FDA enforcement actions or guidance that the alleged misuse alleged by the relator would be considered unsafe. The district court also rejected the relator's argument that multi-patient use of the device component rendered the device adulterated under the Food, Drug and Cosmetic Act (FDCA), noting that the Second Circuit had not recognized violations of the FDCA as giving rise to FCA claims.

In ***U.S. ex rel. Bennett v. Bayer Corp.***,[122] the relator alleged that the defendants made intentionally false misrepresentations to the FDA to get approval to sell fluoroquinolone antibiotics (FQs), which resulted in medical providers prescribing the FQs and improperly seeking "fraudulently induced" reimbursements from government healthcare programs. Describing it as a "fraudulent inducement" theory of falsity, the district court concluded that the relator failed to plead falsity because no contractual relationship existed between the defendants and the FDA by which the FDA could be fraudulently induced to approve of the defendants' drug applications. Moreover, the district court explained that even if such liability might exist without a contractual relationship, the relator failed to establish a strong inference of any knowingly false statements by the defendants to the FDA because the FDA was aware of all information included in the complaint and the defendants complied with all FDA approval requirements.

118 2024 WL 1826427 (9th Cir. Apr. 26, 2024).
119 2024 WL 1051971 (E.D. Pa. Mar. 11, 2024).
120 2024 WL 4242483 (E.D. Ky. Sept. 19, 2024).
121 2024 WL 4165522 (S.D.N.Y. Sept. 12, 2024).
122 2024 WL 1507689 (D.N.J. Apr. 4, 2024).

The relator insurance company in ***U.S. ex rel. Allstate Ins. Co. v. Phoenix Toxicology & Lab Servs., LLC***, alleged that the defendant laboratories sought federal reimbursement for UDTs that the defendants falsely certified were medically necessary.[123] The relator had previously sued the defendants and other parties in state court and the *qui tam* lawsuit was based largely on nonpublic discovery from the underlying state court lawsuit. The district court concluded that the relator's complaint sufficiently pleaded facts to show that definitive UDTs were performed regardless of patient need. The relator provided evidence that boilerplate language was used to support standing orders and cited to CMS guidance explaining that definitive testing was not always required. Together, the complaint sufficiently pleaded an inference that definitive tests were not ordered based on patient-specific history and risk or documented in the medical record.

In ***U.S. ex rel. Schieber v. Holy Redeemer Healthcare Sys., Inc.***, the relator sued a home healthcare and hospice provider and the software company responsible for providing the Software-as-a-Service (SaaS) application used by the provider.[124] The SaaS application allegedly caused the submission of false claims by automatically and repeatedly prompting providers to select a high number of visits, even if such visits were medically unnecessary. Unlike previously unsuccessful cases with similar allegations, the relator provided sufficiently specific information to create an inference that the defendant software company intentionally designed the software to help home health providers inflate Medicare reimbursements. For instance, the SaaS application only alerted providers to the number of additional visits needed to reach a *higher* reimbursement scale. These and other prompts built into the software encouraged upcoding of patient metrics and resulted in allegedly false claims submitted to government healthcare programs.

WORTHLESS SERVICES

Under a worthless services theory of falsity, a claim for reimbursement for a service that lacks any medical value is factually false because the service did not actually occur, regardless of any certification. While difficult to prove in practice, relators continue to pursue worthless services theories of falsity where they view care or services to be deficient.

For instance, the relator in ***U.S. ex rel. Mosley v. Walgreens Co.***, alleged that Walgreens encouraged its pharmacists to perform sham Medication Therapy Management (MTM) services that were not in accordance with industry standards or CMS regulations.[125] While MTM services typically include patient medication management and counseling services, Walgreens allegedly failed to perform these services in accordance with rules, regulations or industry standards regarding the quality of those services. Because the relator was asserting a worthless services theory of falsity, the district court rejected Walgreens' argument that failure to abide by industry standards could not form the basis of an alleged FCA violation because those standards by their terms did not apply to Walgreens. The district court further concluded that the relator adequately alleged that the services violated the regulatory standard of care, pointing to patient medical records that contained identical generic copy and pasted descriptions along with empty and incomplete patient follow-up sheets and medication management plans. Such evidence was sufficient to demonstrate that it was at least plausible that the services at issue were not actually provided by Walgreens, as the relator alleged.

In ***U.S. ex rel. Hunter v. Fillmore Cap. Partners, LLC***, discussed above, the relator's FCA claims also included worthless services theory of falsity. The relator alleged that understaffing at the defendant nursing homes resulted in a lack of adequate care. The district court concluded, however, that allegations of a lack of adequate care "[do] not equate to a worthless services claim." Rather, the district court reiterated that, in order to constitute a worthless service, the "performance of the service [must be] so deficient that for all practical purposes it is the equivalent of no performance at all."

DEVELOPMENTS REGARDING KNOWLEDGE AND SCIENTER

To prevail on an FCA claim, a *qui tam* relator or the government must show that the defendant acted with actual knowledge, deliberate ignorance or reckless disregard that its claims were false. In 2023, the Supreme Court clarified in ***U.S. ex rel. Schutte v. SuperValu Inc.*** that this scienter element focuses on "what the defendant thought when submitting the false claim"—meaning whether the defendant subjectively knew that its claims were false.[126]

Schutte overruled holdings from several federal appellate courts that had applied an objective standard to the FCA's scienter requirement. In those cases, the defendants obtained noteworthy dismissals of FCA actions on motions to dismiss and at summary judgment where they showed that there was an objectively reasonable interpretation of the legal requirement

> ***Following Schutte, a key question remained as to how courts would apply the scienter requirement. Cases have shown that although courts are more likely to consider scienter to be a jury question—and thus less likely to grant dismissal based on scienter—they still are enforcing the scienter requirement where appropriate.***

123 2024 WL 2785396 (D.N.J. May 30, 2024).
124 2024 WL 1928357 (D.N.J. Apr. 30, 2024).
125 2024 WL 2864715 (S.D. Fla. June 5, 2024).

126 598 U.S. 739 (2023).

they were alleged to have violated that permitted their conduct. Following *Schutte*, a key question remained as to how courts would apply the scienter requirement. Cases have shown that although courts are more likely to consider scienter to be a jury question—and thus less likely to grant dismissal based on scienter—they still are enforcing the scienter requirement where appropriate.

An example is the district court's decision on remand in *Schutte* itself. There, the district court denied the relators' and the defendants' cross-motions for summary judgment on the issue of scienter.[127] The allegation in that case was that the defendant pharmacies submitted false claims when they did not factor competitor price-matches into the "usual and customary" price they reported as part of their request for reimbursements. When it first considered this issue, the district court applied an objective standard and held that the defendants could not be liable because the phrase "usual and customary" is ambiguous and could be held to exclude price matches. Following remand, the district court held that "even though the phrase 'usual and customary' may indeed be ambiguous, such facial ambiguity is not sufficient by itself, to prevent a finding that Defendant's knew their claims were false." Considering the evidence presented by the parties, the district court held that the defendants' subjective knowledge was a question to be resolved by the jury.

In ***U.S. ex rel. Behnke v. CVS Caremark Corp.***, the district court similarly denied the defendants' motion for summary judgment as to scienter.[128] The relator alleged that Caremark misreported the cost of drugs reported to the government. The district court construed the relevant question as "whether Caremark subjectively understood what CMS's regulations required—namely, that they mandated reporting guaranteed average prices under the circumstances present here." Although the district court acknowledged that the relator lacked a "smoking gun" document showing "Caremark admitting to (or even acknowledging the possibility of) an interpretation of CMS's regulations at variance with Caremark's own," it nevertheless held that a jury could infer Caremark's subjective understanding that its claims violated CMS requirements.

As yet another example, in ***U.S. ex rel. Allstate Ins. Co. v. Phoenix Toxicology & Lab Servs., LLC***, the district court held that a relator's "perilously sparse" scienter allegations could be enough to survive a motion to dismiss if, in their totality, they identify an alleged practice of recklessly disregarding the submission of false claims.[129] There, the district court held that a relator's allegations that an outpatient clinical laboratory knew about Medicare's guidance on confirmatory drug testing and that the laboratory's standard practice was to perform definitive drug tests without conducting appropriate confirmatory assessments were "just enough" to survive a motion to dismiss.

In contrast to *Schutte*, *Behnke* and *Allstate*, the district court in ***U.S. ex rel. Sheldon v. Forest Laby's, LLC***, granted the defendant's motion to dismiss based on a failure to plead scienter.[130] The relator alleged that the defendant pharmaceutical manufacturer submitted false claims when it failed to include certain customer price concessions in its reported "Best Price." The district court noted that the relator sought to establish scienter by alleging that any entity reading the applicable regulations would know that the defendant's claims were false. The district court disagreed, however, finding the Best Price regulations ambiguous. Without any more factual allegations as to the defendant's scienter, the district court was unwilling to allow the case to proceed based on the facial ambiguity of the regulations alone.

Similarly, in ***U.S. ex rel. Masso v. Cornerstone Reg'l Hosp., L.P.***, the district court granted the defendant's motion for summary judgment where the relator's only evidence of scienter was his own self-serving testimony that the hospital failed to enforce "observation-only" privileges in operating rooms and the hospital's general testimony that staff knew observers in an operating room could not operate on patients.[131] As the district court noted, if a relator's evidence requires an inferential leap to reach a speculative conclusion, the relator has not established scienter for purposes of summary judgment.

The district court in ***U.S. ex rel. Brooks v. Stevens-Henager Coll., Inc.***, grappled with the Supreme Court's *Schutte* opinion.[132] Although not a healthcare case, the district court's decision in *Brooks* is important because of its discussion of the reckless disregard standard. The government alleged that the defendant college provided prohibited incentive compensation to admissions consultants. In considering the parties' cross-motions for summary judgment, the district court reasoned that *Schutte* left open whether an objective theory of scienter may be applied to allegations of reckless disregard. As a result, the district court followed previous circuit precedent that had applied an objective standard to

127 2024 WL 4351951 (C.D. Ill. Sept. 30, 2024).
128 2024 WL 1416499 (E.D. Pa. Apr. 2, 2024).
129 2024 WL 2785396 (D.N.J. May 30, 2024).
130 2024 WL 4544567 (D. Md. Oct. 22, 2024).
131 2024 WL 5047525 (S.D. Tex. Dec. 9, 2024).
132 2024 WL 2857885 (D. Utah Mar. 29, 2024).

such allegations. The district court's opinion in *Brooks*, therefore, suggests that an objective scienter standard may still come into play in appropriate cases. Applying this standard, the district court found the government's evidence of scienter insufficient to warrant summary judgment where the government showed the defendant's "awareness of the *general* legal risks of noncompliance with the Incentive Compensation Ban rather than the *particular* noncompliance of PD 85R," the specific directive the defendant was alleged to have violated.

The FCA's scienter requirement is also vigorously enforced when relators pursue a reverse false claims theory of liability. In ***U.S. ex rel. Angelo v. Allstate Ins. Co.***, the Sixth Circuit held that a relator cannot survive a motion to dismiss by relying on bare allegations that a defendant knew it owed an obligation to the government.[133] There, the relators alleged that an insurance company misrepresented information about its beneficiaries to CMS, which resulted in Medicare covering more than it owed for insurance claims where the company—not Medicare—had primary payor obligations. As the Sixth Circuit observed, the relators did not explain how the insurance company should have known that Medicare made any payments on specific claims, let alone that it knowingly evaded its duty to repay Medicare for those claims.

In ***U.S. ex rel. Frey v. Health Mgmt. Sys., Inc.***, the district court likewise held that a defendant's mere knowledge that it was violating a regulation does not equate to actual knowledge that it was concealing, improperly avoiding or decreasing its obligations to transmit money to the government.[134] The relator alleged that a Medicaid contractor defrauded CMS by failing to submit claims for third-party liability services within 60 days, as required by CMS regulations. The district court granted summary judgment for the contractor because evidence in the record showed that the contractor believed its claims would be timely if they were submitted within three years and that, as a result, it did not know failing to meet the 60-day regulation that would lead to a reverse false claim.

REVERSE FALSE CLAIMS

Under 31 U.S.C. § 3729(a)(1)(G), a defendant may incur liability under the FCA when it: (1) "knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government;" or (2) "knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government." Under either prong, there must exist an "obligation" to pay money to the government, which includes the retention of an overpayment from the government. As such, § 3729(a)(1)(G) is known as the FCA's "reverse" false claim provision because liability results from a party avoiding payment of money due to the government as opposed to submitting a false claim to the government.

133 106 F.4th 441 (6th Cir. 2024).
134 2024 WL 4536461 (N.D. Tex. Oct. 18, 2024).

> ***When a plaintiff fails to plead the presentment of false claims with sufficient particularity, district courts have little difficulty in dismissing allegations purporting to assert violations of the FCA reverse false claim provision.***

Analysis of the FCA's reverse false claim provision often focuses on its relationship to traditional FCA violations. Courts typically require that some additional allegations or evidence be presented to support reverse false claim liability beyond a defendant's alleged "direct" violations of §§ 3729(a)(1)(A) or (a)(1)(B) of the FCA.[135]

As with the other FCA liability provisions, allegations of reverse false claims are subject to the pleading requirements of Rule 9(b) and are often considered at the motion to dismiss stage. When a plaintiff fails to plead the presentment of false claims with sufficient particularity, district courts have little difficulty in dismissing allegations purporting to assert violations of the FCA reverse false claim provision.

In ***U.S. ex rel. Miller v. Citibank, N.A.***, the Second Circuit affirmed the district court's dismissal of a reverse false claim cause of action asserted by a relator for failure to plead with the particularity required by Rule 9(b).[136] In reaching this conclusion, the Second Circuit evaluated the relator's theory that Citibank manipulated internal reports to avoid having to report violations of federal law that would have resulted in civil penalties. According to the Second Circuit, the relator failed to allege the specifics of any particular false statements or reports that might have been at issue and instead merely referred to general categories of reports. In relying on such allegations, the Second Circuit concluded that the relator's complaint was "bereft of the details" required to satisfy Rule 9(b) and state a reverse false claims cause of action.

In contrast, the district court in ***U.S. ex rel. Gill v. CVS Health Corp.***, found the relator's allegations that the defendants failed to refund certain overpayments to have met Rule 9(b)'s requirements.[137] There, the relator asserted that an entity acquired by CVS improperly recognized $98 million and other large amounts in credit balances as income, in effect "pocket[ing] overpayments from its customers." The credit balances taken into income allegedly resulted from the pharmacies improperly billing customers and relying on outdated software systems, which resulted in the alleged failure to correct and refund credit balances

135 *See U.S. ex rel. BakerRipley v. Kids U U.S. Inc.*, 2024 WL 3541499 (S.D. Tex. July 25, 2024) ("The defendant's failure to refund the same money the government allegedly paid in relation to [Relator's] § 3729(a)(1)(A) and (B) claims is not, itself, actionable under the reverse False Claims Act provision." (quotation marks and citation omitted)).
136 110 F.4th 533 (2d Cir. 2024).
137 2024 WL 3950211 (N.D. Ill. Aug. 26, 2024).

to payors, including government healthcare programs. The district court determined that the relator sufficiently alleged that the relator plausibly pleaded that the defendants retained overpayments and "that *some* of those overpayments were government overpayments."

In considering reverse false claim violations, district courts often must evaluate whether certain alleged conduct amounts to an "obligation." In ***U.S. ex rel. Lesnik v. ISM Vuzem d.o.o.***, the relator alleged that the defendants violated the FCA "by fraudulently applying for employment visas for plaintiffs that cost less than the ones for which defendants should have applied."[138] The Ninth Circuit described the key issue as "whether the defendants had an obligation to pay more than they did" and noted that the Ninth Circuit "had not yet interpreted" the FCA's term "obligation" following the 2009 FCA amendments to § 3729(a)(1)(G). Explaining that the district court correctly concluded that the defendants had no established duty to pay for visas for which they did not apply, the Ninth Circuit reiterated the well-established principle that an "obligation" under the FCA cannot be merely a "*potential* liability."

Finally, without significant analysis, the district court concluded that the relator plausibly pleaded a violation of § 3729(a)(1)(G) against Walgreen following reversal of a prior dismissal of the relator's FCA claims by the Fourth Circuit in ***United States v. Walgreen***.[139] This long-running litigation stems from a former employee's criminal misconduct in falsifying pre-authorization paperwork, laboratory reports and drug test results associated with the Virginia Medicaid program for certain prescriptions. The relator alleged that the pharmacy failed to return overpayments based on falsified documentation associated with the employee's illegal actions. As to Walgreen's actions, the relator alleged that it took steps to identify the overpayments that were made as a result of the employee's actions but failed to return the "fraudulently obtained funds." The district court found these allegations sufficient to satisfy Rule 9(b) despite the fact that the allegations were made "upon information and belief."

PUBLIC DISCLOSURE BAR

The FCA's "public disclosure bar" deters relators from filing lawsuits that are based on information that is already in the public eye. A relator who qualifies as an "original source" of allegations, however, can still bring claims even if the public disclosure bar would otherwise prohibit the relator's claims.[140]

The public disclosure bar is a formidable defense for defendants facing allegations of fraud. When a defendant asserts the public disclosure bar as a defense, the district court asks three questions to determine whether the relator's claims must be dismissed: (1) whether a public disclosure previously occurred; (2) whether that disclosure was substantially similar to the relator's allegations; and, if so, (3) whether the relator is nevertheless an "original source" of the FCA allegations.

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- **Whether a public disclosure previously occurred;**
- **Whether that disclosure was substantially similar to the relator's allegations; and, if so**
- **Whether the relator is nevertheless an "original source" of the FCA allegations.**

Has a Public Disclosure Occurred?

By statute, a "disclosure" can occur in one of three ways: "(i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party; (ii) in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or (iii) from the news media."[141] Parties continue to vigorously dispute whether new forms of media—particularly online content—fit into the three aforementioned channels of communication, with a significant portion of litigation focusing on the definition of "news media."

In ***U.S. ex rel. Jacobs v. JP Morgan Chase Bank, N.A.***, the Eleventh Circuit held that the term cannot be limited to traditional news reporting methods.[142] Instead, the key question is whether a website is both publicly available and intended to disseminate information to the public—meaning that even blog posts, regardless of their size or sweep, can be considered public disclosures.

In ***U.S. ex rel. Fitzer v. Allergan, Inc.***, the district court reached a similar conclusion, holding that an online database can be considered a public disclosure if it collects, synthesizes and disseminates information to the public.[143] There, the database provided visitors to the website with a curated list of bariatric surgeons and highlighted specific information about each surgeon for the benefit of potential patients. On the other hand, the district court noted in

138 112 F.4th 816 (9th Cir. 2024).
139 711 F. Supp. 3d 601 (W.D. Va. Jan. 13, 2024).
140 31 U.S.C. § 3730(e)(4).
141 31 U.S.C. § 3730(e)(4)(A).
142 113 F.4th 1294 (11th Cir. 2024).
143 2024 WL 3352824 (D. Md. May 15, 2024), *recons. denied*, 2024 WL 3344627 (D. Md. July 9, 2024).

dicta that a database that does no more than query information inputted by a single user would not be "news media" because, in that instance, the database would not be displaying information to any public user—which is the crux of a public disclosure.

When Are Allegations "Substantially the Same" as a Prior Disclosure?

A prior public disclosure is not enough on its own to preclude a relator's allegations. The relator's claims must also be "based on" or "substantially the same" as the prior public disclosure to trigger the public disclosure bar.

A prior disclosure is "substantially the same" as a relator's allegations if it is enough to set the government on the trail of the alleged fraud without the relator's assistance. Some courts have analyzed substantial similarity through a formulaic method where if "X + Y = Z", and "Z" represents the relator's fraud allegations while "X" and "Y" represent essential elements to the fraud, then the public disclosure bar applies if "X" and "Y" have been previously revealed or if "Z" could be inferred under the circumstances.

For example, in ***U.S. ex rel. Relator LLC v. Kellog***, the district court held that both the "X" and "Y" were publicly disclosed where news articles highlighted the fact that a private tennis club had received PPP loans from the government and publicly available government guidance stated that private clubs like the defendant could not receive PPP loans.[144] While the "Z" was not directly disclosed (that the club had fraudulently obtained PPP loans), it could be inferred because the material elements of the alleged fraud were already in the public eye.

Similarly, in ***U.S. ex rel. Heron v. Nationstar Mortg., LLC***, the Tenth Circuit held that a relator cannot avoid the public disclosure bar by relying on "hyper specific" arguments for how a disclosure is different from the FCA allegations.[145] As a result, the Tenth Circuit ruled that a previous government prosecution can be a prior public disclosure—even if it doesn't mention the defendant by name—if it demonstrates that the government was aware of the alleged fraud and shows that the essential nature of the relator's claims is in the public domain.

Further, in ***U.S. ex rel. Stebbins v. Maraposa Surgical, Inc.***, the Third Circuit held that the public disclosure bar applied where all of the essential elements of a relator's claims were readily available in public databases, including a CMS Medicare Physician & Other Practitioners by Provider and Service payment database and a Pennsylvania Department of Health online searchable database of licensed facilities.[146] As the Third Circuit observed, "[b]ecause anyone could access th[e] publicly available information . . . , anyone could file the same suit."

Other courts were hesitant to apply the public disclosure bar if the similarities were cased in unduly broad terms. In ***U.S. ex rel. Sirls v. Kindred Healthcare, Inc.***, the district court held that the public disclosure bar did not apply where, despite there being an earlier FCA prosecution against the defendant, the two cases were different enough that the relator could not have uncovered the fraud simply by looking at the earlier allegations.[147]

And, in ***U.S. ex rel. Long v. Janssen Biotech, Inc.***, the district court rejected the defendant's argument that the relator's claims should be dismissed under the public disclosure bar because three prior FCA lawsuits disclosed two of the relator's core claims.[148] Stated succinctly: "The basic problem with that argument is that it equates any prior disclosure of [defendant's] marketing techniques to physicians with the disclosure of the kickback scheme alleged [in relator's complaint]."

The prior public disclosure also must reveal a potential fraud on the government. For instance, in ***U.S. ex rel. Grant v. Zorn***, the Eighth Circuit held that the public disclosure bar did not apply where the prior disclosure only revealed the possibility of inaccurate billing, and not that actual fraud occurred.[149] Conversely, in ***U.S. ex rel. Langer v. Zimmer Biomet Holdings, Inc.***, the district court held that the public disclosure bar did apply where news articles and Form 10-K annual reports had already disclosed how the defendant's orthopedic medical device sales reps worked as independent contractors and received sales-based commissions.[150] While the relator tried to argue that his complaint included crucial details not found in the public domain, the district court found that the crux of the relator's allegations were already in the public record and had been for more than two years before the relator came onto the scene.

When Is a Relator an Original Source?

Even if a prior public disclosure was substantially similar to a relator's allegations, a relator nevertheless may proceed if he or she qualifies as an "original source." An "original source" is an individual who either: (1) voluntarily disclosed the information to the government before the relevant public disclosure; or (2) "has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions" and voluntarily provided that information to the government before filing his or her complaint.

In ***U.S. ex rel. Jacobs v. JP Morgan Chase Bank, N.A.***, the Eleventh Circuit ruled that the relator's allegations did not "materially add to" the publicly disclosed allegations but were more properly characterized as "background information" or "details" that supplemented or contextualized the core fraud hypothesis, which was insufficient to grant original source status.[151] The Eleventh Circuit also rejected the relator's argument that he qualified as an original source

144 2024 WL 4887531 (S.D. Cal. Nov. 25, 2024).
145 2024 WL 3770843 (10th Cir. Aug. 13, 2024), *petition for cert. filed*, 2024 WL 4800238 (U.S. Nov. 12, 2024) (No. 24-542).
146 2024 WL 4947274 (3rd Cir. Dec. 3, 2024).
147 2024 WL 3888498 (E.D. Pa. Aug. 20, 2024).
148 2024 WL 665547 (D. Mass. Feb. 15, 2024).
149 107 F.4th 782 (8th Cir. 2024), *reh'g denied*, 2024 WL 4456550 (8th Cir. Oct. 9, 2024), *petition for cert. filed*, 2024 WL 4817380 (U.S. Nov. 13, 2024) (No. 24-549).
150 2024 WL 3633536 (D. Mass. Aug. 2, 2024).
151 113 F.4th 1294 (11th Cir. 2024).

because his law practice provided him with independent knowledge of the fraud, noting that even if his experience "shed light" on how the fraud was carried out, it still did not materially add to the core claims in the disclosures.

In ***U.S. ex rel. Heron v. Nationstar Mortg., LLC***, the Tenth Circuit rejected the relator's argument that to defeat a motion to dismiss, he need only allege—and not demonstrate—that he had the statutorily required knowledge of an original source, stating that the court need not accept that legal conclusion.[152] The Tenth Circuit also held that the relator's aggregation of already-public information in foreclosure proceedings was precisely the type of "secondhand knowledge" that does not qualify a relator as an original source.

In ***Omni Healthcare Inc. v. U.S. Oncology, Inc.***, the Second Circuit held that the relator failed to satisfy either prong of the original source exception.[153] The Second Circuit held that the relator's allegation that it submitted a disclosure statement to the government, as required by the FCA, did not plead that it "voluntarily" disclosed information to the government because to treat that disclosure as both mandatory and voluntary would read the voluntary requirement out of the statute. The Second Circuit also held that information to establish the company's scienter did not materially add to the publicly disclosed allegation that the company "knew its conduct was illegal."

In ***U.S. ex rel. Langer v. Zimmer Biomet Holdings, Inc.***, the district court held that the relator qualified as an original source because he acquired independent knowledge of the alleged fraud through his ten-year employment as a sales associate for the defendant, including by having access to internal company documents and information.[154] The district court also held that the relator's knowledge materially added to the public disclosures because determining whether any particular independent contractor agreement violates the AKS depends on a case-by-case analysis, and the relator provided information about "suspect characteristics" of the contract that "sheds light" on the defendant's intentions and could influence whether the agreement ultimately is found to violate the AKS.

FIRST-TO-FILE BAR

The FCA's first-to-file bar prevents any person or entity other than the government from "interven[ing] or bring[ing] a related action based on the facts underlying the pending action."[155] The rule is intended to encourage relators to promptly bring to light any allegations of fraud and to prevent opportunistic subsequent *qui tam* actions from relying on essential facts that are already the subject of ongoing litigation.

152 2024 WL 3770843 (10th Cir. Aug. 13, 2024), *petition for cert. filed* 2024 WL 4800238 (U.S. Nov. 12, 2024) (No. 24-542).
153 2024 WL 4751635 (2d Cir. Nov. 12, 2024).
154 2024 WL 3633536 (D. Mass. Aug. 2, 2024).
155 31 U.S.C. § 3730(b)(5).

In recent years, the issue of whether the first-to-file bar is a jurisdictional question has been the source of a significant, but shrinking, circuit split. In ***Stein v. Kaiser Foundation Health Plan, Inc.***,[156] the Ninth Circuit initially ruled that although there was some "tension" with the Supreme Court's guidance that a rule should not be interpreted as jurisdictional unless Congress has made a "clear statement" to that effect, the Ninth Circuit held that this tension does not change the long-standing precedent in that circuit that the first-to-file bar is jurisdictional. Eight months later, however, an *en banc* Ninth Circuit overruled this jurisdictional precedent, holding that prior court decisions had simply labeled the rule as jurisdictional without any analysis.[157] The Ninth Circuit noted that in light of the Supreme Court's clear-statement rule, the FCA provision establishing the first-to-file bar says nothing about a court's jurisdiction over a case, but rather addresses "who may bring an action and when." In ruling that the first-to-file bar was not jurisdictional, the Ninth Circuit joined the First, Second, Third, Sixth, and D.C. Circuits, while three circuits (Fourth, Fifth, and Tenth) maintain the jurisdictional nature of the rule.

Most courts addressing the first-to-file bar must determine whether the facts alleged in a subsequent claim involve "a different type of wrongdoing . . . based on different material facts,"[158] than a previous complaint. Courts have also dealt with the issues of whether the method used to include subsequent relators would violate the first-to-file bar. In ***United States v. Tenet Healthcare Corp.***,[159] the district court faced the question of whether a

156 2024 WL 107099 (9th Cir. Jan. 10, 2024).
157 115 F.4th 1244 (9th Cir. 2024). On remand, the Ninth Circuit nonetheless upheld the district court's dismissal on non-jurisdictional grounds, ruling that the district court did not err in determining that the relator's claim was not "completely independent" of the related actions, and that additional details of a subset of the overall scheme alleged in the prior actions was not enough to evade the first-to-file bar. 2024 WL 4784915 (9th Cir. Nov. 14, 2024).
158 *See United States v. Lockheed Martin Corp.*, 2024 WL 3434573 (N.D. Tex. July 16, 2024) (holding that under the essential elements test, a prior complaint alleging fraud in the defendant's F-35 fighter jet program would likely have given the government "enough information to discover [the] related fraud" alleged by the relator in a subsequent complaint concerning the defendant's programs for other aircraft including the F-16, F-22 and C-130).
159 2024 WL 3926474 (E.D. Mich. Aug. 23, 2024).

relator's amendment of a complaint to add additional relators under Federal Rule of Civil Procedure 15 would violate the first-to-file bar. In its motion to dismiss, the defendants argued that the addition of the two new plaintiffs was an impermissible intervening in violation of the first-to-file rule. The district court disagreed and, relying on analysis from the Third and Tenth Circuits, ruled the first-to file-bar is intended to prevent intervention under Rule 24 by successive non-party plaintiffs, not voluntary joinder of new co-relators in the same action under Rule 15. The district court reasoned that since an already existing party sought joinder under Rule 15, this was not barred under the first-to-file rule.[160]

Several courts also considered the question of whether an amended complaint could cure a violation of the first-to-file bar that existed in the relator's initial complaint. In ***U.S. ex rel. Rosales v. Amedisys, Inc.***,[161] the relator alleged that the defendants pressured nurses to admit or falsify documentation to allow the admission of ineligible patients to hospice care. The relator also later amended the complaint to add additional defendants and include allegations of violations of the AKS. In response to the defendants' motion to dismiss that argued the relator's complaint was barred due to existing FCA litigation involving the defendants, the relator argued that the first-to-file bar did not apply because she had amended her claim to include additional defendants and an additional anti-kickback claim that was not included in the prior complaint. Relying on precedent from the Second and D.C. Circuits, the district court rejected the relator's argument noting that it is the initial complaint that matters for the first-to-file bar analysis, and the relators cannot amend their complaints to avoid the first-to-file rule.[162]

GOVERNMENT INTERVENTION AND DISMISSAL

The Government's Dismissal Authority

The FCA provides the government with the authority to dismiss a *qui tam* lawsuit over a relator's objection. The statute specifically states that "[t]he Government may dismiss the action notwithstanding the objections of the person initiating the action if the person has been notified by the Government of the filing of the motion and the court has provided the person with an opportunity for a hearing on the motion."[163] The reasoning behind this provision is straightforward: *qui tam* lawsuits are brought by a relator on behalf of the government and the government remains the real party in interest.

Last year, we covered the Supreme Court's consideration of the government's power to dismiss a *qui tam* lawsuit in ***U.S. ex rel. Polansky v. Executive Health Resources***. In that case, the Supreme Court had little difficulty in concluding that the government had almost unfettered authority in dismissing a *qui tam* lawsuit over a relator's objection.

The Court first confirmed that the government must intervene in an FCA action before it may move to dismiss over a relator's objection. The Court then made it clear that the government must only meet the "good cause" standard to justify exercise of its dismissal authority. Although the Court did not directly address what the government must show to establish "good cause" for later intervention, it observed in a footnote that the Third Circuit had found that the government's desire to dismiss itself amounted to good cause and that the relator had not challenged that conclusion in the Supreme Court. Finally, the Court concluded that government motions to dismiss FCA actions are governed by the ordinary operation of Rule 41(a), subject to the FCA's requirement that the relator receive notice of the motion and an opportunity for a hearing. Under Rule 41(a), if the defendant has already filed an answer and all parties have not stipulated to dismissal, the district court may dismiss the action at the plaintiff's request only by court order and "on terms that the court considers proper." Although the "proper terms" analysis usually focuses on the defendant's interests, the Supreme Court explained in *Polansky* that the analysis in an FCA case must also account for the relator's interests—including the reality that most relators will "want their actions to go forward, and many have by then committed substantial resources." Even so, however, the Court explained that government motions to dismiss FCA actions "will satisfy Rule 41 in all but the most exceptional cases."

In a small number of cases, courts continued to tackle issues related to government dismissal following the Supreme Court's holding in *Polansky* and how the principles articulated in that case should be applied. In ***U.S. ex rel. Jackson v. Ventavia Research Group, LLC***, the government moved to intervene and dismiss the FCA lawsuit following its initial declination.[164] The relator argued that the government could not meet the "good cause" standard because the relator would suffer extreme prejudice and there was no change in circumstance following the government's initial declination. The district court rejected the relator's argument that courts must weigh the government's interest against any prejudice that the relator might suffer as a result of dismissal and stressed the Supreme Court's explanation that the government must only offer a legally sufficient reason. Finding the government's interest to be the "predominant one," the district court found the good cause standard met where it cited to the lack of merit in the allegations and avoidance of discovery and litigation obligations.

In ***U.S. ex rel. Doe v. Credit Suisse AG***, the Fourth Circuit affirmed the district court's decision to grant the government's motion to dismiss a relator's *qui tam* lawsuit.[165] The relator argued that the district court erred in its dismissal because it failed to afford the relator an actual hearing and considered only written submissions from the parties on the government's motion. In a slight distinction from the procedural posture in *Polansky*, the Fourth Circuit

160 *See also United States v. McKesson Corp.*, 729 F. Supp. 3d 340, 344 (E.D.N.Y. 2024) (denying a defendant's motion for partial judgment on the pleadings by holding that although a prior complaint made passing references to the defendant, since the prior complaint did not allege the defendant was a participant in the alleged scheme, those incidental references did constitute "the same material elements of fraud" or "the same essential facts").
161 2024 WL 1559284 (E.D.N.C. Apr. 10, 2024).
162 *See also United States v. Rossi*, 2024 WL 4242482 (C.D. Ill. Sept. 19, 2024) (holding that the "clear answer" to whether a violation of the first-to-file bar can be cured by an amended complaint is "no," and that even a difference of nineteen minutes in filing is sufficient to bar the subsequent action).
163 31 U.S.C. § 3730(c)(2)(A).
164 2024 WL 3812294 (E.D. Tex. Aug. 9, 2024).
165 117 F.4th 155 (4th Cir. 2024).

noted that the dismissal "happened at the pre-answer, pre-summary judgment stage, during which Rule 41(a)(1) applies." Without deciding whether the district court had any discretion whatsoever in dismissing the action because of the procedural posture, the Fourth Circuit concluded that the government had valid reasons for seeking dismissal and consideration of the issues on the pleadings submitted by the parties constituted "an opportunity for a hearing." In a partial dissent, Judge Quattlebaum disagreed that a district court's decision based on the papers submitted by the parties satisfied the requirement of "an opportunity for a hearing" as contemplated by the FCA. Drawing a distinction from the FCA's use of the word "hearing" rather than an "opportunity to be heard," the dissent expressed the view that "hearing" requires, at a minimum, "the opportunity to make oral arguments to a court," even if no answer has been filed.

Delay in Intervention

The FCA requires the government to make an intervention decision within 60 days of the filing of a *qui tam* complaint. The government may seek an extension of that 60 day period if there is good cause shown for such an extension. Many defendants facing FCA litigation initiated by a *qui tam* relator face many months or even many years relative to the government's intervention decision. An increasing number of district courts are no longer willing to rubberstamp government requests for repeated extensions. And, there may be many reasons for this evolving approach.

For defendants facing a *qui tam* pending under seal for what it may consider to be an unreasonably long period of time, however, there are limited avenues by which to seek relief. This reality was reflected in the district court's opinion in ***U.S. ex rel. Hueseman v. Professional Compounding Centers of America.***, in which the district court rejected the defendant's motion to dismiss for want of prosecution under Federal Rule of Civil Procedure 41(b). Following the filing of a *qui tam* lawsuit against the defendant, the government sought and obtained 15 extensions of the seal period and conducted an investigation lasting more than seven years. Noting that a prior denial of the government's request for an extension of the seal period would not have resulted in termination of the action, the district court declined to dismiss the matter. The district court did note, however, that Fifth Circuit precedent was a "prospective warning to the Government and district courts to devote greater attention to future requests for extensions of time and to make intervention decisions."

STATUTE OF LIMITATIONS

The FCA's statute of limitations may limit or even require the dismissal of claims. Under 31 U.S.C. § 3731(b), an action asserting an FCA claim must be brought within the later of the following: (1) six years after the FCA violation occurred; or (2) three years from the date the United States official charged with responsibility to act knew or should have known the material facts, up to 10 years after the violation. In 2019, the Supreme Court held that both limitation periods apply to a declined *qui tam* action.[166] When the government declines to intervene, a relator may proceed with an action filed more than six years after the FCA violation occurs if the action is filed within three years of when the relevant government official, not the relator, should have known the material facts.

When the government intervenes, the inquiry to determine whether the government knew or should have known the relevant material facts is not limited to the initial *qui tam* action. In ***U.S. ex rel. Sirls v. Kindred Healthcare, Inc.***, the district court considered a dispute during discovery of the relator's FCA claims against skilled nursing facility operators.[167] The relator argued the FCA's ten-year statute of limitations applied. The defendants argued that the six-year statute of limitations applied and that the government knew or should have known the facts material to the relator's claim before the *qui tam* action was filed. The district court adopted the special master's recommendation that the ten-year statute of limitations under 31 U.S.C. § 3731(b)(2) applied, rather than the six-year statute of limitations under § 3731(b)(1), to avoid delaying the discovery process. The district court, however, did not address the knowledge requirement and explained that the statute of limitations is best addressed at summary judgment or trial when the full relevant factual record is available.

To relate back to the relator's initial complaint, a new FCA claim or pleading must be tied to a common core of operative facts. In ***U.S. ex rel. Hueseman v. Professional Compounding Centers of America***, the relator raised FCA and AKS claims against a pharmacy supplier and its pharmacy customers.[168] The pharmacy supplier filed a motion for summary judgment and argued that the government's complaint-in-intervention did not relate back to the relator's original complaint. The district court granted the motion in part and denied it in part. The district court held that the government's complaint related back to the relator's complaint with respect to allegations of the supplier's fraudulent reporting and marketing practices.

166 *Cochise Consultancy v. U.S. ex rel. Hunt*, 139 S. Ct. 1507 (2019).
167 2024 WL 3905680 (E.D. Pa. Aug. 20, 2024).
168 2024 WL 1904343 (W.D. Tex. Apr. 30, 2024).

The district court, however, agreed that the government's complaint did not relate back to the relator's complaint with respect to AKS allegations because the original complaint did not mention this conduct. The district court, therefore, dismissed the government's AKS claims as time barred.

Similarly, in ***U.S. ex rel. Dunn v. Procarent, Inc.***, the district court considered a motion to dismiss the relators' FCA claims against an ambulance services provider.[169] The defendant argued that the relators' medical necessity claims were first raised in the second amended complaint and did not relate back to the earlier complaints. The district court agreed and dismissed the relators' claims to the extent the claims were based on a medical necessity theory of liability.

DISCOVERY DEVELOPMENTS

District courts have considered and resolved discovery disputes in an increasing number of litigated FCA cases. Those discovery disputes typically concern the appropriate scope of discovery most often with respect to discovery sought from government and defendants, as well as the validity of assertions of privilege.

Government-Related Discovery Requests

In ***U.S. ex rel. Fischer v. Cmty. Health Network, Inc.***, the relator alleged that the defendants improperly incentivized employed physicians and affiliates to secure their referrals through financial and business relationships.[170] The United States partially intervened and ultimately reached a settlement with Community Health Network (CHN) as to the intervened claims. After that settlement was reached, CHN sought Rule 30(b)(6) depositions from HHS-OIG and CMS with respect to which both objected based on the assertion that the United States was no longer a party in the case and CHN would have to follow *Touhy* procedures. When CHN did so, CMS and HHS-OIG objected to the requested depositions and CHN filed a motion to compel. The district court determined that the agencies' denial of the requested testimony was arbitrary and capricious under the Administrative Procedures Act because the record failed to establish that the agencies adequately considered the requested Rule 30(b)(6) deposition topics.

Assertions of Privilege

The district court considered the question of privilege waiver in ***U.S. ex rel. Omni Healthcare, Inc. v. MD Spine Sols. LLC***. In that case, the relator alleged that the defendant laboratory ordered expensive and medically unnecessary tests for its patients.[171] During the course of the government's investigation, the defendants produced documents to the government, which the government in turn shared with the relator. The government had notified the defendant of its production of a small number of potentially privileged documents to the government, which the defendant clawed back. Following the government's investigation, the relator continued to litigate the declined claims. The defendants learned that the government had shared documents that it had produced to the government when the relator used a potentially privileged document during a deposition in connection with litigation of the declined claims. The defendants then attempted to claw back hundreds of documents from the relator on the basis that the documents were protected by attorney-client privilege and/or the work-product doctrine. The relator then moved to compel production of the clawed-back documents on the basis that the defendants had waived the privilege, in large part, due to the defendants' more than two-year delay in seeking to claw back the documents over which it sought to assert privilege. The district court agreed with the relator that the defendants had waived privilege over the disputed materials because of the delay in clawing back the documents. Notably, because the defendants knew that the relator intended to continue litigating the FCA case after the government's declination, it was reasonable that the government and the relator would share documents produced during the investigation.

The district court examined the common interest privilege asserted between relators and the government in ***U.S. ex rel. Jacobs v. Advanced Dermatology & Skin Cancer Specialists, P.C.***[172] The district court required the relators to produce a complete privilege log, particularly for documents covered by any common interest privileges between the relator and the government. The district court explained that assertions of common interest privilege must be sufficiently supported with respect to timing and circumstances, as the litigation interests of the relators and the government are not always aligned. Accordingly, the district court required the relator to produce a privilege log for all communications with the government before and after filing the complaint, but the district court did not require a privilege log of all attorney-client and co-counsel communications after the filing of the complaint.

Scope of Discovery

Noteworthy decisions considering the scope of discovery highlighted the importance of precisely worded allegations, discovery requests and objections in defining the bounds of discovery.

As an example, in ***U.S. ex rel. Sirls v. Kindred Healthcare, Inc.***, the relator alleged that the defendant's skilled nursing facilities targeted complex patients and understaffed its facilities as part of a scheme to increase profits.[173] After the government declined to intervene, the defendant sought to limit the time frame and subject matter scope of discovery in its continued litigation with the relator. The district court agreed and limited discovery to staffing documents and medical records related to patients' activities of daily living certifications. The district court rejected the relators' argument that broader allegations in the complaint related to inflated resource utilization group scores warranted broader discovery after examining the

169 2024 WL 993310 (W.D. Ky. Mar. 7, 2024).
170 2024 WL 3520357 (S.D. Ind. July 24, 2024).
171 2024 WL 2883365 (D. Mass. June 7, 2024).
172 2024 WL 2107728 (C.D. Cal. Apr. 18, 2024).
173 2024 WL 4438246 (E.D. Pa. Oct. 7, 2024).

specific allegations in the relator's complaint. The district court likewise refused to expand the time period beyond the filing of the complaint based on the relator's vague allegations of "continuing" unlawful conduct.

In ***U.S. ex rel. Everest Principals, LLC v. Abbott Lab.***, the defendants sought to geographically limit discovery to the four states in which FCA claims were alleged.[174] The district court, however, found that the complaint adequately pleaded allegations of a nationwide scheme warranting national discovery. The complaint detailed a national sales training program for sales representatives and sales force use of Abbott's national database to track the efficiency of the referral program in multiple locations.

FCA Damages

Should a defendant be held liable under the FCA, the damages available to the government or a relator can be extensive. In addition to statutory civil penalties for each established violation, the FCA also allows for recovery of treble damages.

Several courts have analyzed FCA damages awards under the Eighth Amendment's Excessive Fines Clause. Damages are unconstitutionally excessive when grossly disproportional to the gravity of the offense, considering non-exhaustive factors such as the reprehensibility of the defendant's conduct, sanctions in analogous cases, the defendant's ability to pay and the maximum penalty that could have been imposed. Courts also assess proportionality by calculating the ratio of punitive to compensatory damages.

In ***Stop Illinois Health Care Fraud, LLC v. Sayeed***, the defendant challenged the district court judgment of nearly $6 million as unconstitutionally excessive.[175] Rather than resolving whether an FCA damages award is a "punishment" under the Eighth Amendment, the Seventh Circuit upheld the judgment as proportional to the defendant's fraudulent scheme. The Seventh Circuit also recognized the judgment could have been steeper, as the district court applied the FCA's lowest per-claim penalty amount of $5,500.

In contrast, the district court in ***U.S. ex rel. Morsell v. Gen Digital Inc.*** awarded the United States the maximum per-claim penalty amount, which totaled over $36 million in civil penalties.[176] The district court found the award to be proportional to the fraudulent conduct alleged and calculated the ratio of punitive-to-compensative damages as roughly between 1:1 or 3:1, but less than the 4:1 ratio the Supreme Court has suggested "might be close to the line of constitutional impropriety." The defendant ultimately paid a total of $55.1 million to satisfy the judgment.[177]

In ***U.S. ex rel. Fesenmaier v. Cameron-Ehlen Group Inc.***, the district court likewise looked to the Supreme Court's 4:1 ratio in its post-judgment review of a $482 million damages award, which included over $43.3 million in actual damages, over $86.6 million in treble damages and over $352 million in penalties. The district court calculated the punitive-to-compensative damages ratio as 10:1 with treble damages considered wholly punitive, but less than 3:1 if regarded purely compensatory. Finding that "[t]he true ratio in this matter…lies somewhere between those two figures," the district court held the penalties unconstitutionally excessive and amended the judgment to $216,675,248.55, or five times the actual damages amount of $43,335,049.71. In reducing the judgment, the district court described the amount of compensatory damages standing alone as "notably severe."

> ***Should a defendant be held liable under the FCA, the damages available to the government or a relator can be extensive. In addition to statutory civil penalties for each established violation, the FCA also allows for recovery of treble damages.***

Treble damages were likewise central to the analysis in ***Grant on behalf of United States v. Zorn***, in which the Eighth Circuit decided the district court's punitive sanction of over $6.7 million was disproportional to the gravity of the offense.[178] The Eight Circuit explained that the gravity of the offense refers to compensatory damages only. As a result, the Eighth Circuit found the district court erred by comparing the punitive sanctions to a compensatory damages calculation that included treble damages, which are a hybrid of compensatory and punitive damages. Although the Eighth Circuit stopped short of determining the correct amount of compensatory damages, it found the punitive sanction unconstitutionally excessive compared to the actual damages of $86,332, particularly given the purely economic nature of the harm.

SETTLEMENT AGREEMENTS

A well-drafted settlement agreement can be broad enough to encompass FCA claims while simultaneously protecting FCA objectives such as the government's interest in prosecuting fraud. This balance is illustrated by the settlement agreement at issue in ***State Farm Mutual Automobile Insurance Company v. Angelo***. In that case, the defendant was alleged to have violated the Racketeer Influenced and Corrupt Organizations Act (RICO) by fraudulently submitting bills for medically unnecessary services and prescriptions provided to patients injured in auto accidents. At the time the defendant and State Farm reached a settlement agreement to resolve the RICO claims, State Farm was unaware that the defendant had filed a *qui tam* action against State Farm, alleging that its practices forced the government to cover expenses State Farm should have paid. The district court granted State Farm's motion

174 2024 WL 304082 (S.D. Cal. Jan. 26, 2024).
175 100 F.4th 899 (7th Cir. 2024).
176 2024 WL 4006077 (D.D.C. Aug. 30, 2024).
177 https://www.justice.gov/opa/pr/gen-digital-pays-551m-false-claims-act-judgment-knowing-overcharges-general-services.

178 107 F.4th 782 (8th Cir. 2024).

to enforce the settlement agreement, finding its terms broad enough to encompass the FCA action. The district court also enforced the settlement agreement's dismissal clause requiring the defendant to "take all steps necessary to … secure the discontinuance of" any lawsuits or other proceedings against State Farm, ordering the defendant to seek the government's consent to dismiss the FCA action.

The Sixth Circuit affirmed the district court's opinion. Relying on the settlement agreement's release provision requiring the defendant to release "known or unknown" claims, the Sixth Circuit rejected the defendant's contention that the defendant could not have released a sealed *qui tam* claim that was unknown to State Farm. The Sixth Circuit also interpreted the FCA action to fall within the release of claims "arising from … MVA Related Health Care Services," rejecting the defendant's invitation to draw a distinction between fraudulent submissions and bills submitted to State Farm. Finally, the Sixth Circuit determined that the FCA's objectives were not threatened by ordering the defendant to seek the government's consent to dismissal. Importantly, the government was not bound by the settlement agreement, and the district court order protected the government's interest in prosecuting fraud by requiring the defendant to obtain consent rather than unilaterally dismissing the action. Moreover, the defendant could not have been deterred from bringing an FCA action by a settlement agreement entered into *after* he filed his FCA complaint.

ISSUES INVOLVING RELATORS

Retaliation

The FCA protects whistleblowers from adverse employment actions related to their efforts to stop violations of the statute.[179] To establish a prima facie FCA retaliation claim, plaintiffs must show the following: (1) they engaged in protected activity; (2) their employer knew that they engaged in a protected activity; and (3) their employer took an adverse employment action against them as a result. If a plaintiff makes this showing, the burden shifts to the employer to give a legitimate, non-retaliatory reason for the adverse action, which the plaintiff can rebut by demonstrating it was pre-textual.

Protected Activity

The first element of an FCA retaliation claim requires that the plaintiff be engaged in a protected activity, which includes either of the following: (1) an employee's lawful actions "in furtherance of" an FCA action; or (2) "other efforts to stop 1 or more violations" of the FCA.[180]

In ***Mooney v. Fife***, the Ninth Circuit considered its test for protected activity in light of the 2009 FCA amendments, in reversing the district court's grant of summary judgment to the employer on the plaintiff's FCA retaliation claim.[181] The Ninth Circuit noted that its pre-2009 test for protected activity included a requirement that an employee "must be investigating matters which are calculated, or reasonably could lead, to a viable FCA action," and held that, with the 2009 amendments, this "investigating" requirement does *not* apply when the plaintiffs allege that they engaged in "other efforts to stop 1 or more violations of [the FCA]." The Ninth Circuit further held that the remainder of its pre-2009 test for protected conduct—whether the plaintiff believes in good faith, and a reasonable employee in similar circumstances might believe, that the employer is possibly committing fraud against the government—still applies after the 2009 amendments.

> ***To establish a prima facie FCA retaliation claim, plaintiffs must show the following: (1) they engaged in protected activity; (2) their employer knew that they engaged in a protected activity; and (3) their employer took an adverse employment action against them as a result.***

Applying the subjective and objective components of that test, the Ninth Circuit held that the plaintiff engaged in protected conduct by raising specific allegations of fraudulent billing with the sole owner of the medical practice that employed him four or five times before his termination. The Ninth Circuit emphasized that the plaintiff's thirty years of experience managing medical practices, combined with the fact that he made his observations and reviewed reports in the course of his work, weighed in favor of finding that his objections were protected.

In contrast, in ***Leverette v. Louis Berger U.S., Inc.***, the Fourth Circuit affirmed the district court's grant of summary judgment in favor of an employer because the plaintiff failed to establish that his conduct amounted to protected activity.[182] There, the employer, an Air Force Base contractor, had requested that the plaintiff modify his internal timesheets by assigning recorded work time to project numbers or project at risk numbers instead of overhead. The plaintiff responded that he was "concerned" it would be "inappropriate" to alter his timesheet as requested. The Fourth Circuit held that because the plaintiff did not show that the time recorded on those timesheets was or would be billed to the federal government, the plaintiff's belief that the employer's requests violated the FCA was not objectively reasonable, and therefore, his FCA retaliation claim failed.

District courts also evaluated whether various alleged activities were protected under the FCA's anti-retaliation provision. For example, in ***Bonds v. Compass Group***, the plaintiff wrote a complaint about operating room cleanliness that mentioned Medicare and Medicaid

179 31 U.S.C. § 3730(h).
180 31 U.S.C. § 3730(h)(1).
181 118 F.4th 1081 (9th Cir. 2024).

182 2024 WL 2355419 (4th Cir. May 23, 2024).

The first element of an FCA retaliation claim requires that the plaintiff be engaged in a protected activity, which includes either of the following:

- **An employee's lawful actions "in furtherance of" an FCA action; or**
- **"Other efforts to stop 1 or more violations" of the FCA.**

reimbursement, but the district court found that complaint did not identify a specific violation of the FCA.[183] As such, the plaintiff was unable to demonstrate his actions were aimed at stopping an FCA violation and his complaint was dismissed for want of a protected activity.

In ***U.S. ex rel. Irizarry v. Innovative Technologies, Inc.***, the plaintiff worked as the defendant company's Senior Program Manager for DOD contracts and asserted two different types of alleged protected activity.[184] First, the plaintiff allegedly conducted an investigation to determine whether the company's contracts were subject to certain labor laws. When he determined the labor laws did apply, he allegedly told the CEO that the company had underpaid its employees more than $1.15 million and that the company had falsely certified compliance with labor laws in DOD contracts. Second, the plaintiff allegedly refused to meet with subcontractors on a contract the plaintiff believed violated labor laws.

As to his alleged refusal to participate in the subcontractor meeting, the district court noted that only the "rare exception"—which the plaintiff's actions were not—would equate refusal to participate to a protected activity under the FCA, and that typically viable FCA retaliation actions predicated on a refusal to participate also involved some *other* alleged actions (*e.g.*, promoting an FCA lawsuit or an effort to stop alleged fraud). The district court determined that the plaintiff's alleged actions failed to meet this threshold. As to the plaintiff's alleged investigative efforts, the district court largely evaluated (and dismissed) those actions under the "notice" element of FCA retaliation claims, addressed in the next section.

183 2024 WL 1315852 (E.D. Mich. Mar. 27, 2024).
184 2024 WL 4345827 (D.D.C. Sept. 30, 2024).

Employer Notice

The second question in assessing FCA retaliation claims is whether an employer had knowledge that the plaintiff-employee tried to stop a potential FCA violation before taking adverse action. Courts consider whether someone with decision-making authority had notice of the protected activity, whether the employee framed their concerns as potentially fraudulent or illegal conduct and whether the employee's protected activity occurred outside the scope of the employee's regular duties.

In ***Mooney v. Fife***, the Ninth Circuit rejected the position of other federal appellate courts that have held that employees with compliance duties must establish a higher standard for notice, showing conduct or communications beyond the scope of their job duties.[185] The Ninth Circuit emphasized that such an approach would "strip protection from the employees who are in the best position to stop, or uncover and expose" fraud against the government. As a result, the Ninth Circuit held that the plaintiff's multiple confrontations during weekly one-on-one meetings with the sole owner of the medical practice that employed him constituted sufficient notice to defeat summary judgment.

District courts in circuits that do require compliance officer plaintiffs to meet a higher burden have provided insight into when that burden might be met. For example, in ***Lockhart v. Gainwell Technologies LLC***, the district court found that the plaintiff's complaint detailed "specific interventions, significant protests, attempts to escalate issues, and direct accusations of fraud against fellow officers."[186] The plaintiff voiced her opposition to potentially fraudulent actions: (1) on numerous occasions; (2) to high-ranking executives; (3) in meetings as noted in agendas and minutes; and (4) in formal written memos. The district court determined these actions were sufficient to put her employer on notice of protected activity.

In ***Irizarry***, the district court acknowledged that the plaintiff's alleged investigation of legal violations was a protected activity, but held that these actions could not support his FCA retaliation claim because he was "simply performing his ordinary duties" in connection with these activities, and thus his employer lacked notice that he was engaging in protected activity.[187] Even though the parties disputed the scope of the plaintiff's normal job duties, it was undisputed that the plaintiff had been ordered to conduct the investigation. The district court held that this order rendered the investigation part of the plaintiff's job duties. Though a "closer question," the district court also found that the plaintiff's internal complaints made to the person who ordered him to conduct the investigation were part of his "ordinary duties" because they "were the natural result" of the order he received to investigate the potential legal violations. Because the plaintiff otherwise failed to allege that he took any actions "outside his chain of command," the district court granted the defendant's motion to dismiss the plaintiff's FCA retaliation claim.

185 118 F.4th 1081 (9th Cir. 2024).
186 2024 WL 3909558 (E.D. Mich. Aug. 22, 2024).
187 2024 WL 4345827 (D.D.C. Sept. 30, 2024).

Adverse Action Because of Protected Activity

Finally, an FCA retaliation plaintiff must show a causal connection between an adverse employment action and the protected activity.

The Fifth Circuit explored two issues concerning causation and material adverse employment actions in ***U.S. ex rel. Johnson v. Raytheon Co.***[188] There, the plaintiff raised four FCA retaliation claims against his employer, a government defense contractor that performed work for the U.S. Navy requiring its employees to have top-secret security clearance. The Fifth Circuit first held that it lacked subject-matter jurisdiction to assess three of those retaliation claims based on *Department of the Navy v. Egan*, which prohibited courts from questioning government determinations regarding individual security clearance. Because it was undisputed that the employer relied on the Navy's revocation of the plaintiff's security clearance, analysis of whether the employer's proffered reasons for monitoring, reporting and terminating the plaintiff were pretextual would have required the Fifth Circuit to scrutinize the government's security clearance decision.

The Fifth Circuit held that the plaintiff failed to establish a prima facie case of FCA retaliation as to his fourth claim that the employer retaliated against him when another employee told the plaintiff not to share his concerns with the Navy. Specifically, the Fifth Circuit determined that the other employee's directions did not amount to a material adverse action because they did not include threats and because the other employee was not the plaintiff's supervisor such that a reasonable worker would have been dissuaded from reporting the alleged false claims.

The Eleventh Circuit had the opportunity to analyze facts surrounding possible pretext in a termination decision. In ***Ruffolo v. Halifax Health, Inc.***, the Eleventh Circuit affirmed summary judgment for an employer where the plaintiff failed to show that the employer's reason for firing her was pretextual.[189] The employer, a health system, terminated the plaintiff after discovering that she had ordered $900,000 worth of N-95 face masks and surgical gowns as part of a plan to sell PPE to China during the COVID-19 pandemic. The Eleventh Circuit determined that, even assuming the plaintiff engaged in protected conduct, the employer's evidence that the plaintiff had used her employment, her employer's relationship to a vendor and her employer's email systems and online ordering system to order products for the benefit of a third party was strong enough to undermine the plaintiff's argument that the employer's reason for terminating her was pretextual.

But, in ***Morris v. ReVIDA Recovery Ctrs., LLC***, the district court denied summary judgment to the employer, rejecting the employer's argument that it terminated the plaintiff solely because she violated company policy and federal law by sending herself communications and documents from her company email to her personal email address.[190] The district court emphasized that the investigation into the plaintiff's emails began "just a few days" after the plaintiff's *qui tam* complaint was unsealed and that the employer did not actually identify the company policy or HIPAA confidentiality rules it believed were violated. Moreover, the district court pointed to a dearth of evidence that the plaintiff actually misused information, that patient confidentiality was actually breached or that the plaintiff did not reasonably believe the emailed documents "might be necessary to protect herself from retaliation."

In ***Brunelle v. PeaceHealth***, the district court reached different conclusions at summary judgment on causation in evaluating two plaintiffs' FCA retaliation claims against their employer, a multi-state health system.[191] The first plaintiff alleged two adverse employment actions: (1) threats and intimidation; and (2) being forced to resign (*i.e.,* "constructive discharge"). In assessing the alleged threats and intimidation, the district court explained that an action is adverse under the FCA "if it is reasonably likely to deter employees from engaging" in protected activity and drew a distinction between "petty slights" like flippant comments or exclusion from a social lunch and materially adverse conditions. In ruling that a reasonable jury could find that the first plaintiff suffered an adverse action, the district court focused particularly on one email from the health system's medical director, in which he threatened legal action against the plaintiff for speaking about his actions with other health system employees. Turning to causation, the district court looked to the temporal proximity between when the plaintiff stopped following up on her initial reported concern and when the medical director sent his email to her—which was "two to three months"—and concluded that this "gap is not so large that a reasonable jury could not find the two are related."

By comparison, the second plaintiff alleged the employer cancelled his scheduled work shifts and terminated his *locums* contract because of an anonymous report he made about a psychiatrist's billing practices—all of which effectively "blackballed" him from the health system. In granting summary judgment in favor of the health system, the district court reasoned that because the decision to cancel his shifts *pre-dated* the health system's awareness that the second plaintiff submitted the anonymous report, the second plaintiff failed to demonstrate causation.

Arbitration of Retaliation Claims

At least one district court addressed ancillary arbitration issues in connection with an alleged adverse employment action. In ***Calcaterra v. Baptist Health S. Fla., Inc.***,[192] the plaintiff was employed as the Chief of Cardiac Surgery by Baptist Health South Florida, Inc. (Baptist) and Bethesda Health Physician Group, Inc. (Bethesda). In consideration for his employment, the plaintiff and Bethesda signed an employment agreement that contained an arbitration provision. The plaintiff alleged that he was terminated in retaliation for complaining about various issues, in violation of the FCA. The defendants then moved to compel arbitration. In granting the defendants' motion, the district court held that: (1) Baptist could enforce the arbitration provision despite being a non-signatory to the employment agreement, pursuant to the doctrine of equitable estoppel; (2) because the plaintiff's FCA retaliation claim involved

188 93 F.4th 776, 789 (5th Cir. 2024).
189 2024 WL 1733968 (11th Cir. Apr. 23, 2024).
190 2024 WL 3836083 (M.D. Tenn. Aug. 15, 2024).
191 2024 WL 4529267 (W.D. Wash. Oct. 18, 2024).
192 2024 WL 2109349 (S.D. Fla. May 9, 2024).

a series of complaints and disputes in connection with his employment agreement, the claim fell within the scope of the arbitration clause; and (3) the defendants did not waive their right to arbitrate.

Relator's Share

Under the FCA, a relator is entitled to a share of the proceeds of the action or settlement of the claim.[193] Two decisions from this past year illustrate a divergence of views in determining whether a relator's share is impacted by which particular claims are settled.

In ***U.S. ex rel. Conyers v. Conyers***, the relator filed a *qui tam* suit against the defendant, and the government subsequently intervened in the suit and filed its own complaint. During discovery, the government notified the parties and the district court that it was no longer pursuing the relator's original claims.[194] The parties settled just before trial, and the settlement agreement did not include the relator's original claims. The relator moved for his share of the settlement, and the district court granted the motion, reasoning that there was factual overlap between the relator's allegations and the settled claims. The Fifth Circuit reversed, holding that under the FCA, a relator is only entitled to a share of the settlement of the claim that he or she brought, not claims that the government added. The Fifth Circuit also found no relevant factual overlap between the relator's claims and the settled claims and thus concluded that the relator's estate was not entitled to any share of the settlement proceeds.

A contrary conclusion was reached in ***U.S. ex rel. Birchall v. Spinefrontier, Inc.***[195] In that case, the district court held that the relators were entitled to a share of the settlement even though the settlement resolved claims with individuals who the relators did not name as defendants in their *qui tam* complaint. After examining how claims are compared in the FCA's first-to-file and alternative remedies provisions, the district court determined that the relators were not required to name each settling party as a defendant. Rather, the relators "must specifically, and with particularity, allege the fraud, the mechanism, the essential facts, and the conduct giving rise to the claim settled by the government," which the district court held that the relators had done.

Following the FCA's Filing Requirements

The FCA requires *qui tam* relators to file FCA lawsuits under seal in order to allow the government an opportunity to investigate the allegations and determine whether to intervene in the lawsuit.[196] Where a relator fails to follow this procedural requirement, such a failure can jeopardize a relator's ability to pursue the claims asserted in their complaint. Where the government declines to intervene and the relator's *qui tam* lawsuit is unsealed, the relator's decision to file an amended complaint can implicate this procedural requirement if the amended complaint includes new claims or theories of liability that were not included in the original *qui tam* lawsuit.

We previously reported on ***U.S. ex rel. Williams v. Landmark Hosp. of Athens, LLC***, in which the district court held that newly alleged claims included in an amended complaint had to be filed under seal to allow the government to consider those claims, and dismissed those claims in the amended complaint without prejudice.[197] In contrast, in ***U.S. ex rel. Kyer v. Thomas Health Sys., Inc.***, the district court ruled that a relator was not required to file an amended complaint under seal, despite the defendants' contention that the amended complaint contained "an incredible number of new and substantially different allegations of fraud."[198] The district court explained that while the sealing requirement is "mandatory for *original* complaints," courts disagree as to whether the sealing requirement also applies to amended complaints filed after the initial seal is lifted. In the district court's view, requiring the relator to file the amended complaint under seal would not further the primary purpose of the sealing requirement—"to allay the Government's concern that a relator filing a civil complaint would alert defendants to a pending federal criminal investigation." As a result, the district court declined to dismiss the relator's newly added fraud allegations on this basis.

193 31 U.S.C. § 3730(d).
194 108 F.4th 351 (5th Cir. 2024).
195 2024 WL 4686985 (D. Mass. Nov. 4, 2024).
196 31 U.S.C. § 3730(b)(2).

197 676 F. Supp. 3d 1323 (M.D. Ga. 2023).
198 2024 WL 4707811 (S.D.W. Va. Nov. 7, 2024).

STARK LAW/ ANTI-KICKBACK STATUTE

The Stark Law and AKS remain key components of the government's enforcement efforts concerning healthcare providers and others within the healthcare industry. Many FCA cases are premised on allegations that referral source financial arrangements violate these laws. Enforcement efforts involving the Stark Law and AKS resulted in a number of Noteworthy Settlements, as detailed earlier. Beyond those settlements, a number of court cases considered important elements of these laws.

INTENT UNDER THE AKS

In recent years, there have been several important decisions regarding the element of intent required to plead and prove AKS violations. In ***U.S. ex rel. Hart v. McKesson Corp.***, the Second Circuit issued an important opinion defining the boundaries of the AKS intent element.[199] In that case, the relator filed a *qui tam* complaint asserting claims under the FCA and the numerous state false claims acts based on allegations that McKesson provided oncology practices free access to valuable business management tools if they agreed to use McKesson as their primary wholesale drug supplier. The district court dismissed the claims asserted against McKesson, concluding that the relator failed to plead the AKS intent element.

The Second Circuit affirmed the district court, concluding that to act "willfully" under the AKS, a defendant "must act knowing that its conduct is in some way unlawful." In doing so, the Second Circuit found that "willfully" under the AKS "means what it typically means in federal criminal law"—that is, the defendant must act "with a 'bad purpose,'" although it need not be specifically aware of or intend to violate the AKS. The Second Circuit specifically rejected the relator's broader interpretation under which a defendant would act willfully when it provides something of value in connection with a medical purchase while having the general knowledge "that it is illegal to provide things of value in connection with such purchases." The Second Circuit, however, did not affirm the district court's

199 96 F.4th 145 (2d Cir. 2024).

decision in its entirety. It vacated the dismissal of the relator's state false claims act causes of action, citing the relator's argument that many state anti-kickback laws have less stringent scienter requirements than the federal AKS, leaving open the possibility of McKesson's liability on state law grounds in the future.

Questions regarding the intent required to plead and prove AKS violations have arisen in direct challenges to unfavorable OIG advisory opinions. These disputes, discussed below in our review of **Pharmaceutical and Medical Device Developments**, have involved assertions that the word "induce," as used in the AKS, requires both a *quid pro quo* exchange and an element of corruption. The Fourth Circuit rejected this type of challenge in ***Pharmaceutical Coalition for Patient Access v. U.S. Dept. Health & Human Servs.***[200] The issue is also pending before the district court in ***Vertex Pharm. Inc. v. U.S. Dept. of Health & Human Servs.***, where the plaintiff asserts that "induce" means criminal solicitation, not mere "influence."[201]

CAUSATION UNDER THE AKS

Courts have continued to wrestle with questions of causation for FCA claims premised on alleged AKS violations. Pursuant to an amendment made to the AKS by the Affordable Care Act, a claim for items or services "resulting from" an AKS violation automatically "constitutes a false or fraudulent claim for purposes of [the FCA]." What exactly is required to prove that a claim "resulted from" an AKS violation continues to divide courts.

In ***Stop Illinois Health Care Fraud, LLC v. Sayeed***, the Seventh Circuit considered the issue but declined to reach a conclusion on this issue.[202] The Seventh Circuit explained that the "resulting from" language requires a "causal nexus" between the underlying kickback violation and the alleged false claim—that, "at a minimum, every claim that forms the basis of FCA liability must be false *by virtue of* the fact that the claims are for services that were referred in violation of the [AKS]." The Seventh Circuit observed that the Sixth Circuit has required "but-for" causation—i.e., a showing that the defendant would not have submitted a claim had it not engaged in an unlawful kickback scheme—but that the Third Circuit has required only that the defendant sought reimbursement for care that was provided in violation of the AKS.[203] The Seventh Circuit ultimately found it unnecessary to decide whether the AKS requires a showing of "but-for" causation or something less in reaching its outcome.

> ***"Courts have continued to wrestle with questions of causation for FCA claims premised on alleged AKS violations. Pursuant to an amendment made to the AKS by the Affordable Care Act, a claim for items or services "resulting from" an AKS violation automatically "constitutes a false or fraudulent claim for purposes of [the FCA]."***

Early in 2025, in ***United States v. Regeneron Pharma., Inc.***, the First Circuit did join this debate, siding with the Sixth and Eighth Circuits and splitting with the Third Circuit, in ruling that "resulting from" requires "but-for" causation between the AKS violation and the alleged false claim for payment.[204] There, the government contends that Regeneron violated the AKS by improperly subsidizing patients' co-payments through a patient assistance foundation. Before the First Circuit, Regeneron argued that the plain meaning of the AKS's "resulting from" provision requires proof of "but-for" causation, while the government countered that the standard is less demanding—that if kickbacks are given to induce the purchase of a particular drug, and the intended purchase then happens, then the claim should be said to have "resulted from" an AKS violation. In examining the issue, the First Circuit conducted a textual analysis, reviewed Supreme Court precedent and considered contextual arguments from the government (*e.g.*, legislative history). Following this analysis, the First Circuit concluded that it could find no convincing reason "to deviate from the default presumption that the phrase 'resulting from'" in the 2010 amendment "imposes a but-for causation standard." We are closely watching to see whether the Supreme Court will intervene to resolve this circuit split or instead continue to allow other courts of appeals to evaluate the issue.

CMS INTERPRETATION OF STARK LAW EXCEPTION CHALLENGED

Legal challenges to government interpretations of fraud and abuse laws arose in other contexts as well. In ***Community Oncology Alliance v. Becerra***, the plaintiff challenged CMS's publication of a September 2021 frequently asked questions (FAQ) document that restricts delivery of medications, including chemotherapy, to patients in their homes.[205] The FAQ states that items are not considered to be "furnished" for purposes of the "location requirement" of the Stark Law's in-office ancillary services exception if a patient receives an item by mail outside the physician's office, as they would not have been dispensed to the patient in the office. Community Oncology Alliance claimed that CMS issued a rule under the guise of an FAQ in violation of federal rulemaking requirements and that the change,

200 2025 WL 271562 (4th Cir. 2025).
201 No. 1:24-cv-02046 (D.D.C.).
202 100 F.4th 899 (7th Cir. 2024).
203 *See U.S. ex rel. Martin v. Hathaway*, 63 F.4th 1043 (6th Cir. 2023); *U.S. ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89 (3d Cir. 2018).
204 *United States v. Regeneron Pharms., Inc.*,---F.4th---, 2025 WL 520466 (1st Cir. Feb. 18, 2025); *see also U.S. ex rel. Martin v. Hathaway*, 63 F.4th 1043 (6th Cir. 2023) (but-for causation); *U.S. ex rel. Cairns v. D.S. Medical LLC*, 42 F.4th 828 (8th Cir. 2022) (but-for causation); *U.S. ex rel. Greenfield v. Medco Health Solutions*, 880 F.3d 89 (3d Cir. 2018) (less stringent "link" between the services or products at issue and the alleged inducement).
205 2024 WL 4006049 (D.D.C. Aug. 30, 2024).

"in one fell swoop, placed a nationwide and indefinite freeze on the furnishing of cancer medications dispensed by physicians (or physician-owned pharmacies) to their patients via delivery, causing substantial and irreparable harm to oncologists and their patients alike." The district court initially declined the plaintiff's request for a preliminary injunction and then granted the government's motion to dismiss, holding that the FAQ was consistent with the statute and regulations. As a result, CMS was not required to go through notice-and-comment rulemaking to issue the FAQ.

STARK LAW IN THE WAKE OF *LOPER BRIGHT*

As noted earlier, much has been said about the potential implications of the Supreme Court's landmark decision in ***Loper Bright Enterprises v. Raimondo***.[206] The decision, in which the Court overruled so-called "Chevron deference," held that courts are not required to defer to administrative agency interpretations of statutes in the context of Administrative Procedure Act challenges. This ruling creates uncertainty in many areas, especially in the context of healthcare regulations.

In ***U.S. ex rel. Kyer v. Thomas Health Sys.***, the district court questioned whether and how *Loper Bright* might affect the Stark Law. In that case, the relator, a nurse formerly employed by the defendant health system, filed a lawsuit under the FCA premised on alleged Stark Law and AKS violations.[207] The district court ordered the parties to file supplemental briefing on the effect, if any, of *Loper Bright* on the relator's pending Stark Law claims.

The district court explained that the Stark Law and its implementing regulations have "evolved into a labyrinth of multipart compliance requirements where the exception-to-the-exception-to-the-exception is the norm." Applying *Chevron* deference, courts "[p]erhaps … could wade through Stark Law claims by deferring and defaulting to an agency's interpretation." Under *Loper Bright*, however, such deference is no longer required and, in fact, "no longer acceptable."

The parties filed briefs on the subject (notably, DOJ requested leave to file a statement of interest but declined to weigh in). The district court ultimately dismissed the case in November on other grounds, without addressing the parties' *Loper Bright* arguments. Although the district court did not consider the merits of the parties' arguments, its decision highlights the uncertainty following from *Loper Bright* and portends future arguments in Stark Law-based and other FCA cases as to its impact.

206 603 U.S. 369 (2024).
207 2024 WL 4707811 (S.D.W. Va. Nov. 7, 2024).

MANAGED CARE/ MEDICARE ADVANTAGE

Medicare Advantage (MA) enrollment continues to steadily climb. In 2024, 54% of eligible Medicare beneficiaries (or 32.8 million individuals) elected to enroll in MA plans. Payments made by CMS to MA plans amounted to $462 billion (or 55% of total federal Medicare spending). MA enrollment is projected to reach 57% of Medicare-eligible beneficiaries in the coming year. This growth has brought increased scrutiny by regulators with enforcement largely focusing on marketing practices and risk-adjustment coding. At the same time, the Supreme Court's decision in *Loper Bright* overruling *Chevron* deference has opened the door to challenges to agency action.

MA plans are operated by privately-owned Medicare Advantage Organizations (MAOs), which administer the Medicare benefit under Medicare Part C. Unlike Medicare's fee-for-service reimbursement model, MA plans are compensated on a monthly basis with a fixed capitation payment for each member. The amount of the capitated payment is based on a "risk score" assigned to each beneficiary and is based on medical history, demographics and other considerations. A beneficiary's risk score and corresponding capitated payment amount are intended to reflect the anticipated cost to manage a beneficiary's care relative to other beneficiaries.

LITIGATION AND ENFORCEMENT

Sales and Marketing Practices

At year's end, there were two settlements resolving alleged FCA violations related to sales and marketing practices associated with MA plans.

Oak Street Health, a wholly-owned subsidiary of CVS Health Corporation, agreed to pay $60 million to resolve allegations that it violated the FCA by compensating third-party insurance agents for referring their clients to Oak Street's primary care

clinics.[208] The government alleged that, under its Client Awareness Program, Oak Street paid insurance agents to contact seniors who were eligible for or enrolled in MA plans and market Oak Street to them, and then refer any interested seniors to Oak Street via a three-way phone call or electronic form submission. In announcing the settlement, DOJ emphasized its commitment to investigating illegal practices by MA providers, insurance agents and brokers.

MMM Holdings, LLC, a Puerto Rico-based MA plan, entered into a $15.2 million settlement to resolve FCA allegations that the company implemented an unlawful gift card incentive program.[209] The government alleged that MMM distributed gift cards to administrative assistants of providers in exchange for referrals of Medicare beneficiaries to MMM's MA plan. Those Medicare beneficiaries translated to $6 million of premium payments. As part of the settlement, DOJ considered MMM's cooperation and implementation of internal controls. In connection with the settlement, MMM entered into a five-year CIA with HHS-OIG, which requires MMM to develop procedures to ensure that new or existing marketing programs do not violate the AKS and to engage an Independent Review Organization. This settlement highlights the government's increased scrutiny of marketing arrangements between MAOs and providers.

Risk Adjustment

There were a number of enforcement actions and case developments involving MA plans and the risk adjustment process.

As discussed in last year's Review, in ***U.S. ex rel. Ross v. Indep. Health Corp.***, the defendants are alleged to have improperly retained overpayments from CMS. The defendant DxID LLC, a vendor of risk-adjustment services to MA plans, offered two services that captured diagnosis codes for the defendant Independent Health Association, Inc.: (1) a retrospective chart review program, which allegedly included mining of MA enrollees' medical records for risk-adjusting conditions that predated the encounter; and (2) an addenda process whereby medical providers were allegedly "nudged" to retroactively add unsupported diagnoses to medical records, sometimes months after the encounter in question.[210] More than 12 years after the initial relator complaint was filed, the government announced in December 2024 that a settlement of up to $98 million was reached to resolve the FCA allegations.[211] Under the terms of the settlement, Independent Health will also be subject to a five-year CIA with HHS-OIG.

In ***U.S. ex rel. Khushwinder Singh v. Aledade Inc.***, the complaint describes how the defendant allegedly promoted the use of higher-weighted diagnosis codes, resulting in "upcoding" through partner Accountable Care Organizations (ACOs).[212] This alleged scheme was accomplished through tools such as the Aledade App and dashboards used to monitor and ensure the conversion of suggested codes into billed codes. The parties stipulated to dismissal of the substantive FCA claims in August 2024, but the remaining FCA retaliation claims are set for trial in October 2025.

We highlighted earlier certain developments associated with ***Zafirov v. Florida Medical Associates, LLC***.[213] While this case has transformed into a constitutional law exercise concerning the FCA's *qui tam* provision, the matter arose out of allegations that the defendants knowingly submitted false and unsupported risk adjustment data to CMS. This scheme was allegedly achieved, in part, through the use of "5 Star Check Lists" created in advance of every patient visit, prompting each physician to consider the conditions on the list, including unsubstantiated conditions never before associated with that patient.

The trend of risk adjustment litigation undoubtedly will continue into the coming years. We are monitoring a case regarding improper use of addenda[214] and another case regarding an improper chart review program and failure to delete unsupported diagnosis codes,[215] and in both of those cases, discovery is well underway. Finally, we are awaiting a ruling on summary judgment motions in another case alleging an improper chart review program and failure to delete unsupported diagnosis codes.[216] This litigation bears continued watching as it progresses.

ADMINISTRATIVE ACTIONS

Against the backdrop of the Supreme Court's *Loper Bright* decision, a number of regulated entities have sued CMS over its Star Ratings methodology and calculations. In ***UnitedHealthcare Benefits of Texas, Inc. v. Centers for Medicare & Medicaid Services***,[217] various health insurance plans challenged CMS downgrading their Star Ratings based on how the plans' call center handled a single phone call. The district court agreed with the plans that CMS's assessment of the disputed call was arbitrary and capricious, and ordered CMS to revise the plans' ratings without consideration of the call.

Similarly, in ***Humana Inc. v. U.S. Department of Health & Human Services***,[218] Humana filed a lawsuit over a drop in its Star Ratings, alleging that CMS had acted in an arbitrary and capricious manner when calculating its scores. The parties are scheduled to brief summary judgment this year. Similar allegations were made in ***Elevance Health, Inc. v. Becerra***[219] and ***Centene Corp. v. Becerra***.[220] The latter was stayed in light of CMS revising Centene's Star Ratings and paying the company $200 million in bonus payments.

208 https://www.justice.gov/opa/pr/oak-street-health-agrees-pay-60m-resolve-alleged-false-claims-act-liability-paying-kickbacks.
209 https://www.justice.gov/usao-pr/pr/mmm-holdings-llc-agrees-pay-152-million-dollars-resolve-allegations-it-violated-false.
210 No. 1:12-cv-00399-WMS (W.D.N.Y.).
211 https://www.justice.gov/usao-wdny/pr/medicare-advantage-provider-independent-health-pay-98m-settle-false-claims-act-suit.
212 No. 2:21-cv-00410-KKE (W.D. Wash.).
213 No. 8:19-cv-01236-SDM-SPF (M.D. Fla.).
214 *U.S. ex rel. Osinek v. Permanente Medical Group, Inc., et al.*, No. 3:13-cv-03891 (N.D. Cal.).
215 *United States v. Anthem, Inc.*, No. 1:20-cv-02593 (S.D.N.Y.).
216 *United States v. United Health Group, Inc.*, 2:16-cv-08697 (C.D. Cal.).
217 No. 6:24-cv-00357-JDK (E.D. Tex.).
218 No. 4:24-cv-01004-O (N.D. Tex.).
219 No. 4:24-cv-01064-P (N.D. Tex.).
220 No. 4:24-cv-01415-HEA (E.D. Mo.).

There have also been developments relating to administrative actions discussed in last year's Review. As previously reported in 2023, CMS issued a final rule implementing a new methodology for risk adjustment data validation audits in the MA program. In ***Humana Inc. v. Becerra***,[221] Humana challenged the rule as arbitrary and capricious, and the parties are currently briefing summary judgment.

We also previously referenced increased oversight of MA marketing activities and related compensation to agents, brokers and field marketing organizations (FMOs). In May 2024, in ***Americans for Beneficiary Choice v. U.S. Department of Health & Human Services***,[222] a coalition of health insurance industry leaders and workers, third-party firms contracting with MA plans and firms providing administrative services to agents and brokers opposed a final rule governing compensation for agents and brokers and the payment of fees to FMOs to cover administrative costs and services. Summary judgment briefing is underway.

221 No. 4:23-cv-00909-O (N.D. Tex.).
222 No. 4:24-cv-00439-O (N.D. Tex.).

PHARMACEUTICAL AND MEDICAL DEVICE DEVELOPMENTS

Government regulators continued to monitor the activities of pharmaceutical and medical device manufacturers with heightened scrutiny.

PATIENT ASSISTANCE PROGRAMS

Patient assistance programs (PAPs) and other charitable funds continued to receive enforcement scrutiny with possible AKS considerations defining the enforcement and regulatory activity involving the pharmaceutical industry. PAPs provide financial assistance or free drug products to low-income individuals who otherwise could not afford their prescriptions and are most often sponsored or funded by pharmaceutical manufacturers. These manufacturers risk potential AKS violations when they directly or indirectly subsidize cost-sharing obligations for their own products. The government typically views improperly structured donations to PAPs as violations of the AKS if they are made with the intent to induce Medicare-funded referrals or purchases of particular drugs.[223]

Highlighting the risk associated with PAPs, **Teva Pharmaceuticals** resolved FCA allegations that it paid two co-pay assistant foundations in violations of the AKS.[224] The $425 million settlement brought long-running litigation between DOJ and Teva to an end, which involved allegations that Teva manipulated patient co-payment assistance programs over more than a decade by conspiring with third parties to direct supposed charitable payments to patients taking its multiple sclerosis drug. At the same time, DOJ alleged that Teva steadily raised the price of that drug by thousands of dollars. An additional $25 million paid as part of the settlement resolved allegations that Teva conspired with other generic drug manufacturers to fix prices for certain drugs, with DOJ asserting that the benefits Teva received under its price fixing scheme constituted illegal kickbacks. DOJ's press release reflects that the settlement was based on Teva's ability to pay.

Seeking more certainty around potential AKS enforcement regarding PAPs, pharmaceutical company **Vertex** filed suit against HHS-OIG to determine its right to provide fertility assistance to patients who receive its gene therapy for sickle

223 https://oig.hhs.gov/documents/special-advisory-bulletins/880/2005PAPSpecialAdvisoryBulletin.pdf.

224 https://www.justice.gov/usao-ma/pr/teva-pharmaceuticals-agrees-pay-425-million-resolve-kickback-allegations.

cell disease.[225] Vertex stated that its fertility preservation program provides support of up to $70,000 for those who had private insurance. Vertex sought an advisory opinion from OIG in June 2023 regarding whether its fertility program would violate the AKS and received indication that the advisory opinion would be negative. As of the date of filing suit, however, OIG had not issued its opinion, but released the negative opinion shortly after the suit was filed. Vertex's complaint seeks to aside the negative advisory opinion and its motion for summary judgment remains pending.

Favorable results in such litigation have proven difficult for plaintiffs to achieve. In ***Pharmaceutical Coalition for Patient Access v. U.S. Dept. of Health & Human Servs.***, a charitable organization comprised of a coalition of drug manufacturers (PCPA) challenged an unfavorable OIG advisory opinion concerning its proposed PAP to assist Medicare Part D beneficiaries in affording oncology drugs.

In Advisory Opinion No. 22-19, OIG concluded that the proposed cost-sharing would likely influence beneficiaries' regarding whether to purchase the oncology drugs at issue. OIG acknowledged the possibility of a "coalition model" previously, but the Advisory Opinion stated that its enforcement experience in the intervening decades had led it to conclude that allowing manufacturers to subsidize co-payments for their own drugs may encourage manufacturers to increase their list prices—among the pillars of OIG's traditional concerns when evaluating an advisory opinion request. OIG concluded that the proposed cost-sharing subsidies could inappropriately increase costs to the federal healthcare programs, interfere with or skew clinical decision-making and result in beneficiary steering.

PCPA's lawsuit filed in 2022 challenged the Advisory Opinion's overly broad interpretation of the AKS. In ruling on cross-motions for summary judgment, the district court granted HHS-OIG's motion and denied the coalition's competing motion. The district court determined that the AKS elements "remuneration" and "inducement" did not require a corrupt intent and that the proposed program could be viewed as an improper quid pro quo under the AKS. In early 2025, the Fourth Circuit affirmed the district court's decision, likely bringing a close to PCPA's challenge to the unfavorable Advisory Opinion concerning its proposed PAP.[226]

OTHER FCA LITIGATION AND SETTLEMENTS

High-dollar FCA settlements and judgments involving the pharmaceutical and device sectors of the healthcare industry typically account for significant portions of the overall FCA settlement totals touted by DOJ each year. In addition to the settlement involving Teva referenced above, there were a number of other large FCA settlements and judgments.

Pharmaceutical manufacturer **Janssen Products** faced a $150 million jury verdict in FCA litigation stemming from allegations that it engaged in off-label promotion of certain HIV drugs. The relators alleged that Janssen engaged in a nationwide scheme to promote those drugs off-label through deceptive sales communications that misstated the drugs' indications and adverse side effects. The relators are seeking entry of a judgment of more than $1 billion inclusive of trebling and per claim penalties.

Pharmaceutical company **QOL Medical LLC** and its CEO paid $47 million to resolve allegations that the company violated the AKS in connection with paying kickbacks to induce claims for its drug Sucraid, which is used to treat certain genetic gastrointestinal issues.[227] DOJ alleged that QOL distributed free test kits to healthcare providers and asked providers to give the kits to patients with particular gastrointestinal symptoms. QOL then paid a laboratory to process the tests and provided the results to its sales force with direction to the sales force to target providers whose patients had tested positive for low sucrase activity. QOL tracked whether its sales force converted positive tests into prescriptions for its drug. The allegations resolved by QOL were part of a *qui tam* lawsuit filed by former QOL employees.

Medical device companies entered into a number of high dollar settlements as well. **Lincare Inc.**, entered into a $25.5 million settlement to resolve allegations that it violated the FCA by billing government healthcare programs for the rental of non-invasive ventilators when patients no longer needed or used the devices. The settlement also included allegations that Lincare violated the AKS by waiving co-insurance payments to induce beneficiaries to rent the ventilators. The allegations were first brought against Lincare as part of a *qui tam* lawsuit filed in 2018.

Device manufacturer **Innovasis** and two of its senior executives settled FCA claims based on allegations arising from a *qui tam* lawsuit that they paid kickbacks to spine surgeons in the form of consulting fees, intellectual property acquisition and licensing fees, registry payments, performance shares in the company and other remuneration. DOJ alleged that the kickbacks induced surgeons to use Innovasis spinal implants, devices and other equipment. As part of the settlement, Innovasis agreed to pay $12 million.

Ra Medical Systems, Inc. agreed to pay $8 million to settle FCA allegations stemming from a *qui tam* lawsuit, which alleged that the company violated the AKS by paying illegal remuneration to induce physicians to use its DABRA Laser for use in atherectomies. That illegal remuneration consisted of cash payments and fees paid in connection with purported training events and consulting services. DOJ also alleged that the company tracked utilization of high-volume physicians through an internal tracking document, which was used to identify physicians to target.

Beyond FCA settlements, developments in on-going litigation involving pharmaceutical and device companies continue to warrant attention. Many of those developments involved FCA theories of liability stemming from alleged AKS violations or alleged regulatory violations associated with reporting drug pricing.

225 *Vertex Pharm. Inc. v. U.S. Dept. of Health & Human Servs.*, No. 1:24-cv-02046 (D.D.C.).
226 2025 WL 271562 (4th Cir. Jan. 23, 2025).
227 https://www.justice.gov/opa/pr/pharmaceutical-company-qol-medical-and-ceo-agree-pay-47m-allegedly-paying-kickbacks-induce.

For example, in ***U.S. ex rel. Schroeder v. Hutchinson Reg. Med. Ctr.***, the district court issued a ruling on cross motions for summary judgment concerning the relator's theory that the AKS was violated by Medtronic and Hutchinson Regional Medical Center in connection with bundled discounts associated with the sale of certain Medtronic devices used to treat peripheral artery disease in the legs.[228] In ruling in favor of the defendants, the district court considered the AKS's discount safe harbor and determined that the safe harbor does not impose onerous reporting requirements on buyers or sellers to transactions. The district court also noted the distinction between the regulatory discount safe harbor and the statutory discount exception, and noted that each provides independent grounds for protection under the AKS.

Litigation involving pharmaceutical manufacturer **Regeneron** continued, with DOJ filing an intervened FCA complaint alleging that Regeneron knowingly submitted false average sales price reports to Medicare by failing to disclose that it had paid credit card processing fees for distributors.[229] DOJ alleged that those payments included hundreds of millions of dollars and resulted in falsely inflated Medicare reimbursements. Regeneron's motion to dismiss remains pending.

CRIMINAL ENFORCEMENT

The government has continued to pursue a number of significant criminal enforcement matters involving pharmaceutical and device-related fraud schemes.

DOJ charged the owners and executives of a wholesale distributor of pharmaceutical drugs in connection with a $90 million fraud scheme that involved the introduction of adulterated and misbranded HIV drugs into the market.[230] The HIV drugs at issue were allegedly acquired through so-called "buyback" schemes in which previously dispensed prescription drugs were purchased from vulnerable patients. The defendants purchased these drugs from the black-market and resold the drugs to pharmacies, which in turn dispensed the drugs to unsuspecting patients.

There also was noteworthy criminal enforcement under the FDCA. Pharmaceutical manufacturer **KVK Research, Inc.**, pleaded guilty to criminal charges that it introduced adulterated drugs into interstate commerce in violation of the FDCA and entered into a deferred prosecution agreement as part of the resolution of those charges.[231] KVK admitted that it introduced at least 62 batches of adulterated tablets resulting from the manufacturing of the tablets with an active pharmaceutical ingredient made at a foreign facility. The company also acknowledged manufacturing drugs in violation of current good manufacturing practices by failing to exercise appropriate controls over computer and related systems. KVK also agreed to pay $2 million to resolve related FCA claims.

DOJ also charged numerous defendants associated with digital technology company **Done Global, Inc.**, and **Done Health, P.C.**, for unlawful distribution of Adderall pills.[232] The CEO and Clinical President were each charged in a scheme to distribute those pills over the internet. Providers allegedly prescribed millions of Adderall pills without interaction with patients pursuant to a company "auto-refill" policy, which allowed patients to obtain refills without any further interaction with providers. According to DOJ, the consequences of this conduct were extreme and included continued prescribing of Adderall to patients suffering from addiction and continuing months after the overdose deaths of patients.

228 2024 WL 4298655 (D. Kan. Sept. 26, 2024).
229 *U.S. ex rel. Nunnelly v. Regeneron Pharm., Inc.*, No. 1:20-cv-11401-PBS (D. Mass.).
230 https://www.justice.gov/criminal/criminal-fraud/health-care-fraud-unit/2024-national-hcf-case-summaries.
231 https://www.justice.gov/opa/pr/generic-pharmaceuticals-manufacturer-pleads-guilty-agrees-15-million-criminal-penalty#:~:text=KVK%20Research%20Inc.%2C%20a%20generic,adulterated%20drugs%20into%20interstate%20commerce.
232 https://www.justice.gov/criminal/criminal-fraud/health-care-fraud-unit/2024-national-hcf-case-summaries.

APPENDIX
2024 NOTABLE SETTLEMENTS

HOSPITALS AND HEALTH SYSTEMS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
1/4/2024	ChristianaCare	Hospital system agreed to pay $42.5 million to resolve allegations that it provided ancillary support providers such as nurse practitioners, hospitalists and physician assistants to surgeons and neonatologists to induce referrals to the system, in violation of the AKS and Stark Law.[1]	**$42.5 million**
1/4/2024	Methodist Le Bonheur Healthcare Methodist Healthcare-Memphis Hospitals	Hospital system agreed to pay $7.25 million to resolve allegations that payments to an oncology practice pursuant to a multi-agreement affiliation for management and professional services violated the AKS and resulted in the submission of false claims to Medicare.[2]	**$7.25 million**
1/16/2024	Columbus LTACH d/b/a Silver Lake Hospital	Long-term care hospital agreed to pay over $18.6 million to resolve allegations that it improperly distorted Medicare's cost outlier payment program to keep excessive payments. Certain Silver Lake investors also agreed to pay $12 million to resolve alleged Federal Debt Collection Procedures Act (FDCPA) violations related to the transfer of money by the hospital to investors when the hospital had reason to believe it would not be able to make required cost outlier reconciliation payments to Medicare. As part of the resolution, the hospital agreed to a five-year CIA with HHS-OIG.[3]	**$18.6 million**
1/16/2024	Asante Health System Dr. Charles Carmeci	Hospital system and one of its cardiothoracic surgeons agreed to pay $430,000 to resolve allegations that they submitted false claims to Medicare, Medicaid and TRICARE for various cardiothoracic procedures that they knew did not meet reimbursement criteria.[4]	**$430,000**
2/2/2024	Pomona Valley Hospital Medical Center	Medical center agreed to pay nearly $2.1 million to resolve self-disclosed allegations that it overbilled Medi-Cal for prescription medication by charging its usual and customary cost rather than the lower actual acquisition cost after a federal court lifted a stay on a California law requiring 340B Drug Pricing Program participants to bill Medi-Cal at actual acquisition cost rates.[5]	**$2.1 million**
2/7/2024	Penn State Health	Multi-hospital health system agreed to pay over $11.7 million to resolve self-disclosed allegations that it billed Medicare for Annual Wellness Visit services that were not supported by patients' medical records.[6]	**$11.71 million**

1 https://www.justice.gov/usao-de/pr/christianacare-pays-425-million-resolve-health-care-fraud-allegations-0.
2 https://www.justice.gov/usao-mdtn/pr/memphis-based-methodist-le-bonheur-healthcare-and-methodist-healthcare-memphis.
3 https://www.justice.gov/opa/pr/new-jersey-hospital-and-investors-pay-united-states-306-million-alleged-false-claims-related.
4 https://www.justice.gov/usao-or/pr/southern-oregon-hospital-system-and-physician-agree-pay-430000-settle-health-care-fraud.
5 https://www.justice.gov/usao-cdca/pr/pomona-hospital-agrees-pay-more-2-million-after-self-reporting-overbilling-medi-cal.
6 https://www.justice.gov/usao-mdpa/pr/penn-state-health-agrees-pay-more-eleven-million-dollars-following-its-voluntary.

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
3/12/2024	New York-Presbyterian Brooklyn Methodist Hospital	Hospital agreed to pay $17.3 million to resolve self-disclosed allegations that it compensated physicians at its chemotherapy infusion center in a way that was tied to the volume of their referrals to the hospital, in violation of the AKS. The settlement also resolved allegations that chemotherapy services billed to federal healthcare programs were not properly supervised by physicians.[7]	**$17.3 million**
5/6/2024	Baptist Health System Inc.	Health system agreed to pay $1.5 million to resolve self-disclosed allegations that it offered discounts to patients not based on financial need to induce the purchase or referral of the health system's services, in violation of the AKS.[8]	**$1.5 million**
5/7/2024	CHI Franciscan Health St. Joseph Medical Center	Nonprofit health system and its hospital agreed to pay over $745,000 resolve allegations that the hospital billed the VA, Medicare and TRICARE for spinal surgeries at more spinal levels than necessary and for medically unnecessary spinal fusions.[9]	**$745,654**
5/9/2024	University of Pittsburgh Medical Center	Nonprofit hospital agreed to pay $38 million to settle a *qui tam* lawsuit, filed in 2012, involving allegations that certain employed neurosurgeons received above FMV compensation for referring procedures to the hospital, in violation of the Stark Law. The government declined to intervene in these allegations. In 2016, the government partially intervened in this *qui tam* lawsuit to reach a settlement with the hospital as to different allegations concerning the employed neurosurgeons' claims for assisting with or supervising surgical procedures.[10]	**$38 million**
5/16/2024	Cape Cod Hospital	Hospital agreed to pay $24.3 million to resolve allegations that it billed for transcatheter aortic valve replacement procedures that did not comply with Medicare rules relating to the evaluation of patients for suitability for the procedure prior to performing it. The hospital received cooperation credit for voluntarily producing materials, identifying the most relevant documents for the government and implementing appropriate remedial measures. As part of the resolution, the hospital entered into a five-year CIA with HHS-OIG.[11]	**$24.3 million**
5/28/2024	Penn Highlands Healthcare Penn Highlands DuBois	Nonprofit hospital operator and its hospital agreed to pay $735,000 to resolve allegations in a partially intervened lawsuit that it violated the Stark Law, resulting in the submission of false claims to Medicaid and Medicare. The settlement resolves allegations related to the hospital compensating two non-employed referring physicians for services provided pursuant to a Consulting, Medical Director and Related Services Agreement before the agreement went into effect.[12]	**$735,000**

7 https://www.justice.gov/usao-edny/pr/new-york-presbyterianbrooklyn-methodist-hospital-settles-health-care-fraud-claims-173.
8 https://www.justice.gov/opa/pr/florida-hospital-system-agrees-pay-15-million-resolve-liability-relating-self-disclosure.
9 https://www.justice.gov/usao-wdwa/pr/doj-resolves-allegations-tacoma-spine-surgeon-billed-unnecessary-surgeries.
10 https://www.fiercehealthcare.com/providers/upmc-pays-38m-settle-12-year-old-whistleblower-case.
11 https://www.justice.gov/opa/pr/cape-cod-hospital-pay-243-million-resolve-false-claims-act-allegations-concerning-its.
12 https://www.justice.gov/usao-wdpa/pr/penn-highlands-healthcare-pay-735000-settle-false-claims-act-allegations.

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
6/24/2024	Baylor St. Luke's Medical Center Baylor College of Medicine Surgical Associates of Texas P.A.	Teaching hospital, its affiliated medical school and surgical group agreed to pay $15 million to resolve allegations that they billed for concurrent heart surgeries in violation of Medicare regulations relating to teaching physician supervision, presence and informed consent when residents were performing surgeries.[13]	**$15 million**
8/14/2024	Shore Memorial Health System, Inc. Shore Memorial Physicians' Group, P.C. Dr. David P. May	Nonprofit health system, physician group and the former president of the physician group agreed to pay $3.15 million to resolve allegations that the group received a PPP loan for which it was not eligible and subsequently sought and received forgiveness on the loan.[14]	**$3.15 million**
8/27/2024	St. Peter's Health	Nonprofit healthcare system agreed to pay over $10.8 million to resolve self-disclosed allegations that it submitted false claims to federal healthcare programs for services by an employed oncologist. The government alleged that: (1) the oncologist submitted claims for office visits that were coded at a higher level than performed or did not meet the requirements for a separate service when performed on the same day as chemotherapy administration; and (2) these false claims led the healthcare system to pay the oncologist a salary that was inconsistent with FMV.[15]	**$10.84 million**
9/16/2024	Siouxland Surgery Center LLP d/b/a Dunes Surgical Hospital United Surgical Partners International Inc. USP Siouxland Inc.	Surgical hospital and related entities agreed to pay approximately $12.76 million to resolve self-disclosed allegations that the hospital: (1) made financial contributions to a nonprofit affiliate of a referring physician group to fund the salaries of athletic trainers who generated referrals to both the group and the hospital; and (2) provided another physician group with free or below FMV clinic space, staff and supplies, both in violation of the AKS and Stark Law.[16]	**$12.76 million**
11/4/2024	Horizon Medical Center of Denton	Medical center agreed to pay $14.2 million to resolve self-disclosed allegations that it failed to include PN modifiers and location information on Medicare claims to identify services that were provided at non-excepted off-campus outpatient surgery centers. The medical center also self-disclosed possible Stark Law violations related to management agreements with companies affiliated with physicians performing surgery at the outpatient facilities and lease agreements for equipment from companies owned by a physician performing procedures at the surgery centers.[17]	**$14.2 million**
11/12/2024	University of Colorado Health	University health system agreed to pay $23 million to resolve allegations that it automatically coded certain claims for emergency room visits using the highest E&M code in the series based on the frequency of vital sign checks without regard for the severity of the patient's medical condition or the actual resources used for treatment.[18]	**$23 million**

13 https://www.justice.gov/usao-sdtx/pr/texas-medical-center-institutions-agree-pay-15m-record-settlement-involving-concurrent.
14 https://www.justice.gov/usao-nj/pr/atlantic-county-health-system-settles-matter-alleging-it-received-improper-paycheck.
15 https://www.justice.gov/usao-mt/pr/us-attorney-jesse-laslovich-announces-108-million-civil-settlement-st-peters-health-over.
16 https://www.justice.gov/opa/pr/south-dakota-surgical-hospital-agrees-pay-more-127m-resolve-alleged-false-claims-act.
17 https://www.justice.gov/usao-ndtx/pr/north-texas-medical-center-pays-142-million-resolve-potential-false-claims-act.
18 https://www.justice.gov/opa/pr/uchealth-agrees-pay-23m-resolve-allegations-fraudulent-billing-emergency-department-visits.

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
11/15/2024	Inova Health System Foundation Inova Health Care Services, Inc. Inova Physician Partners, LLC	Hospital system and affiliated entities agreed to pay over $2.37 million to resolve self-disclosed allegations that it submitted claims for sterilization and hysterectomy procedures that contained improperly modified documentation.[19]	**$2.37 million**
12/12/2024	Oroville Hospital	Hospital agreed to pay $10.25 million to resolve allegations related to: (1) medically unnecessary inpatient hospital admissions; (2) payment of bonuses to hospital physicians that took into account the volume or value of their inpatient admissions; and (3) false diagnosis codes for Systemic Inflammatory Response Syndrome. As part of the resolution, the hospital entered into a five-year CIA with HHS-OIG.[20]	**$10.25 million**
12/31/2024	Community Health Network Inc.	Health system agreed to pay $135 million to resolve a *qui tam* lawsuit involving allegations that it paid above FMV compensation to employed physicians so that they would refer patients to the health system's facilities, in violation of the Stark Law, and that the health system paid above FMV rent to a physician-owned real estate partnership to induce referrals to the health system's surgery centers, in violation of the AKS. The government previously declined to intervene as to these Stark Law and AKS allegations. In 2023, the government partially intervened in this *qui tam* lawsuit to reach a $345 million settlement with the health system as to different alleged Stark Law violations.[21]	**$135 million**

19 https://www.justice.gov/usao-edva/pr/virginia-hospital-system-agrees-237m-false-claims-settlement.
20 https://www.justice.gov/opa/pr/california-hospital-pay-1025m-resolve-false-claims-allegations.
21 https://www.indystar.com/story/news/health/2025/01/03/community-health-network-pays-135-million-to-settle-remaining-claims-on-kickbacks/77434222007.

HOSPICE, HOME HEALTH AND NURSING FACILITIES

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
1/5/2024	Atlantic Home Health Care LLC	Home healthcare agency agreed to pay over $9.99 million to resolve allegations that it submitted claims to a Department of Labor healthcare program for Department of Energy employees for nursing and personal care services when the provider was not present in patients' homes. The settlement also resolves self-disclosed allegations that the agency gave cash and in-kind benefits to patients and their families, in violation of the AKS.[22]	**$9.99 million**
3/12/2024	Family First Home Health Care, Inc. d/b/a Gaston Piedmont Health Care Inc. Marion James	Home healthcare agency and its owner agreed to pay $600,000 to resolve allegations that they submitted false claims to Medicaid for services that were: (1) never performed, such as when patients were hospitalized; (2) purportedly provided by employees who were not in the area at the time of service; and (3) provided by family members' aides in violation of Medicaid regulations but billed as if they were performed by non-related aides.[23]	**$600,000**
4/26/2024	ReNew Health Group LLC ReNew Health Consulting Services LLC Crystal Solorzano Chaim Kolodny	Nursing home operator, related consulting entity and two corporate executives agreed to pay over $7 million to resolve allegations that they submitted false claims for nursing home residents who did not have any acute illness or injury, but who had merely been near other people who had COVID-19, during a period when CMS waived the requirement that a person must have had a hospital stay of at least three days before being eligible for reimbursement for skilled care in a nursing home. As part of the resolution, the parties entered into a five-year CIA with HHS-OIG.[24]	**$7.08 million**
5/1/2024	Elara Caring JHH/CIMA Holdings Inc. CIMA Healthcare Management Inc. CIMA Hospice of Texarkana L.L.C. CIMA Hospice of East Texas L.L.C. CIMA Hospice of El Paso L.P.	Hospice company and subsidiaries agreed to pay $4.2 million to resolve allegations that they submitted false claims and retained overpayments for the care of patients who were ineligible for hospice benefits because they were not terminally ill.[25]	**$4.2 million**
6/20/2024	Tapestry Hospice of Northwest Georgia, LLC Dr. David Lovell Stephanie Harbour Ben Harbour Andrew Nall	Hospice company and its owners and managers agreed to pay $1.4 million to resolve allegations that they paid monthly stipends and signing bonuses to medical directors in exchange for patient referrals, in violation of the AKS.[26]	**$1.4 million**

22 https://www.justice.gov/opa/pr/home-healthcare-company-agrees-pay-nearly-10-million-resolve-false-claims-act-allegations.
23 https://www.justice.gov/usao-wdnc/pr/north-carolina-home-health-care-agency-and-owner-agree-pay-600000-resolve-false-claims.
24 https://www.justice.gov/usao-cdca/pr/san-gabriel-valley-based-nursing-home-chain-and-executives-pay-over-7-million-settle.
25 https://www.justice.gov/opa/pr/elara-caring-agrees-pay-42-million-settle-false-claims-act-allegations-it-billed-medicare.
26 https://www.justice.gov/usao-ndga/pr/tapestry-hospice-settles-healthcare-kickback-claims-14-million.

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
7/1/2024	Guardian Health Care Inc. Gem City Home Care LLC Care Connection of Cincinnati LLC Evolution Health LLC	Related home health agencies and their corporate owner agreed to collectively pay nearly $4.5 million to resolve self-disclosed allegations that they provided lease payments, wellness services and other items of value to assisted living facilities and physicians in exchange for Medicare referrals, in violation of the AKS.[27]	**$4.49 million**
7/10/2024	Strauss Ventures LLC d/b/a The Grand Health Care System	Healthcare system and 12 of its skilled nursing facilities agreed to pay $21.3 million to resolve allegations that they billed federal healthcare programs for rehabilitation services that were unnecessary, unreasonable, unskilled or that did not occur or did not last as long as billed. As part of the resolution, the company admitted that management-level employees implemented facility quotas that incentivized unnecessary services, and the company entered into a five-year CIA with HHS-OIG.[28]	**$21.3 million**
7/17/2024	Gentiva	Hospice and home healthcare company agreed to pay $19.42 million to resolve allegations that its predecessor, Kindred at Home and related entities, submitted false claims and retained overpayments for services provided to patients who were ineligible for hospice care because they were not terminally ill. The settlement also resolves self-disclosed allegations that one entity violated the AKS by paying remuneration to a consulting physician to induce Medicare referrals for hospice care.[29]	**$19.42 million**
8/20/2024	Intrepid U.S.A. Inc.	Home healthcare and hospice company and it's subsidiaries agreed to pay $3.85 million to resolve allegations that they submitted false claims to Medicare for home health services that were: (1) provided to patients who did not qualify or were not accurately certified for home health benefits; (2) not reasonable or not medically necessary; (3) provided by untrained staff; or (4) not actually performed. The settlement also resolves allegations that hospice facilities submitted claims for services to patients who were ineligible for hospice care because they were not terminally ill. [30]	**$3.85 million**
9/30/2024	Edison Home Health Care of New York LLC Preferred Home Health Care of New York LLC	Two related home healthcare companies agreed to pay $9.75 million to resolve allegations that they submitted false claims to Medicaid when they failed to pay home healthcare aides the minimum wages required by state law, upon which Medicaid reimbursement is contingent. The companies also agreed to pay an additional $7.5 million in wages and benefits to current and former aides under New York's Wage Parity Act.[31]	**$9.75 million**

27 https://www.justice.gov/opa/pr/home-health-providers-pay-45m-resolve-alleged-false-claims-act-liability-providing-kickbacks.
28 https://www.justice.gov/opa/pr/grand-health-care-system-and-12-affiliated-skilled-nursing-facilities-pay-213m-allegedly.
29 https://www.justice.gov/opa/pr/kindred-and-related-entities-agree-pay-19428m-settle-federal-and-state-false-claims-act.
30 https://www.justice.gov/opa/pr/nationwide-home-healthcare-and-hospice-provider-pay-385m-resolve-false-claims-act.
31 https://www.justice.gov/usao-edny/pr/brooklyn-based-home-health-care-agencies-settle-fraud-claims-975-million-and-agree-pay.

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
10/11/2024	Allstar Health Providers Inc. Maria Chua	Home health agency and its owner agreed to pay $399,990 to resolve allegations that they applied for, received and retained more than one PPP loan prior to December 31, 2020, in violation of program rules.[32]	**$399,990**
12/5/2024	Home Care VNA LLC Shakira Lubega Constant Ogutt	Home health company and its current and former owners agreed to pay over $360,000 to resolve allegations that they were reimbursed for services that did not comply with Medicaid conditions of payment related to having signed plans of care.[33]	**$361,520**

32 https://www.justice.gov/opa/pr/california-home-health-agency-and-owner-settle-false-claims-act-allegations-relating.
33 https://www.justice.gov/usao-ct/pr/home-health-care-company-and-its-owners-pay-more-360k-settle-false-claims-allegations.

PHARMACEUTICAL AND DEVICE

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
1/26/2024	Hill-Rom Holdings, Inc. Hill-Rom Company, Inc. Hill-Rom Services, Inc. Advanced Respiratory Inc.	DME company and related entities agreed to pay $2.1 million to resolve allegations that they submitted claims for: (1) used beds as if they were new; (2) certain products under a miscellaneous code, resulting in a higher reimbursement; and (3) travel time mischaracterized as repair time for it to be reimbursable.[34]	**$2.1 million**
2/15/2024	Lincare Inc.	DME supplier agreed to pay $25.5 million to resolve allegations that it billed for the rental of non-invasive ventilators to patients when the ventilator was either not being used or not needed by the patient. The settlement also resolves allegations that the company waived patient co-payments to induce patients to rent the company's ventilators instead of a competitor's, in violation of the AKS.[35]	**$25.5 million**
2/15/2024	Sentynl Therapeutics Inc.	Specialty pharmaceutical company agreed to pay $750,000 to resolve allegations that it employed and made bonus payments to a physician's girlfriend to induce the physician to prescribe two opioid medications the company sold, in violation of the AKS.[36]	**$750,000**
2/29/2024	Endo Health Solutions Inc.	Drug manufacturer agreed to pay $475.6 million to resolve civil allegations that the company engaged in a marketing scheme to target its opioid drug to providers the company knew were prescribing it for non-medically accepted indications or at high volumes. The company also agreed to plead guilty to FDCA violations related to misbranding of drugs, with the criminal resolution including a fine of $1.08 billion and an additional $450 million in forfeiture. A condition of a global bankruptcy resolution was that the company would cease operating in its current form and would not emerge from the bankruptcy.[37]	**$475.6 million**
3/6/2024	KVK Tech Inc.	Generic drug manufacturer agreed to pay $2 million to resolve civil allegations that it failed to exercise proper controls as required by good manufacturing practice regulations in connection with using an active pharmaceutical ingredient manufactured in a foreign facility, causing the company to introduce adulterated drugs into interstate commerce. Those drugs were then used in claims submitted to multiple federal healthcare programs. The manufacturer agreed to a three-year deferred prosecution agreement for related criminal charges. An affiliated entity pleaded guilty on charges that it violated the FDCA, with a fine and forfeiture in the amount of $1.5 million.[38]	**$2 million**

34 https://www.justice.gov/usao-sc/pr/durable-medical-equipment-companies-pay-millions-false-claims-settlement.
35 https://www.justice.gov/usao-sdny/pr/us-attorney-announces-255-million-settlement-durable-medical-equipment-supplier.
36 https://www.justice.gov/usao-nj/pr/california-pharmaceutical-company-pay-750000-resolve-false-claims-act-liability.
37 https://www.justice.gov/opa/pr/opioid-manufacturer-endo-health-solutions-inc-agrees-global-resolution-criminal-and-civil.
38 https://www.justice.gov/usao-edpa/pr/generic-pharmaceuticals-manufacturer-pleads-guilty-agrees-15-million-criminal-penalty.

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
3/13/2024	Caribe Holdings Cayman Co. Ltd.	Pharmaceutical manufacturer agreed to pay $1.99 million to resolve allegations that it took a PPP loan to which it was not entitled based on restrictions on certain foreign organization and ownership, and then sought and received forgiveness of the loan.[39]	**$1.99 million**
5/14/2024	Comfort Care Medical Equipment, Inc. Patrick Chalmers	DME company and one of its owners agreed to pay $352,800 to resolve allegations that they submitted claims to the Federal Employees Health Benefit Program (FEHBP) for compression stockings using an improper HCPCS code.[40]	**$352,800**
5/29/2024	Innovasis Inc. Brent Felix Garth Felix	Spinal device manufacturer and two senior executives agreed to pay $12 million to resolve allegations that they gave remuneration including excessive consulting fees, excessive IP acquisition and licensing fees, company performance shares and other extravagant benefits to 17 surgeons to induce them to use the company's spinal devices, in violation of the AKS.[41]	**$12 million**
7/25/2024	Precision Lens Estate of Paul Ehlen	Ophthalmic device company and the estate of its former principal agreed to pay $12 million to resolve a judgment related to their provision of luxury travel and entertainment to surgeons to induce the use of their product in procedures, in violation of the AKS. The parties reached this agreement after a jury found the company liable for FCA violations in 2023, and a court entered a judgment of more than $216 million.[42]	**$12 million**
8/26/2024	United Seating and Mobility, LLC d/b/a Numotion	DME company agreed to pay $13.5 million to resolve self-disclosed allegations that it submitted false claims for custom wheelchairs and wheelchair parts based on patient evaluations that were not properly authored, completed or signed by qualified medical professionals.[43]	**$13.5 million**
9/4/2024	Glenmark Pharmaceuticals Inc. USA	Generic pharmaceutical manufacturer agreed to pay $25 million to resolve allegations that it conspired to fix the price of its generic drug, paying and receiving compensation in violation of the AKS through arrangements on price, supply and allocation of customers with other manufacturers. The company previously resolved related criminal charges.[44]	**$25 million**
9/6/2024	THD America, Inc. THD SpA of Italy	Medical device manufacturer and its corporate parent agreed to pay $700,000 to resolve allegations that they encouraged surgeons to bill using improper CPT codes to obtain inflated Medicare and Medicaid reimbursements for a hemorrhoid removal system.[45]	**$700,000**
9/19/2024	Azon Medical, LLC	Medical device distributor agreed to pay over $1 million to resolve allegations that it caused improper billing for P-Stim devices when it marketed and sold its device as reimbursable under a code used for surgically implanted neurostimulators, even though the company's customers applied this electro-acupuncture device using only adhesive without any surgery.[46]	**$1.01 million**

39 https://www.justice.gov/usao-nj/pr/pharmaceutical-company-settles-allegations-it-received-improper-paycheck-protection.
40 https://www.justice.gov/usao-md/pr/comfort-care-medical-equpment-inc-and-its-owner-agree-pay-352800-settle-false-claims-act.
41 https://www.justice.gov/opa/pr/medical-device-manufacturer-innovasis-inc-and-two-top-executives-agree-pay-12m-settle.
42 https://www.justice.gov/usao-mn/pr/precision-lens-agrees-pay-12-million-united-states-kickbacks-doctors-violation-false.
43 https://www.justice.gov/usao-az/pr/united-seating-and-mobility-llc-dba-numotion-agrees-pay-13500000-resolve-alleged-false.
44 https://www.justice.gov/opa/pr/pharmaceutical-company-pays-25m-resolve-alleged-false-claims-act-liability-price-fixing.
45 https://www.justice.gov/usao-md/pr/medical-device-company-pay-700000-resolve-false-claims-act-allegations-concerning.
46 https://www.justice.gov/usao-edpa/pr/medical-device-distributor-pay-1019000-resolve-false-claims-act-liability-arising.

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
9/25/2024	Ra Medical Systems, Inc.	Medical device company agreed to pay $7.5 million to resolve allegations that it: (1) marketed its DABRA Laser for use in atherectomy procedures for which it was not FDA approved; (2) marketed the DABRA Laser despite performance issues that prompted a recall; and (3) paid cash, training fees and consulting fees to physicians to induce them to use the DABRA Laser, in violation of the AKS. Two of the physicians entered into separate related settlements.[47]	**$7.5 million**
9/27/2024	Electrostim Medical Services, Inc. Mario Garcia, Jr.	DME supplier and its founder agreed to pay $20 million to resolve allegations that they billed federal healthcare programs for excessive and medically unnecessary supplies used with Transcutaneous Electrical Nerve Stimulation and related devices.[48]	**$20 million**
10/10/2024	Teva Pharmaceuticals USA, Inc.	Generic pharmaceutical manufacturer agreed to pay $25 million to resolve allegations that it conspired to fix the price of its generic drug by paying and receiving compensation in violation of the AKS through arrangements on price, supply and allocation of customers with other manufacturers. The company previously resolved related criminal charges.[49]	**$25 million**
10/10/2024	Teva Pharmaceuticals USA, Inc. Teva Neuroscience, Inc.	Generic pharmaceutical manufacturer agreed to pay $425 million to resolve allegations that it violated the AKS by conspiring with two co-pay assistance foundations to direct its charitable donations to patients taking its own multiple sclerosis drug.[50]	**$425 million**
11/1/2024	Medisca Inc.	Compound ingredient supplier agreed to pay $21.75 million to resolve allegations that it overstated the average wholesale price (AWP) of two ingredients used in compound prescriptions, causing pharmacies to submit false claims to the Defense Health Agency. Because compounding pharmacies' reimbursement is based in part on listed AWP, the supplier allegedly used the inflated AWP to create a profit potential for its customers as an inducement to purchase its ingredients.[51]	**$21.75 million**
11/15/2024	QOL Medical LLC Frederick E. Cooper	Pharmaceutical company and its CEO/co-owner agreed to pay $47 million to resolve allegations that they caused the submission of false claims by offering providers free testing kits that they claimed could rule in or out congenital sucrase-isomaltase deficiency (CSID) in the providers' patients. The company allegedly paid a lab to provide de-identified test results to the company in addition to the providers, so that the company's sales team could market its CSID drug to providers whose patients tested positive. As part of the resolution, the parties entered into a five-year CIA with HHS-OIG.[52]	**$47 million**

47 https://www.justice.gov/usao-edmi/pr/ra-medical-systems-inc-physicians-pay-over-8-million-resolve-false-claims-act.
48 https://www.justice.gov/usao-edpa/pr/electrostim-medical-services-inc-and-mario-garcia-jr-pay-20-million-resolve.
49 https://www.justice.gov/usao-edpa/pr/generic-pharmaceutical-company-pays-25-million-resolve-false-claims-act-liability.
50 https://www.justice.gov/usao-ma/pr/teva-pharmaceuticals-agrees-pay-425-million-resolve-kickback-allegations.
51 https://www.justice.gov/opa/pr/compound-ingredient-supplier-medisca-inc-pay-2175m-resolve-allegations-false-and-inflated.
52 https://www.justice.gov/opa/pr/pharmaceutical-company-qol-medical-and-ceo-agree-pay-47m-allegedly-paying-kickbacks-induce.

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
12/13/2024	ASD Specialty Healthcare, LLC d/b/a Besse Medical	Specialty medical and pharmaceutical distributor agreed to pay $1.67 million to resolve allegations that it provided a free inventory management system to retina practices who entered into prime vendor agreements with the distributor that required the practices to purchase a certain percentage of their specialty drugs from the distributor, in violation of the AKS.[53]	**$1.67 million**

53 https://www.justice.gov/usao-ma/pr/asd-specialty-healthcare-dba-besse-medical-agrees-pay-167-million-allegedly-paying.

PHARMACY SERVICES

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
1/23/2024	Jai Shri Krishna LLC Pennmark Pharmacy Inc. Antim Patel	Pharmacy, its current owner, former owner and pharmacist agreed to collectively pay over $4.6 million to resolve allegations that they billed Medicare and Medicaid for prescriptions that were not dispensed and billed Medicare for high-cost formulations of specific medications when they actually dispensed a lower-cost formulation to program beneficiaries. As part of the resolution, the current owner and the pharmacist entered into a three-year IA with HHS-OIG.[54]	**$4.66 million**
7/10/2024	Rite Aid Corporation Rite Aid Hdqtrs Corp. Rite Aid of Connecticut Inc. Rite Aid of Delaware Inc. Rite Aid of Maryland Rite Aid of Michigan Rite Aid of New Hampshire Rite Aid of New Jersey Rite Aid of Ohio Rite Aid of Pennsylvania Rite Aid of Virginia	Pharmacy company and 10 of its subsidiaries and affiliates agreed to pay $7.5 million and have an additional $401.8 million allowed in its bankruptcy case to resolve FCA and CSA allegations that they knowingly distributed hundreds of thousands of prescriptions for controlled substances that: (1) lacked legitimate medical purpose and were not issued in the usual course of professional practice; and/or (2) were not valid prescriptions, were not for a medically accepted indication or were medically unnecessary. Rite Aid allegedly filled the prescriptions despite clear "red flags" indicating the prescriptions were unlawful. Where Rite Aid sought reimbursement from the federal government, those claims allegedly gave rise to FCA liability in addition to violating the CSA. As part of the resolution, Rite Aid entered into a Memorandum of Agreement (MOA) with DEA and a five-year CIA with HHS-OIG.[55]	**$409.3 million**
7/10/2024	Rite Aid Corporation Elixir Insurance Company RX Options LLC RX Solutions LLC	Pharmacy company and three subsidiaries that offer PBM services agreed to pay $101 million and have an additional $20 million allowed in the company's bankruptcy case to resolve allegations that they inaccurately reported drug rebates to Medicare. The government alleged the companies improperly reported portions of rebates received from pharmaceutical manufacturers as bona fide service fees, even though manufacturers did not negotiate with the defendants to pay such fees.[56]	**$121 million**
7/18/2024	PharMerica	Pharmacy company agreed to pay $100 million to settle a *qui tam* lawsuit, in which the government declined to intervene, involving allegations the company violated the AKS by offering below-cost, flat per-diem rates for servicing nursing home customers' Medicare A patients, in order to secure lucrative contracts to supply drugs to patients covered under Medicare Part D for which the company could bill on a cost basis.[57]	**$100 million**

54 https://www.justice.gov/usao-edpa/pr/current-and-former-owners-center-city-philadelphia-pharmacy-agree-pay-over-46-million.
55 https://www.justice.gov/opa/pr/rite-aid-corporation-and-affiliates-agree-settle-false-claims-act-and-controlled-substance.
56 https://www.justice.gov/opa/pr/rite-aid-corporation-and-elixir-insurance-company-agree-pay-101m-resolve-allegations-falsely.
57 https://www.mcknights.com/news/pharmerica-reaches-100-million-settlement-over-alleged-snf-pharmacy-kickbacks.

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
9/13/2024	Walgreens Boots Alliance Inc. Walgreen Co.	Pharmacy chain agreed to pay $106.8 million to resolve allegations that it submitted claims to federal healthcare programs for prescriptions that it filled but which were never picked up by beneficiaries. The companies received cooperation credit for self-disclosing certain conduct and implementing relevant enhancements to their electronic pharmacy management system.[58]	**$106.8 million**
9/25/2024	Farmacia Beatriz, LLC Edwin Valentin-Rosario	Pharmacy and its owner agreed to pay over $725,000 to resolve allegations that they submitted claims to Medicare and Medicaid for prescription drugs dispensed to patients in excess of the total volume of those drugs that the pharmacy purchased from legitimate wholesalers.[59]	**$725,640**
9/25/2024	CDT Policlínica Familiar Florida Jesús Vázquez	Pharmacy and its owner agreed to pay $1.4 million to resolve allegations that they submitted claims to Medicare and Medicaid for prescription drugs dispensed to patients in excess of the total volume of those drugs that the pharmacy purchased from legitimate wholesalers.[60]	**$1.4 million**
12/11/2024	Granby Pharmacy, Inc. a/k/a Center Pharmacy	Independent retail pharmacy agreed to pay over $230,000 to resolve allegations that it submitted false claims for a prescription vitamin by misrepresenting to physicians that their nursing home patients had requested the prescriptions when they had not. As part of the resolution, the pharmacy will implement a three-year compliance monitoring program.[61]	**$230,000**
12/11/2024	Atlas Pharmahealth, Inc. d/b/a Galaxy Pharmacy	Independent retail pharmacy agreed to pay over $270,000 to resolve allegations that it submitted claims to Medicaid for automatically refilled prescription medications that were not explicitly requested by a beneficiary or caregiver. As part of the resolution, the pharmacy will implement a three-year compliance monitoring program.[62]	**$270,000**
12/20/2024	Covid Test DMV LLC d/b/a Rapid Health	Pharmacy agreed to pay over $8.2 million to resolve allegations that it submitted claims for over-the-counter COVID-19 tests that were not actually provided to Medicare beneficiaries.[63]	**$8.24 million**
12/23/2024	K-VA-T Food Stores Inc. d/b/a Food City	Regional grocery store chain agreed to pay over $8.5 million to resolve allegations that its store pharmacies dispensed opioids and other controlled substances that: (1) were medically unnecessary; (2) lacked a legitimate medical purpose or medically accepted indication; and/or (3) were not dispensed pursuant to valid prescriptions, resulting in false claims being submitted to federal healthcare programs.[64]	**$8.56 million**

58 https://www.justice.gov/opa/pr/walgreens-agrees-pay-1068m-resolve-allegations-it-billed-government-prescriptions-never.
59 https://www.justice.gov/usao-pr/pr/2125640-recouped-civil-settlements-violations-false-claims-act-local-pharmacies-cidra.
60 https://www.justice.gov/usao-pr/pr/2125640-recouped-civil-settlements-violations-false-claims-act-local-pharmacies-cidra.
61 https://www.mass.gov/news/pharmacies-in-granby-and-dorchester-to-pay-over-500000-to-resolve-allegations-of-false-billing-to-masshealth.
62 https://www.mass.gov/news/pharmacies-in-granby-and-dorchester-to-pay-over-500000-to-resolve-allegations-of-false-billing-to-masshealth.
63 https://www.justice.gov/opa/pr/rapid-health-agrees-pay-82m-allegedly-billing-medicare-over-counter-covid-19-tests-were-not.
64 https://www.justice.gov/opa/pr/food-city-agrees-pay-over-8m-settle-false-claims-act-allegations-related-opioid-dispensing.

LABORATORY, PATHOLOGY, RADIOLOGY AND DIAGNOSTICS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
1/10/2024	RDx Bioscience Inc. Eric Leykin	Clinical laboratory and its owner/CEO agreed to pay a total of $13.25 million to resolve allegations that they engaged in several kickback schemes to induce referrals for lab testing in violation of AKS, including: (1) commission payments to third-party marketers based on the volume and value of referrals; (2) purported Management Services Organization (MSO) payments, disguised as investment returns, from third-party marketers to providers; (3) payments to providers disguised as consulting or medical director fees; and (4) specimen collection fee payments to staff members of referring providers. The settlement also resolved allegations that the lab and its owner submitted or caused false claims to be submitted for laboratory tests that were: (1) not reasonable and necessary; (2) not covered because they were blanket orders of UDT panels for all patients within a physician's practice without an individualized assessment of need; or (3) not covered because they were improperly duplicative of other claims for UDT for the same date of service, the same patient and the same drugs.[65]	**$13.25 million**
1/30/2024	AccuLab, LLC d/b/a Thoroughbred Diagnostics	Laboratory entered into an agreed judgment for over $4.9 million, holding it liable for the submission of false claims to Medicare and Kentucky Medicaid for UDT services that it knew were not typically used for medical diagnosis or treatment, and for urine drug screens without a proper medical order. To satisfy the judgment, the lab was required to pay in part the proceeds resulting from ceasing its lab operations.[66]	**$4.92 million**
2/16/2024	LabTox, LLC Ronald Coburn Erica Baker	Toxicology lab, its owner and its compliance officer agreed to civil judgments totaling more than $10.4 million and holding them liable for the submission of false claims for UDTs that were court-ordered or referred from places that did not provide medical treatments (like faith-based residential programs or homeless shelters) and that they knew were not performed for any medical purpose. The owner and compliance officer were convicted in December 2023 for related criminal violations.[67]	**$10.45 million**
2/28/2024	Capstone Diagnostics Andrew (Drew) Maloney	Clinical laboratory and its owner agreed to pay $14.3 million to resolve allegations that they paid volume-based commissions to contract sales representatives in exchange for their recommendations for medically unnecessary respiratory pathogen panels and UDTs, in violation of the AKS. The owner has also pleaded guilty to criminal charges, along with four others in connection to the scheme.[68]	**$14.3 million**

65 https://www.justice.gov/opa/pr/new-jersey-laboratory-and-its-owner-and-ceo-agree-pay-over-13-million-settle-allegations.
66 https://www.justice.gov/usao-edky/pr/kentucky-lab-agrees-49-million-civil-judgment-and-drug-treatment-center-enters.
67 https://www.justice.gov/usao-edky/pr/lexington-lab-agrees-104-million-civil-judgments-resolve-false-claims-act-allegations.
68 https://www.justice.gov/opa/pr/georgia-laboratory-owner-pleads-guilty-felony-charge-and-pays-143-million-resolve-liability.

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
3/22/2024	Dr. Mohammad Athari United Neurology P.A.	Doctor and his diagnostic centers agreed to pay $1.8 million to resolve allegations that they billed for services that were: (1) not reasonable or medically unnecessary because they were unsupported by the patients' diagnosis or medical records; or (2) because unlicensed and untrained technicians had incorrectly or inadequately rendered them. The settlement also resolved allegations that the doctor referred patients to his personally owned diagnostic centers, in violation of the Stark Law.[69]	**$1.8 million**
3/27/2024	Gamma Healthcare Inc. Jerry W. Murphy Jerrod W. Murphy Joel W. Murphy	Laboratory and three of its owners agreed to pay over $13.6 million to resolve allegations that they billed for PCR urinalysis lab tests that were medically unnecessary and not ordered by the patients' treating physician. The lab and two of the owners also agreed to be excluded from participating in federal healthcare programs for 15 years.[70]	**$13.61 million**
3/28/2024	Mako Medical Laboratories, LLC	Laboratory agreed to pay $2.1 million to resolve allegations that it submitted false claims to North Carolina's Medicaid program for medically unnecessary definitive UDTs where the lab performed both presumptive and definitive UDTs on the same sample, at or near the same time.[71]	**$2.1 million**
3/28/2024	The Radiology Group LLC Anand Lalaji	Teleradiology company and its CEO and part owner agreed to pay $3.1 million to resolve allegations that they submitted false claims to federal healthcare programs that: (1) misrepresented who performed the radiology services; (2) included services performed by non-U.S.-based radiologists; and (3) included services for imaging that a U.S.-based radiologist did not meaningfully and adequately review.[72]	**$3.1 million**
4/2/2024	CorePath Laboratories, PA	Diagnostic reference laboratory agreed to pay more than $2.7 million to resolve allegations that it entered into a kickback arrangement with an oncology practice where the lab paid the practice for each biopsy it referred. The government contended that these payments violated the AKS and that the written agreement between the lab and the practice failed to satisfy any AKS safe harbor.[73]	**$2.74 million**
5/24/2024	Daniel Hurt Fountain Health Services LLC Verify Health Landmark Diagnostics LLC First Choice Laboratory LLC Sonoran Desert Pathology Associates LLC	Health and diagnostic companies and their owner agreed to collectively pay over $27 million to resolve allegations that they submitted false claims to Medicare for cancer genomic tests that were medically unnecessary and procured via illegal kickbacks, in violation of the AKS. All parties agreed to be excluded by HHS-OIG from all federal healthcare programs. The owner previously pleaded guilty to related criminal violations.[74]	**$27.9 million**

69 https://www.justice.gov/usao-sdtx/pr/physician-pays-18m-settle-false-claims-act-liability.
70 https://www.justice.gov/opa/pr/gamma-healthcare-and-three-its-owners-agree-pay-136-million-allegedly-billing-medicare-lab.
71 https://ncdoj.gov/attorney-general-josh-stein-reaches-2-1-million-medicaid-settlement-with-mako-medical.
72 https://www.justice.gov/usao-sdny/pr/us-attorney-announces-31-million-false-claims-act-settlement-radiology-company-and-its.
73 https://www.justice.gov/usao-wdtx/pr/oncology-practice-physicians-and-reference-laboratory-pay-over-4-million-settle-false.
74 https://www.justice.gov/usao-sdfl/pr/florida-businessman-daniel-hurt-pay-over-27-million-medicare-fraud-connection-cancer.

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
6/20/2024	Avertest, LLC d/b/a Averhealth	Forensic drug testing company agreed to pay over $1.3 million to settle allegations that it submitted false claims for positive drug tests for oral fluid samples that were not confirmed using a mass spectrometric method analytically different than the screening method and did not conform to the terms of its contract with the Michigan Department of Health and Human Services to provide screening and confirmation testing for the state children's protective services and foster care program.[75]	**$1.34 million**
7/10/2024	Pacific Toxicology Laboratories	Laboratory agreed to pay $1 million to resolve allegations that it improperly billed Medicare for confirmatory UDTs for certain opioid use disorder patients when Medicare had already paid for that testing pursuant to a bundled payment rate for Opioid Treatment Programs.[76]	**$1 million**
7/11/2024	Vista Clinical Diagnostics, LLC Access Dermpath, Inc. Advanced Clinical Laboratories, Inc.	Three laboratory companies agreed to pay $2.45 million to resolve allegations that they submitted claims with manipulated diagnosis codes to Medicare and Medicaid. As part of the resolution, the companies entered into a five-year CIA with HHS-OIG. One of the companies filed for relief under Chapter 11 and the bankruptcy court approved this settlement agreement.[77]	**$2.45 million**
7/24/2024	Admera Health LLC	Former clinical laboratory (now biopharmaceutical research provider) agreed to pay over $5.3 million to resolve allegations that they paid value and volume-based commissions to third-party independent contractor marketers, in exchange for recommendations of genetic testing services, in violation of the AKS. The government alleged that Admera was informed that commission payments to independent contractors did not comply with the AKS but continued to enter into such contractual arrangements.[78]	**$5.38 million**
8/20/2024	National Interventional Radiology Partners PLLC Dr. Andrew Gomes	Radiology practice and its founder/CEO agreed to pay over $8.8 million to resolve allegations that they engaged in an improper arrangement with physicians investing in their clinics to induce referrals to the clinics for treatment of peripheral arterial disease, in violation of the AKS. The government contended, for example, that the founder/CEO's pitch to physician investors was that they could ensure high returns on their investment in each clinic from referring large numbers of patients to the clinics.[79]	**$8.88 million**

75 https://www.justice.gov/usao-edmi/pr/averhealth-pay-over-13-million-resolve-false-claims-act-allegations-related-drug-tests.
76 https://www.justice.gov/usao-ma/pr/pacific-toxicology-laboratories-agrees-pay-1-million-resolve-allegations-fraudulent.
77 https://www.justice.gov/usao-mdfl/pr/three-clermont-labs-agree-pay-245-million-settle-false-claims-act-liability.
78 https://www.justice.gov/usao-edca/pr/admera-health-agrees-pay-over-5-million-settle-false-claims-act-allegations-kickbacks.
79 https://www.justice.gov/usao-sdtx/pr/nirp-and-founder-pay-nearly-9m-resolve-alleged-kickback-referral-violations.

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
9/27/2024	Physicians' Medical Center, LLC Bluewater Toxicology Bobby Sturgeon Derrick Arthur Steve Moore	Hospital and its clinical laboratory, an independent laboratory and employees of the labs agreed to pay more than $7.2 million to resolve allegations that they submitted, or caused the submission of, false claims for UDTs that were not used for medical diagnosis or treatment as required for reimbursement, and instead were only used by homeless shelters, peer recovery centers and other non-medical entities to monitor clients' compliance with programs and court orders. The settlement also resolves related allegations that a sales representative for the labs and the hospital paid kickbacks to a physician and his wife/office manager to induce referrals to the labs. The hospital's settlement also resolves allegations related to claims for lab tests referred by providers at a practice owned by the hospital's lab manager, which directed practice providers' referral of tests to the lab and then received most of the reimbursement, in violation of the AKS.[80]	**$7.2 million**
10/2/2024	Precision Toxicology d/b/a Precision Diagnostics	Laboratory agreed to pay $27 million to resolve allegations that it: (1) billed federal healthcare programs for medically unnecessary UDTs, in part by promoting to physicians "custom profiles," which effectively were standing orders that caused physicians to order a significant number of tests without an individualized patient assessment; and (2) provided free urine test cups to physicians who agreed to refer lab testing, in violation of the AKS. As part of the resolution, the laboratory entered into a five-year CIA with HHS-OIG.[81]	**$27 million**
10/11/2024	LabXperior Corporation Tina Ball	Laboratory and its owner agreed to pay $235,000 to resolve allegations that they billed Medicaid for UDTs that were medically unnecessary and were tainted by illegal kickbacks between the lab and a referring entity (BPolloni Consulting, LLC), in violation of the AKS. The CEO of BPolloni previously pleaded guilty to related criminal charges.[82]	**$235,000**
10/22/2024	Veni-Express Inc. Myrna Steinbaum Sonny Steinbaum	Mobile phlebotomy laboratory and its owners agreed to pay a minimum of $135,000 to resolve allegations that they: (1) billed federal healthcare programs for services not performed and travel mileage related to these services that is not reimbursable; and (2) paid illegal kickbacks to a third-party marketer, in violation of the AKS. The laboratory agreed to pay additional amounts based on the sale of company property.[83]	**$135,000 (minimum)**
11/8/2024	Ethos Laboratories	Laboratory agreed to pay $6.5 million to resolve allegations that it submitted false claims to Medicare for: (1) concurrent presumptive and definitive UDTs performed regardless of the results of the presumptive UDT and without determining that definitive UDT was necessary; (2) UDTs pursuant to blanket orders for all patients from a specific provider's practice that lacked any individualized determination of medical necessity; and (3) proprietary tests for chronic pain that were medically unnecessary and at times performed without the provider's knowledge. As part of the resolution, the laboratory entered into a five-year CIA with HHS-OIG.[84]	**$6.5 million**

80 https://www.justice.gov/usao-edky/pr/hospital-laboratory-referring-physician-and-lab-employees-pay-more-72-million-resolve.
81 https://www.justice.gov/usao-co/pr/precision-toxicology-agrees-pay-27m-resolve-allegations-unnecessary-drug-testing-and.
82 https://www.justice.gov/usao-wdnc/pr/urine-drug-testing-laboratory-and-owner-agree-resolve-false-claims-act-allegations.
83 https://www.justice.gov/usao-edca/pr/california-mobile-phlebotomy-lab-and-its-owners-pay-135000-resolve-allegedly-false.
84 https://www.justice.gov/usao-ma/pr/ethos-laboratories-agrees-pay-65-million-resolve-allegations-fraudulent-billing.

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
12/2/2024	American Health Imaging, Inc. Scott Arant	Health imaging company and its former CEO agreed to pay $5.25 million to resolve allegations that they: (1) provided physicians with meals, event tickets and other gifts to induce them to refer diagnostic scans to the company's independent testing facilities; and (2) entered into above FMV personal services agreements with referring physicians, in violation of the AKS.[85]	**$5.25 million**
12/10/2024	Carter Clinic, P.A. Dr. Myleme Nyerere Ojinga Harrison	Clinical laboratory and its owner agreed to pay $825,000 to resolve allegations that they billed Medicaid for medically unnecessary UDTs and for peer support services that it failed to document and/or were unnecessary.[86]	**$825,000**
12/23/2024	Inform Diagnostics, Inc.	Clinical laboratory agreed to pay $2.9 million to resolve self-disclosed allegations that it had purchased test arrangements with physician practice customers, in violation of the AKS, resulting in the submission of false claims.[87]	**$2.9 million**
12/26/2024	R & B Medical Group Inc. d/b/a Universal Diagnostic Laboratories Southern California Medical Center Dr. Mohammad Rasekhi Sheila Busheri	Physician, a medical center he founded, his reference and esoteric laboratory, and an executive at these entities agreed to pay $15 million to resolve allegations that they submitted false claims to Medicare and Medi-Cal by: (1) compensating marketers for referrals to the medical center, in violation of the AKS; (2) providing above-market rent, complimentary and discounted services, and payment balance write-downs to third-party clinics in exchange for referrals to the lab, in violation of the AKS; and (3) referring beneficiaries from the medical center to the lab, in violation of the Stark Law.[88]	**$15 million**

85 https://www.justice.gov/usao-ndga/pr/american-health-imaging-inc-and-scott-arant-pay-over-5-million-resolve-allegations.
86 https://ncdoj.gov/attorney-general-josh-stein-reaches-825000-health-care-fraud-settlement.
87 https://www.justice.gov/usao-ma/pr/inform-diagnostics-agrees-pay-29-million-resolve-potential-false-claims-act-liability.
88 https://www.justice.gov/usao-cdca/pr/southern-california-based-clinics-laboratory-and-owners-pay-15-million-false-claims.

BEHAVIORAL HEALTH AND SUBSTANCE ABUSE TREATMENT

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
1/30/2024	Edgewater Recovery Center, LLC	Operator of residential and outpatient drug rehabilitation facilities agreed to pay $2.2 million to resolve allegations that it caused the submission of false claims for UDT services that were medically unnecessary. The government alleged that the facility requested the same complex panel of tests for all its patients weekly, without an individualized determination of need and often without using the results for diagnosis. As part of the resolution, the facility entered into a five-year CIA with HHS-OIG. [89]	**$2.2 million**
6/13/2024	Supportive Care Holdings, LLC Joseph "Dov" Newmark	Behavioral health company, its related healthcare companies and its CEO agreed to collectively pay over $4.5 million to resolve allegations that they submitted false claims to Medicare and Connecticut Medicaid for telehealth originating site facility fees using HCPCS code Q3014, while providing psychological services to patients residing in skilled nursing facilities, when the site fees should have been billed only by the nursing facilities. The settlement also resolved allegations that the companies and their CEO billed for psychological services allegedly provided to nursing home residents who were not, in fact, residing in the nursing homes, but had been transferred to various hospitals and admitted as inpatients.[90]	**$4.59 million**
6/13/2024	Evergreen Treatment Services	Nonprofit substance abuse treatment facility agreed to pay over $1.4 million to resolve allegations that it double-billed Medicare for drug treatment services that had already been paid pursuant to weekly bundled billing codes.[91]	**$1.45 million**
6/26/2024	Visiting Nurse Service of New York d/b/a VNS Health Visiting Nurse Service of New York Home Care II d/b/a Visiting Nurse Service of New York Home Care VNS Health Behavioral Health, Inc.	Operator of nonprofit home- and community-based healthcare organization and related entities agreed to pay over $950,000 to resolve allegations that they submitted claims to Medicaid for Assertive Community Treatment Program services that were not provided or not properly documented for persons with serious mental illness, as required by program regulations, guidelines and contracts.[92]	**$954,416**
7/24/2024	Texas Behavioral Health PLLC United Psychiatry Institute LLC	Two mental healthcare providers agreed to pay over $1 million to resolve allegations that they billed federal healthcare programs for physician services when physicians had not rendered or provided the requisite direct supervision of the services.[93]	**$1.08 million**

89 https://www.justice.gov/usao-edky/pr/kentucky-lab-agrees-49-million-civil-judgment-and-drug-treatment-center-enters.
90 https://www.justice.gov/usao-ct/pr/behavioral-health-companies-ceo-pay-nearly-46-million-settle-allegations-related.
91 https://www.justice.gov/usao-wdwa/pr/doj-and-evergreen-treatment-services-settle-allegations-regarding-double-billing.
92 https://www.justice.gov/usao-sdny/pr/us-attorney-announces-settlement-civil-fraud-lawsuit-against-vns-health-and-related.
93 https://www.justice.gov/usao-sdtx/pr/mental-health-services-providers-pay-over-million-settle-false-claims-liability.

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
7/25/2024	Crossroads Treatment Center of Petersburg P.C. ARS Treatment Centers of New Jersey P.C. Crossroads Treatment Center of Greensboro P.C. Starting Point of Virginia P.C.	Group of substance treatment clinics agreed to pay over $860,000 to resolve allegations that they submitted false claims to Virginia Medicaid for high-level E&M services when the patient meetings were actually routine check-ins.[94]	**$863,934**
9/26/2024	Acadia Healthcare Company Inc.	Operator of behavioral health facilities agreed to pay $19.85 million to resolve allegations that certain of its facilities submitted false claims to Medicare, Medicaid and TRICARE for inpatient behavioral health services that were not reasonable or medically necessary. The government also alleged that the facilities did not provide adequate staffing, training and/or supervision of staff, and provided care that did not comply with certain federal and state regulations.[95]	**$19.85 million**
10/1/2024	First Psychiatric Planners, Inc. d/b/a Bournewood Health Systems Bournewood Hospital	Behavioral health organization and hospital agreed to pay a minimum of $5.5 million and up to $6.5 million to resolve allegations that they entered into improper contractual arrangements with sober homes to house patients in their partial hospitalization program (PHP), through which they only paid housing fees to sober homes for government beneficiaries that remained in the PHP program and did not require that patients be homeless or housing insecure to receive the housing, in violation of the AKS. One of the contracted sober home operators was sentenced to multiple years in prison for criminal violations related to his conduct overseeing the sober home, and other operators have been indicted or found civilly liable for misconduct in managing the sober homes.[96]	**$5.5 million (minimum)** **$6.5 million (maximum)**
10/29/2024	KA Health Services Khalid Ameri	Healthcare company and its owner agreed to pay over $320,000 to resolve allegations that they submitted or caused the submission of false claims to Medicaid for psychotherapy, language interpretation and other services that were not provided or were not provided by a qualified professional. A former therapist also consented to a judgment of $40,000 as a result of the investigation.[97]	**$321,576**
10/30/2024	Evolve Health, P.C.	Physician group that focuses on substance abuse treatment agreed to pay $650,000 to resolve allegations that it billed MassHealth and MassHealth Managed Care Organizations (MCOs) for confirmatory urine tests that it did not actually provide and for upcoded E&M office visits. As part of the resolution, the company entered into a three-year independent compliance monitoring program.[98]	**$650,000**

94 https://www.justice.gov/opa/pr/substance-use-disorder-treatment-clinics-pay-more-850000-resolve-allegations-they-knowingly.
95 https://www.justice.gov/opa/pr/acadia-healthcare-company-inc-pay-1985m-settle-allegations-relating-medically-unnecessary.
96 https://www.justice.gov/usao-ma/pr/brookline-hospital-pay-65-million-resolve-false-claims-act-liability-concerning-kickback.
97 https://www.justice.gov/usao-id/pr/boise-health-care-company-and-former-therapist-resolve-fraudulent-psychotherapy-billing.
98 https://www.mass.gov/news/quincy-based-physician-group-to-pay-650000-to-resolve-allegations-of-false-billing-to-masshealth.

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
12/2/2024	Southeastern Behavioral Healthcare Services Bertha Hutchinson Virgil Hutchinson	Behavioral healthcare provider and its owners agreed to pay over $2.5 million to resolve allegations that they billed North Carolina Medicaid for services that were not medically necessary, not performed as billed, and billed for beneficiaries who were incarcerated or deceased. As part of the resolution, the company entered into a three-year IA with HHS-OIG.[99]	**$2.5 million**
12/19/2024	SaVida Health, P.C.	Behavioral health and substance use treatment provider agreed to pay $2 million to resolve allegations that it billed MassHealth and MassHealth MCOs for medically unnecessary confirmatory urine tests and for upcoded E&M office visits. As part of the resolution, the provider entered into a three-year independent compliance monitoring program.[100]	**$2 million**

99 https://www.justice.gov/usao-ednc/pr/lumberton-based-behavioral-health-provider-agrees-pay-over-25-million-settle-medicaid.
100 https://www.mass.gov/news/ag-campbell-announces-2-million-settlement-with-savida-health-to-resolve-allegations-of-false-billing-to-masshealth.

MANAGED CARE AND HEALTH PLANS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
5/23/2024	RiverSpring Living Holding Corp. Elderserve Health, Inc. d/b/a RiverSpring at Home	Nonprofit corporations that administer a Managed Long Term Care Plan for Medicaid beneficiaries agreed to pay over $10.1 million to resolve allegations that they failed to provide, or failed to adequately document, certain long-term care services to members as obligated by the applicable Medicaid contract.[101]	**$10.15 million**
8/16/2024	Humana Inc.	Health insurance company agreed to pay $90 million to settle a *qui tam* lawsuit, in which the government declined to intervene, involving allegations that the insurer mispresented its anticipated costs in submitting bids to CMS for Medicare Part D prescription drug contracts, resulting in overcharges to the government.[102]	**$90 million**
12/20/2024	Independent Health Association Independent Health Corporation	MA operators agreed to pay more than $34 million, with additional contingent payments of more than $63 million, to resolve allegations that they knowingly submitted diagnoses to Medicare that were not supported by the beneficiaries' medical records in order to inflate Medicare's payments to the companies. As part of the resolution, Independent Health Association entered into a five-year CIA with HHS-OIG.[103]	**Up to $98 million**
12/23/2024	MMM Holdings, LLC	MA plan agreed to pay over $15 million to resolve allegations that it distributed gift cards to administrative assistants of providers to induce the referral, recommendation or arrangement for enrollment of Medicare beneficiaries in its Medicare Advantage plan, in violation of the AKS. As part of the resolution, the company entered into a five-year CIA with HHS-OIG.[104]	**$15.23 million**

101 https://www.justice.gov/usao-sdny/pr/us-attorney-announces-101-million-settlement-managed-long-term-care-plan-improper.
102 https://www.reuters.com/legal/government/humana-pay-90-mln-settle-claim-that-it-overcharged-medicare-drugs-2024-08-16.
103 https://www.justice.gov/usao-wdny/pr/medicare-advantage-provider-independent-health-pay-98m-settle-false-claims-act-suit.
104 https://www.justice.gov/usao-pr/pr/mmm-holdings-llc-agrees-pay-152-million-dollars-resolve-allegations-it-violated-false.

SPECIALTY CARE AND OTHER PROVIDER ENTITIES

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
1/4/2024	H. Lee Moffitt Cancer Center & Research Institute Hospital Inc.	Nonprofit cancer treatment and research center agreed to pay over $19.5 million to resolve self-disclosed allegations that it submitted false claims for services and items provided as part of clinical trial research that should have been billed to non-government trial sponsors under CMS rules.[105]	**$19.56 million**
1/17/2024	AmeriHealth Ryan Hatch Alban Hatch	Health clinic operator and its owners consented to a $2 million civil judgment after admitting to FCA violations stemming from their use of vulnerable and inexperienced staff who they then pressured into providing unnecessary and worthless care, which resulted in false claims to federal healthcare programs. The consent judgment also resolved additional, unadmitted allegations relating to the CSA, AKS and PPP loan program.[106]	**$2 million**
2/6/2024	STAT Ambulance Services, Inc. Southcoast Emergency Medical Services, Inc. Carol Mansfield	Two healthcare transportation providers and their owner agreed to pay $1.6 million to resolve allegations that the companies submitted medically unnecessary and upcoded claims to MassHealth and Medicare. The two companies also agreed to retain an independent compliance monitor and to implement future training and auditing.[107]	**$1.6 million**
2/28/2024	Brynwood Myofascial Therapy LLC Malgorzata Zasadny Marla Monge	Physical therapy provider and its current and former owners agreed to pay $1.5 million to resolve allegations that they submitted false claims to Medicare for therapy services: (1) when the provider was not in the United States; (2) performed by massage therapists rather than licensed physical or occupational therapists; (3) performed by an OTA or PTA that were not properly supervised; (4) improperly coded to avoid service caps; and (5) when there was no licensed physical or occupational therapist on site.[108]	**$1.5 million**
4/2/2024	Oncology San Antonio, PA Affiliated Physicians Dr. Jayasree Rao	Oncology practice and its affiliated physicians agreed to collectively pay $1.3 million to resolve allegations that they entered into a kickback scheme where the laboratory (CorePath Laboratories) paid for each biopsy referred by the oncology practice, in violation of the AKS. The settlement also resolves that the practice, one of its doctors and that doctor's own practice entity billed for medically unnecessary services, treatments and tests provided by the doctor. As part of the resolution, the parties entered into a three-year IA with HHS-OIG.[109]	**$1.3 million**
4/2/2024	Croas 1 LLC d/b/a Chiropractic Associates Dr. Scott Kirkpatrick Dr. Cash Biddle Dr. Chad Keeney	Chiropractic, medical and DME provider, and a group of doctors, agreed to collectively pay $465,000 to resolve allegations that they either paid or received remuneration to induce referrals of DME, in violation of the AKS and Stark Law.[110]	**$465,000**

105 https://www.justice.gov/usao-mdfl/pr/florida-research-hospital-agrees-pay-more-195-million-resolve-liability-relating-self.
106 https://www.justice.gov/usao-id/pr/amerihealth-clinics-consent-2-million-judgment-resolve-healthcare-fraud-allegations.
107 https://www.mass.gov/news/ag-campbell-reaches-16m-settlement-with-north-dartmouth-ambulance-companies-to-resolve-false-billing-allegations.
108 https://www.justice.gov/usao-ndil/pr/rockford-skilled-therapy-provider-pay-15-million-settle-federal-health-care-fraud-suit.
109 https://www.justice.gov/usao-wdtx/pr/oncology-practice-physicians-and-reference-laboratory-pay-over-4-million-settle-false.
110 https://www.justice.gov/usao-wdok/pr/oklahoma-chiropractic-clinic-owner-and-referring-physicians-pay-465000-settle-federal.

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
5/3/2024	Apollo Health Inc. Brian J. Weinstein	Now-dissolved healthcare company and its owner agreed to a consent judgment and settlement agreement through which they will pay $1 million to resolve allegations that they billed Medicare for care plan oversight services that the company did not physically perform. The owner pleaded guilty in 2023 to a criminal federal healthcare fraud charge and was sentenced to three years of probation.[111]	**$1 million**
5/6/2024	Dr. Bohun Choi Dr. Michong Son C&S Family Dental New Britain, LLC C&S Family Dental Waterbury, LLC	Two dentists and their dental practices agreed to collectively pay over $498,000 to resolve allegations that they paid a patient recruiting company for each referral of Connecticut Medical Assistance Program patients whenever the patient received services above routine preventative care, and then submitted claims for those services, in violation of the AKS and their Medicaid provider agreements.[112]	**$498,310**
5/8/2024	Dr. James Aronovitz Michigan Ear Care PLLC	Otolaryngologist and his practice agreed to pay over $2 million to resolve allegations that they submitted claims to Medicare and Medicaid for ear care services under the physician's NPI that were conducted by physician assistants without the physician providing the requisite supervision.[113]	**$2 million**
6/5/2024	Bluestone Physician Services of Florida LLC Bluestone Physician Services, P.A. Bluestone National LLC	Group of chronic disease management providers agreed to pay over $14.9 million to resolve allegations that they submitted false claims to Medicaid, Medicare and TRICARE for E&M services that did not support the level of service provided. As part of the resolution, the companies entered into a five-year CIA with HHS-OIG.[114]	**$14.9 million**
6/6/2024	Dr. Sheldon Rabin Sheldon Rabin, M.D., P.C. d/b/a New York Eye Care	Ophthalmologist and his ophthalmology practice agreed to pay $2.5 million to resolve allegations that they billed for services that: (1) were medically unnecessary by manipulating test readings to make the services appear necessary, when the readings did not in fact indicate such a need; and (2) could not have been performed due to the doctor being out of the country or out of the office when services were stated as rendered.[115]	**$2.5 million**
6/7/2024	City Medical of the Upper East Side, PLLC Summit Medical Group, P.A. Summit Health Management, LLC Village Practice Management Company, LLC d/b/a CityMD	Several entities that collectively operate and manage multiple urgent care practices agreed to pay over $12 million to resolve allegations that they submitted or caused the submission of false claims for COVID-19 testing for uninsured patients to the HRSA program. The government alleged in part that they did not adequately confirm whether these patients had health insurance coverage prior to submitting their claims to the HRSA's uninsured program, including in instances where they already had a patient's insurance card on file. In connection with the resolution, they received cooperation credit from the government for voluntarily contracting with a third-party to assist in determining the amount of losses that the government contends were caused by the alleged false claims.[116]	**$12.03 million**

111 https://www.justice.gov/usao-ndil/pr/chicago-health-care-company-and-its-owner-pay-1-million-settle-false-claims-act.
112 https://www.justice.gov/usao-ct/pr/connecticut-dentists-pay-498k-settle-false-claims-allegations.
113 https://www.justice.gov/usao-edmi/pr/local-physician-and-practice-agree-pay-over-2-million-settle-false-claims-act.
114 https://www.justice.gov/opa/pr/chronic-disease-management-provider-pay-149m-resolve-alleged-false-claims.
115 https://www.justice.gov/usao-edny/pr/queens-and-brooklyn-based-eye-doctor-settles-health-care-fraud-claims-more-24-million.
116 https://www.justice.gov/opa/pr/citymd-agrees-pay-over-12-million-alleged-false-claims-covid-19-uninsured-program.

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
6/18/2024	KareFirst Management	Independent nurse practitioner group and its former owners agreed to pay almost $2 million to resolve allegations that they required staff to use its proprietary patient charting software knowing it caused upcoded claims to be submitted to Medicare and Medicaid.[117]	**$1.99 million**
6/28/2024	Tareen Dermatology, P.A. Dr. Mohiba Tareen Basir Tareen	Dermatology practice, its dermatologist and CEO have agreed to collectively pay $1.63 million to resolve allegations that they submitted false claims for dermatology services, including for: (1) services billed as if they were performed under the supervision of the dermatologist when she was not physically in the clinic; (2) office visits where the practice improperly waived beneficiary co-pays; and (3) the use of specific skin grafts in situations where their usage was not justified as billed.[118]	**$1.63 million**
7/16/2024	Guardant Health, Inc.	Precision oncology company agreed to pay over $910,000 to resolve self-disclosed allegations that it submitted claims for diagnostic tests referred by a physician with whom Guardant had an improper financial arrangement under the Stark Law, due to its employment of a family member of the physician.[119]	**$913,932**
7/18/2024	DaVita Inc.	Dialysis clinic provider agreed to pay over $34 million to resolve allegations that it paid improper kickbacks to: (1) a competitor by paying to acquire certain of its dialysis clinics and agreeing to extend a prior commitment to purchase dialysis products from the competitor, in order to induce referrals to a former DaVita subsidiary that provided pharmacy services for dialysis patients; (2) physician owners of vascular access centers in the form of uncollected management fees to induce referrals to the company's dialysis centers; and (3) a large nephrology practice through a right of first refusal to staff the medical director position at any new dialysis center that opened near the nephrology practice and a $50,000 payment despite the practice's decision not to staff the medical director position for those clinics, to induce referrals to the company's clinics, all in violation of the AKS.[120]	**$34.48 million**
7/29/2024	Burlington County Eye Physicians Dr. Gregory H. Scimeca	Ophthalmology practice and its owner-ophthalmologist agreed to pay nearly $470,000 to resolve allegations that they submitted or caused the submission of claims to Medicare and the FEHBP that were false because: (1) the transcranial doppler tests were medically unnecessary; (2) the professional services were not performed; and (3) the practice entered into an improper kickback arrangement with a radiology company that interpreted the test results.[121]	**$469,232**
8/1/2024	Escambia County, Florida	Florida County agreed to pay $3.5 million to resolve allegations that it billed government healthcare programs for emergency medical services and transportation by technicians who did not have the necessary certifications.[122]	**$3.5 million**

117 https://www.justice.gov/usao-ndil/pr/chicago-health-care-company-and-its-former-owners-pay-nearly-2-million-settle-false.
118 https://www.justice.gov/usao-mn/pr/tareen-dermatology-agrees-pay-more-16-million-resolve-alleged-false-claims-act.
119 https://www.justice.gov/usao-ndca/pr/cooperating-cancer-testing-company-agrees-pay-over-900000-resolve-allegations-false.
120 https://www.justice.gov/opa/pr/davita-pay-over-34m-resolve-allegations-illegal-kickbacks.
121 https://www.justice.gov/usao-ma/pr/eye-practice-and-its-physician-owner-agree-pay-more-460000-resolve-allegations-false.
122 https://www.justice.gov/usao-ndfl/pr/escambia-county-pays-35-million-settle-fca-lawsuit.

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
8/8/2024	West Coast Dental Administrative Services LLC Dr. Soleyman Cohen-Sedgh Dr. Farid Pakravan Dr. Farhad Manavi	Dental network operator and its founders and former owners agreed to pay $6.3 million to resolve allegations that they received seven improper loans under the PPP.[123]	**$6.3 million**
8/19/2024	PA Green Wellness	Medical provider agreed to pay $600,000 to resolve allegations that it improperly billed for the application of electro-acupuncture devices.[124]	**$600,000**
8/28/2024	Family Dentistry of Bridgeport PC Family Dentistry of Hartford, PLLC Family Dentistry of Stamford, PC Dr. Stanislav Gintautas Dr. Tatiana Agababaeva	Two dentists and their three dental practices agreed to collectively pay $1.7 million to resolve allegations that they paid a patient recruiting company for each referral of Connecticut Medical Assistance Program patients whenever the patient received services above routine preventative care, and then submitted claims for those services, in violation of the AKS and their Medicaid provider agreements.[125]	**$1.7 million**
9/18/2024	Oak Street Health	Company operating primary care centers that contracts with MA plans agreed to pay $60 million to resolve allegations that it paid kickbacks to third-party insurance agents in exchange for recruiting patients to its clinics, in violation of the AKS. The government alleged that: (1) the company developed a program to increase patient membership, through which third-party insurance agents contacted seniors eligible for or enrolled in MA and sent marketing messages intended to create interest in the company; (2) the agents then referred interested seniors to a company employee via a "warm-transfer" three-way phone call or e-mail; and (3) in exchange, the operator paid agents typically $200 per beneficiary referred or recommended.[126]	**$60 million**
9/25/2024	The Pain Center of Virginia, PLLC d/b/a The Pain Center of West Virginia	Pain clinic agreed to pay $750,000 to resolve allegations that it submitted or caused the submission of false claims to Medicare for the use of amniotic fluid injections for pain management that it knew Medicare did not cover. As part of the resolution, the clinic entered into a three-year IA with HHS-OIG.[127]	**$750,000**
10/18/2024	Apple Corporate Wellness, Inc. n/k/a Bryn Medical Center and Basket Medical PLLC	Primary care provider agreed to pay over $1.1 million to resolve allegations that it billed Medicare for the surgical implantation of neurostimulator devices when the patients received electro-acupuncture devices that were not surgically implanted.[128]	**$1.14 million**

123 https://www.justice.gov/usao-cdca/pr/brentwood-based-dental-offices-company-and-former-owners-pay-63-million-resolve-false.
124 https://www.justice.gov/usao-edpa/pr/provider-pay-600000-resolve-false-claims-act-liability-arising-billing-electro.
125 https://www.justice.gov/usao-ct/pr/connecticut-dentists-pay-17-million-settle-false-claims-allegations.
126 https://www.justice.gov/opa/pr/oak-street-health-agrees-pay-60m-resolve-alleged-false-claims-act-liability-paying-kickbacks.
127 https://www.justice.gov/usao-ndwv/pr/usao-ndwv-secures-false-claims-act-settlement-relating-use-amniotic-fluid-injections.
128 https://www.justice.gov/usao-edtn/pr/chattanooga-provider-settles-allegations-improper-billing-electro-acupuncture-devices.

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
10/29/2024	RM Transportation, Inc.	Medical transportation company agreed to pay $380,000 to resolve allegations that it billed for services that were not actually provided to MassHealth members, including at times when relevant medical facilities were closed. As part of the resolution, the company implemented a three-year independent compliance monitoring program.[129]	**$380,000**
11/12/2024	Brandon Eye Associates P.A.	Ophthalmology practice agreed to pay $1.3 million to resolve allegations that it submitted false claims for transcranial doppler ultrasounds (TCDs) that were: (1) medically unnecessary; (2) premised on false diagnoses; and (3) tainted by an arrangement with a third-party TCD provider, in violation of the AKS and Stark Law.[130]	**$1.3 million**
12/3/2024	Assure Holdings Corp. Assure Neuromonitoring LLC Preston Parsons Dr. Brent Kimball James Mathew McAlpin	Neuromonitoring company, its parent company, its founder, a neurosurgeon and an associated businessman agreed to collectively pay more than $2 million to resolve allegations that they engaged in a kickback arrangement involving the payment of illegal remuneration to surgeons through joint venture companies to induce the surgeons to order intraoperative neuromonitoring services from the company, in violation of the AKS.[131]	**$2 million**
12/20/2024	Various cardiology practices and associated physicians	Sixteen cardiology practices and their associated physicians across 12 states agreed to pay amounts totaling more than $17.7 million to resolve allegations that they overbilled Medicare for diagnostic radiopharmaceuticals. The government alleged the settling cardiology practices regularly reported inflated acquisition costs to Medicare for these drugs, even though Medicare contractors with jurisdiction over these states have issued guidance explaining the reimbursement methodology and providers' obligation to accurately report their invoice costs for diagnostic radiopharmaceuticals.[132] Some of the settling practices and physicians include the following: • Western Kentucky Heart & Lung Associates PSC and Mohammed Kazimuddin ($6.75 million) • Heart Clinic of Paris P.A. and Arjumand Hashmi ($2.6 million) • Scranton Cardiovascular Physician Services LLC ($2.37 million) • Shannon Clinic ($996,856) • Edward W. Leahey M.D. Professional Association and Edward Leahey ($894,679) • Metropolitan Cardiovascular Consultants LLC and Ayim Djamson ($846,888) • Cardiology Center of New Jersey LLC, Mario Criscito, Frank Iacovone and Sameer Kaul ($740,000) • Clovis Cardiology Associates LLC and Mahamadu Fuseini ($600,000)	**$17.7 million**

129 https://www.mass.gov/news/ags-office-reaches-settlement-with-swampscott-based-medical-transportation-company-to-resolve-false-billing-allegations.
130 https://www.justice.gov/opa/pr/florida-ophthalmology-practice-agrees-pay-13m-resolve-allegations-fraudulent-claims-0.
131 https://www.justice.gov/usao-co/pr/2-million-resolves-kickback-allegations-relating-denver-neuromonitoring-company.
132 https://www.justice.gov/usao-wdky/pr/sixteen-cardiology-practices-pay-total-177m-resolve-false-claims-act-allegations-0.

INDIVIDUAL PROVIDERS

DATE	PROVIDER	FCA ALLEGATIONS	AMOUNT
1/16/2024	Ijeoma Bethel Yvonne Hernandez Nick Bryant Villegas	Two nurse practitioners and a chiropractor, all owners of a wellness clinic, agreed to pay up to $108,000 to resolve allegations they billed Medicare for the surgical implantation of neurostimulator devices when patients received electro-acupuncture devices, which do not require surgery. As part of the resolution, the clinic (Texas Wellness Clinic) agreed to a five-year exclusion from all federal healthcare programs. In 2021, the chiropractor-owner of the providers' former employer agreed to a $2.6 million settlement and a ten-year exclusion from federal healthcare programs for related allegations.[133]	**$108,000**
1/29/2024	Dr. Daniel Case	Physician agreed to pay $95,000 to resolve allegations that he ordered medically unnecessary DME and participated in a kickback scheme with his employer, a nationwide telemedicine company (RediDoc LLC), whereby he received kickbacks to sign DME orders, in violation of the AKS. The owners of the telemedicine company previously pleaded guilty to various federal offenses, including conspiracy to violate the AKS.[134]	**$95,000**
2/22/2024	Dr. Arun Sehgal Preventive & Diagnostic Medical Center P.A.	Doctor and his medical practice agreed to pay nearly $700,000 to resolve allegations that they: (1) upcoded E&M CPT codes; (2) billed for more services than could possibly be provided in one day; and (3) billed for services the physician never provided.[135]	**$693,490**
2/29/2024	Dr. Peter J. Baddick, III	Doctor agreed to pay $60,000 to resolve allegations that he prescribed the opioid medication Subsys without a legitimate medical purpose to patients who lacked a cancer diagnosis and then billed Medicaid and TRICARE for the associated visits.[136]	**$60,000**
3/11/2024	Dr. Nishi Patel	Physician agreed to pay $95,000 to resolve allegations that he ordered medically unnecessary genetic tests for Medicare beneficiaries with whom he did not have a medical relationship.[137]	**$95,000**

133 https://www.justice.gov/usao-sdtx/pr/richmond-clinic-owners-agree-settle-allegations-regarding-acupuncture-devices.
134 https://www.justice.gov/usao-edwa/pr/doctor-agrees-pay-95000-settle-allegations-health-care-fraud.
135 https://www.justice.gov/usao-nj/pr/doctor-pay-nearly-700000-resolve-false-claims-act-allegations.
136 https://www.justice.gov/usao-mdpa/pr/medical-doctor-pay-6000000-resolve-civil-liability-alleged-violations-false-claims-act.
137 https://www.justice.gov/usao-edpa/pr/physician-pays-95000-resolve-allegations-genetic-testing-fraud.

DATE	PROVIDER	FCA ALLEGATIONS	AMOUNT
3/15/2024	Dr. Edward William Salko Jackson & Coker LocumTenens, LLC (JCLT)	Doctor and a healthcare staffing company for which the doctor was independently contracted to provide telemedicine services agreed to pay $700,000 to resolve allegations that they participated in a kickback scheme to bill Medicare for medically unnecessary DME and diagnostic laboratory testing, in violation of the AKS. Under the alleged arrangement, a client of the staffing company (Nationwide Health Advocates) employed telemarketing companies to obtain personal information and supporting documentation from Medicare beneficiaries to generate physician orders for DME and laboratory tests. The physician and JCLT allegedly received payment in exchange for reviewing and approving the client's orders. The government noted that the staffing company's cooperation was significant in facilitating its investigation and that the company had taken significant remedial measures, including improving its internal controls in placing providers with telemedicine clients, which was accounted for in the resolution. The former owner and president of Nationwide Health Advocates previously pleaded guilty to criminal charges for related conduct.[138]	**$700,000**
4/1/2024	Dr. Paul Bierig Paul C. Bierig M.D., P.A.	Physician and his medical practice agreed to pay over $120,000 to resolve allegations that they received kickbacks from laboratory marketers' MSOs in return for ordering lab tests from affiliated laboratories, in violation of the AKS.[139]	**$120,634**
4/1/2024	Dr. Mohd Azfar Malik	Physician agreed to pay over $217,000 to resolve allegations that he and his medical practice received kickbacks from laboratory marketers' MSOs in return for ordering lab tests from affiliated laboratories, in violation of the AKS. The government previously settled related allegations with Dr. Malik's practice and one of the clinical laboratories.[140]	**$217,430**
4/1/2024	Dr. Robert Ain Comprehensive Pain Treatment LLC	Physician and his pain management practice agreed to pay more than $100,000 to resolve allegations that they received kickbacks from a laboratory marketer's MSO in return for ordering lab tests from an affiliated clinical laboratory, in violation of the AKS.[141]	**$100,632**
4/1/2024	Dr. Barry Feinberg Dr. Rachel Feinberg BIF Family Trust	Two physicians and their family trust agreed to pay over $340,000 to resolve allegations that they received kickbacks from laboratory marketers' MSOs in return for ordering lab tests from an affiliated clinical laboratory, in violation of the AKS.[142]	**$342,466**
4/3/2024	Dr. Gerald Knouf	Family medicine doctor agreed to pay $96,000 to resolve FCA and CSA allegations that he: (1) wrote unlawful prescriptions; (2) prescribed dangerous combinations of drugs; and (3) billed Medicare and Medicaid for services that were not performed. As part of the resolution, the doctor's DEA registration was restricted for five years.[143]	**$96,000**

138 https://www.justice.gov/usao-edwa/pr/richland-physician-health-care-staffing-company-agree-pay-700000-resolve-false-claims.
139 https://www.justice.gov/opa/pr/marketers-and-physicians-five-states-agree-pay-over-15-million-settle-laboratory-kickback.
140 https://www.justice.gov/opa/pr/marketers-and-physicians-five-states-agree-pay-over-15-million-settle-laboratory-kickback.
141 https://www.justice.gov/opa/pr/marketers-and-physicians-five-states-agree-pay-over-15-million-settle-laboratory-kickback.
142 https://www.justice.gov/opa/pr/marketers-and-physicians-five-states-agree-pay-over-15-million-settle-laboratory-kickback.
143 https://www.justice.gov/usao-id/pr/pocatello-doctor-pays-96000-settle-allegations-he-wrote-unlawful-prescriptions.

DATE	PROVIDER	FCA ALLEGATIONS	AMOUNT
4/25/2024	Ashley Brown, DNP, ARNP	Nurse practitioner agreed to pay more than $50,000 to resolve allegations that she signed hundreds of medically unnecessary prescriptions for expensive orthotic braces in exchange for kickbacks, in violation of the AKS.[144]	**$52,560**
4/29/2024	Dr. Steven Bauer Ballantyne Medical Associates PLLC	Doctor and his medical practice agreed to pay $205,000 to resolve allegations that they received kickbacks in the form of purported office space rental and phlebotomy payments from a laboratory in return for ordering testing, in violation of the AKS. In connection with the resolution, they received cooperation credit for providing information that assisted the government's investigation.[145]	**$205,000**
4/29/2024	Dr. Larry Berman Larry F. Berman, M.D., P.C.	Doctor and his medical practice agreed to pay more than $380,000 to resolve allegations that they received kickbacks disguised as purported office space rental and phlebotomy payments from a laboratory in return for ordering testing, in violation of the AKS.[146]	**$385,000**
4/29/2024	Dr. Alireza Nami Joint and Muscle Medical Care, P.C.	Doctor and his medical practice agreed to pay $383,400 to resolve allegations that they received kickbacks from a laboratory disguised as the purchase price for used laboratory equipment, office space rental and phlebotomy payments in return for ordering testing, in violation of the AKS.[147]	**$383,400**
5/7/2024	Dr. Kevin Schoenfelder	Orthopedic surgeon agreed to pay over $197,000 to resolve allegations that he performed spinal surgeries at more spinal levels than necessary and medically unnecessary spinal fusions. He retired in 2018 and surrendered his license in 2019.[148]	**$197,054**
5/31/2024	Dr. Tony Tannoury	Doctor agreed to pay $200,000 to resolve allegations that he solicited and received free products from a medical device company in return for ordering the company's products for use in his procedures, including some performed overseas, in violation of the AKS. The medical device company settled related allegations with the government in January 2023.[149]	**$200,000**
6/11/2024	Dr. Nehal Modh Progressive Pain Management	Doctor and his pain management company agreed to pay $1.2 million to resolve allegations that they: (1) falsely indicated that ultrasound guidance was used on certain pain management injections; (2) submitted claims for facet joint injections that did not meet billing requirements; and (3) improperly coded claims to receive excess reimbursement.[150]	**$1.2 million**

144 https://www.justice.gov/usao-ndia/pr/iowa-nurse-practitioner-agrees-pay-over-50000-resolve-suit-alleging-fraudulent-durable.
145 https://www.justice.gov/opa/pr/laboratory-marketer-and-north-carolina-physicians-agree-pay-over-13m-settle-kickback.
146 https://www.justice.gov/opa/pr/laboratory-marketer-and-north-carolina-physicians-agree-pay-over-13m-settle-kickback.
147 https://www.justice.gov/opa/pr/laboratory-marketer-and-north-carolina-physicians-agree-pay-over-13m-settle-kickback.
148 https://www.justice.gov/usao-wdwa/pr/doj-resolves-allegations-tacoma-spine-surgeon-billed-unnecessary-surgeries.
149 https://www.justice.gov/usao-ma/pr/massachusetts-surgeon-pay-200000-resolve-allegations-soliciting-and-receiving-illegal.
150 https://www.justice.gov/usao-edmo/pr/united-states-reaches-12-million-civil-settlement-festus-pain-management-doctor-over.

DATE	PROVIDER	FCA ALLEGATIONS	AMOUNT
6/14/2024	Joseph M. Childs, DC Charles H. Durr, DC Active Integrated Medical Centers, PC	Two chiropractors and their clinic agreed to pay $1.9 million to resolve allegations that they improperly billed federal healthcare programs for medically unnecessary treatments involving Sanexas, an electric stimulation device used to treat diabetic neuropathy, and two other related testing modalities, including TM Flow devices and epidermal nerve fiber density (ENFD) testing, used to identify nerve damage or other diseases that could be treated with the Sanexas device, in violation of various federal billing requirements.[151]	**$1.9 million**
6/14/2024	Taylor Vanden Wynboom, DC Nova Integrated Health, PC	Chiropractor and his company agreed to pay $52,000 to resolve allegations that they improperly billed federal healthcare programs for medically unnecessary treatments involving Sanexas, an electric stimulation device used to treat diabetic neuropathy, and ENFD testing, used to identify nerve damage that could be treated with the Sanexas device, in violation of various federal billing requirements. The government filed a complaint and finalized a settlement following the chiropractor's declaration of Chapter 7 bankruptcy.[152]	**$52,000**
6/21/2024	Dr. Jamie P. Loggins	Doctor agreed to pay nearly $630,000 to resolve allegations that he prescribed medically unreasonable and unnecessary orthotic braces to individuals with whom he did not have a valid prescriber-patient relationship on the basis of a telemedicine company's prepared prescriptions.[153]	**$629,056**
6/25/2024	Dr. Mustafa A. Hammad	Neurologist and pain management physician entered into a consent judgment and agreed to pay $550,000 to resolve FCA and CSA allegations that he falsified records and improperly billed Medicare and Medicaid for sleep studies and prescriptions that he conducted, interpreted or issued while residing outside the U.S. As part of the resolution, the physician also agreed: (1) to the government's sale of his real property in Panama City, Florida; (2) not to contest a forfeiture judgment of $506,017 in a separate case with the government; and (3) not to reapply for a DEA registration.[154]	**$550,000**
7/17/2024	Dongxin Ma Ma Acupuncture Center PC	Acupuncturist and his clinic agreed to pay $2.3 million to resolve allegations that they billed the VA for acupuncture services that were not provided or were unreasonable.[155]	**$2.3 million**
7/23/2024	Kevin Michael Brown	Chiropractor agreed to pay $180,000 to resolve allegations that he, through his companies Revive Medical of San Diego and Revive Medical LLC, billed Medicare for surgically implanted neurostimulators when surgery or implantation was not performed. As part of the resolution, he agreed to a five-year exclusion from all federal healthcare programs.[156]	**$180,000**

151 https://www.justice.gov/usao-edpa/pr/us-attorney-announces-two-additional-civil-settlements-part-national-effort-combat.
152 https://www.justice.gov/usao-edpa/pr/us-attorney-announces-two-additional-civil-settlements-part-national-effort-combat.
153 https://www.justice.gov/usao-me/pr/provider-agrees-pay-over-629000-settle-allegations-false-claims-act-violations.
154 https://www.justice.gov/usao-ndfl/pr/former-panama-city-doctor-agrees-550000-consent-judgment-resolve-fca-and-csa-lawsuit.
155 https://www.justice.gov/usao-wdtx/pr/acupuncturist-and-acupuncture-clinic-ordered-pay-23-million-resolve-civil-false-claims.
156 https://www.justice.gov/usao-edca/pr/riverside-county-chiropractor-agrees-pay-18000-resolve-allegations-health-care-fraud.

DATE	PROVIDER	FCA ALLEGATIONS	AMOUNT
8/7/2024	Justin Leland	Owner of a DME and medical supply company agreed to pay nearly $225,000 to resolve allegations that he participated in a scheme to bill Medicare for medically unnecessary DME ordered by physicians who solicited and received kickbacks in exchange for ordering the DME, in violation of the AKS.[157]	**$224,620**
8/9/2024	Dr. Azhar Shakeel	Doctor and owner/operator of two urgent cares and a medical clinic agreed to pay nearly $620,000 to resolve allegations that he submitted claims to federal healthcare programs for services rendered when he was out of the office and traveling.[158]	**$619,994**
8/19/2024	Dr. Ashikkumar A. Raval Dr. Manish A. Raval Orange Medical Care, P.C.	Two physicians and their practice agreed to pay $600,000 to resolve allegations that they submitted claims for primary care services that were not rendered or supervised by the physician identified in the claim and were rendered by non-credentialed providers, including nurse practitioners and physician assistants. As part of the resolution, the parties executed a $1.65 million consent judgment, which will be enforced if the settlement payments are not made.[159]	**$600,000**
8/26/2024	Young Sam Kim	Acupuncturist agreed to pay $850,000 to resolve allegations that he billed the VA for healthcare services that were not actually provided or were significantly overstated, such as claims totaling more than 24 hours in a single day.[160]	**$850,000**
8/27/2024	Tracy Ellis, D.C. Tristan Ellis Mark L. Wells, PA-C Oklahoma Medical Clinic, LLC	Chiropractic physician, his clinic, a partial owner of the clinic, and a certified physician assistant working at the clinic agreed to collectively pay $246,000 to resolve allegations that they billed Medicare for medically unnecessary ultrasound services that the physician assistant performed.[161]	**$246,000**
9/11/2024	Dr. Vishal Patel	Physician agreed to pay $1.08 million to resolve allegations that he ordered medically unnecessary DME, particularly orthotic devices, for Medicare and FEHBP patients with whom the physician had no medical relationship. Patients' records were allegedly provided to the physician by a telemedicine company that previously pleaded guilty to healthcare fraud conspiracy.[162]	**$1.08 million**
9/25/2024	Dr. Elias Kassab Dr. David Allie	Two physicians and their respective companies agreed to collectively pay $700,000 to resolve allegations that they accepted cash, training fees and consulting fees from a medical device company, in exchange for using the company's DABRA Laser, in violation of the AKS. The medical device company entered into a separate related settlement.[163]	**$700,000**

157 https://www.justice.gov/usao-edwa/pr/owner-spokane-valley-medical-supply-company-agrees-pay-224620-resolve-allegations.
158 https://www.justice.gov/usao-ndok/pr/tulsa-physician-pays-over-600k-resolve-allegations-false-claims-act-violations.
159 https://www.justice.gov/usao-sdny/pr/us-attorney-announces-600000-false-claims-act-settlement-medical-practice-and-its.
160 https://www.justice.gov/usao-edca/pr/us-attorneys-office-obtains-850000-settlement-fresno-acupuncturist-resolve-false.
161 https://www.justice.gov/usao-wdok/pr/oklahoma-medical-clinic-owners-and-treating-physician-pay-246000-settle-allegations.
162 https://www.justice.gov/usao-de/pr/united-states-settles-claims-durable-medical-equipment-fraud-against-wilmington.
163 https://www.justice.gov/usao-edmi/pr/ra-medical-systems-inc-physicians-pay-over-8-million-resolve-false-claims-act.

DATE	PROVIDER	FCA ALLEGATIONS	AMOUNT
9/27/2024	Dr. Pablo Merced Theresa Merced	Physician and his office manager/wife agreed to pay $450,000 to resolve allegations that they received kickbacks from two laboratories in the form of cash and payment of additional salaries for lab specimen collectors working in the physician's office to induce referrals of lab tests, in violation of the AKS. The specimen collectors, who were employed by one of the laboratories, were also alleged to be performing work unrelated to specimen collection. The settlement also resolved allegations that the physician violated the CSA by writing invalid prescriptions. A hospital, a laboratory and three lab employees resolved related allegations.[164]	**$450,000**
10/1/2024	Dr. Maneesh Ailawadi	Bariatric and general surgeon agreed to pay $45,000 to resolve allegations that he improperly billed Medicare and Medicaid for esophagogastroduodenoscopy (EGD) procedures that were only partially completed.[165]	**$45,000**
10/2/2024	Jeffrey Madison	Former critical access hospital CEO agreed to pay over $5.3 million to resolve the government's lawsuit alleging that he: (1) agreed to a kickback scheme in which the hospital paid commissions to recruiters using MSOs to pay physicians to induce lab test referrals to the hospital; (2) falsely certified AKS compliance on the hospital's Medicare cost reports; and (3) paid a referring physician monthly medical director fees to induce lab test referrals, all in violation of the AKS. As part of the resolution, the CEO agreed to a 25-year exclusion from federal healthcare programs.[166]	**$5.34 million**
10/7/2024	Gregory Thomas White Jr, DC Healing Place Medical, P.C.	Chiropractor and his clinic agreed to pay $170,000 to resolve allegations that they improperly billed Medicare for medically unnecessary or non-reimbursable treatments involving Sanexas devices and various related modalities, including vitamin injections, TM Flow testing and ENFD testing, used to treat pain and other medical conditions.[167]	**$170,000**
10/9/2024	Dr. Eric Troyer Troyer Medical Inc. P.C.	Doctor and his practice agreed to pay $625,000 to resolve allegations that they received kickbacks from a laboratory disguised as payments for phlebotomy services, rental of office space and lease of a chemistry analyzer machine in return for lab test referrals, in violation of the AKS.[168]	**$625,000**
10/11/2024	Dr. Janette J. Gray The Center for Health & Wellbeing in San Diego	Physician and her former practice agreed to pay $3.8 million to resolve allegations that they billed Medicare and TRICARE for non-covered services by: (1) disguising the rendering provider; (2) misrepresenting the services provided; (3) unbundling services that should have been billed as a single code; and (4) billing for medically unnecessary services. As part of the resolution, the doctor is excluded from participating in all federal healthcare programs for five years.[169]	**$3.8 million**

164 https://www.justice.gov/usao-edky/pr/hospital-laboratory-referring-physician-and-lab-employees-pay-more-72-million-resolve.
165 https://www.justice.gov/usao-edpa/pr/lehigh-valley-area-doctor-agrees-pay-45000-resolve-false-claims-act-liability.
166 https://www.justice.gov/opa/pr/texas-hospital-ceo-pay-over-53m-settle-kickback-allegations-involving-laboratory-testing.
167 https://www.justice.gov/usao-edpa/pr/us-attorney-announces-additional-civil-settlement-chiropractor-and-his-practice-part.
168 https://www.justice.gov/opa/pr/north-carolina-physician-and-medical-practice-agree-pay-625000-settle-kickback-allegations-0.
169 https://www.justice.gov/usao-sdca/pr/san-diego-physician-and-medical-practice-pay-38-million-resolve-false-claims-act.

DATE	PROVIDER	FCA ALLEGATIONS	AMOUNT
10/25/2024	Dr. Joseph Upton	Doctor agreed to pay over $65,000 to resolve allegations that, through his work for a purported telemedicine company (REMN), he billed Medicare for DME and genetic testing that were medically unnecessary or unreasonable.[170]	**$65,680**
10/29/2024	Dr. Adam B. Smith a/k/a Adam Bryant	Plastic surgeon agreed to pay nearly $199,000 to resolve allegations that he billed federal healthcare programs for medically unnecessary procedures and procedures that were more complex than were actually performed, including claiming to perform complicated hernia repair or tissue transfer procedures when actually performing various uncovered cosmetic procedures, and for upcoded wound care procedures and office visits. In February 2021, the doctor pleaded guilty to falsely describing a cosmetic procedure as medically necessary and reimbursable by Medicare. The doctor voluntarily surrendered his medical licenses in South Dakota and Iowa in 2019 and 2021. In 2021, the government resolved the same allegations with the physician's employer.[171]	**$198,755**
11/4/2024	Dr. Stephen Swetech Yasser Maisari GMAJOS, LLC	Doctor, pharmacist and office complex owner agreed to collectively pay over $700,000 to resolve allegations that: (1) the doctor accepted above FMV rent from a lab for a room rented from the office complex owner to induce patient referrals; and (2) the doctor prescribed multiple medically unnecessary drugs, including opioids, which were filled at a pharmacy onsite, owned by the pharmacist. As part of the resolution, the doctor agreed to void his DEA registration and cease prescribing, dispensing or administering controlled substances.[172]	**$700,948**
11/21/2024	Dr. Jagpreet Mukker Jay Mukker, DPM Inc.	Podiatrist and his medical corporation agreed to collectively pay nearly $1.6 million to resolve allegations that the podiatrist received kickback payments, described as investment returns, in connection with investments in purported MSOs, in exchange for directing prescriptions to mail order pharmacies, all of which were controlled by a third-party individual (Matthew Peters). The settlement also resolved allegations that the podiatrist and his medical corporation submitted false claims for peripheral venous studies that they knew were not covered by Medicare, under the guise of covered E&M services.[173]	**$1.59 million**
11/21/2024	Dr. Amitabh Goswami California Pain Consultants	Pain medicine specialist and his medical corporation agreed to pay $835,000 to resolve allegations that they participated in an illegal kickback arrangement causing false claims to be submitted to federal healthcare programs, in violation of the AKS.[174]	**$835,000**
12/9/2024	Dr. Basem Hamid	Neurologist and pain medicine doctor agreed to pay nearly $950,000 to resolve allegations that he billed Medicare for the surgical implantation of neurostimulator devices when the patients received electro-acupuncture devices that were not surgically implanted.[175]	**$948,359**

170 https://www.justice.gov/usao-wdwa/pr/washington-doctor-settles-allegations-he-submitted-false-claims-federal-healthcare.
171 https://www.justice.gov/usao-ndia/pr/former-sioux-city-plastic-surgeon-agrees-pay-nearly-200000-settle-allegations-he.
172 https://www.justice.gov/usao-edmi/pr/macomb-county-doctor-and-pharmacist-agree-pay-700948-settle-false-claims-act.
173 https://www.justice.gov/usao-edca/pr/fresno-doctors-agree-pay-24-million-resolve-kickback-allegations.
174 https://www.justice.gov/usao-edca/pr/fresno-doctors-agree-pay-24-million-resolve-kickback-allegations.
175 https://www.justice.gov/usao-sdtx/pr/neurologist-pays-nearly-1m-settle-false-billing-allegations-electro-acupuncture.

OTHER

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
4/1/2024	George Carralejo Michael Jeresaty OC Genetic Consultants Inc. Ralston Health Group Inc.	Two laboratory marketers and their marketing companies agreed to pay $720,000 to resolve allegations that they entered into illegal schemes to pay kickbacks, including payments disguised as consulting and medical director fees, to physicians for laboratory referrals, in violation of the AKS.[176]	**$720,000**
4/1/2024	Victoria Shaw	Owner of a nonprofit entity that secures and administers grants from the Substance Abuse and Mental Health Services Administration to address youth substance use agreed to pay $500,000 to resolve admitted allegations that she and another company official forged signatures of community leaders on federal grant applications, diverted federal funds received for personal use and misappropriated grant funds for unallowable costs.[177]	**$500,000**
4/29/2024	Thomas Anthony Carnaggio South Ventures LLC	Laboratory marketer and his marketing company agreed to pay $400,000 to resolve allegations that they: (1) offered physicians kickbacks disguised as purported office space rental and phlebotomy payments to induce physicians to order lab tests; and (2) received commissions from the lab as independent contractors based on the volume and/or value of Medicare and TRICARE referrals they arranged for and/or recommended, in violation of the AKS.[178]	**$400,000**
5/1/2024	Insight Global LLC	Staffing company agreed to pay $2.7 million to resolve allegations that it failed to implement adequate cybersecurity measures to protect patient health information obtained during COVID-19 contact tracing. Allegations included that the company: (1) transmitted subjects' personal health and/or personally identifiable information in unencrypted emails; (2) used shared passwords among staff; (3) stored and transmitted patient information in non-password-protected Google files that were potentially publicly accessible; and (4) failed to timely remediate these issues despite receiving staff complaints.[179]	**$2.7 million**

176 https://www.justice.gov/opa/pr/marketers-and-physicians-five-states-agree-pay-over-15-million-settle-laboratory-kickback.
177 https://www.justice.gov/usao-ndny/pr/grant-administrator-pay-500000-resolve-false-claims-act-investigation-involving-misuse.
178 https://www.justice.gov/opa/pr/laboratory-marketer-and-north-carolina-physicians-agree-pay-over-13m-settle-kickback.
179 https://www.justice.gov/opa/pr/staffing-company-pay-27m-alleged-failure-provide-adequate-cybersecurity-covid-19-contact.

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
5/17/2024	Cleveland Clinic Foundation	Academic medical foundation agreed to pay $7.6 million to resolve allegations that it: (1) submitted federal grant applications and progress reports to the NIH that failed to disclose that the employee designated as principal investigator on the three grants had pending and/or active financial research support from foreign institutions; (2) falsely certified to the truth and accuracy of grant submissions; and (3) violated NIH password policies by allowing employees to share passwords, enabling unqualified employees to access the grant reporting platform. As part of the resolution, NIH imposed Specific Award Conditions on all the foundation's grants for a minimum of one year. These conditions include requiring a high-level employee to attest to information provided to the NIH and development of a corrective action plan.[180]	**$7.6 million**
10/3/2024	Conduent State Healthcare, LLC	Operator of South Carolina Medicaid's member call center agreed to pay $11.35 million to resolve self-disclosed allegations that it fraudulently reported call center performance metrics and adjusted invoices to increase reimbursement. Two former employees pleaded guilty for their role in the alleged conduct.[181]	**$11.35 million**
10/15/2024	ASRC Federal Data Solutions LLC	Medicare support services contractor agreed to pay over $300,000 and waive its rights to reimbursement for at least $877,578 of data breach remediation costs to resolve self-disclosed allegations that it and a subcontractor stored Medicare beneficiaries' personally identifiable information and potentially personal health information on the subcontractor's server without appropriate encryption measures, in violation of contractual cybersecurity requirements.[182]	**$306,722**

180 https://www.justice.gov/usao-ndoh/pr/cleveland-clinic-pay-over-7-million-settle-allegations-undisclosed-foreign-sources.
181 https://www.justice.gov/usao-sc/pr/operator-south-carolina-medicaid-call-center-agrees-pay-113-million-resolve-false-claims.
182 https://www.justice.gov/opa/pr/virginia-contractor-settles-false-claims-act-liability-failing-secure-medicare-beneficiary.

CONTROLLED SUBSTANCES ACT SETTLEMENTS CHART

DATE	ENTITY	CSA ALLEGATIONS	AMOUNT
1/31/2024	eBay Inc	E-commerce company agreed to pay $59 million to resolve allegations that it failed to comply with CSA requirements of identity verification, recordkeeping and reporting to DEA in connection with pill presses and encapsulating machines sold through its website. The company also agreed to enhance its compliance program with respect to its prohibited and restricted items policy.[183]	**$59 million**
2/6/2024	Kroger Pharmacy Harris Teeter Pharmacy	Two pharmacies agreed to collectively pay $1.3 million to resolve allegations that they filled invalid prescriptions for opioids and benzodiazepines that were prescribed outside the scope of the prescribing physician's medical practice.[184]	**$1.3 million**
2/7/2024	Morris & Dickson Co., LLC	Pharmaceutical distributor agreed to forfeit $19 million in the first-ever DEA administrative forfeiture to resolve allegations that it failed to maintain effective controls against diversion, including failure to report thousands of unusually large orders of oxycodone and hydrocodone to DEA. The company agreed to maintain a new compliance program for five years and will surrender one of its DEA registrations as part of the resolution.[185]	**$19 million**
2/9/2024	King Drug Co., Inc. Traci Revels McCoy	District court entered into a consent decree requiring a pharmacy and its owner to pay $110,000 to resolve violations that they did not keep accurate, complete and timely inventories related to Schedule II controlled substances, resulting in thousands of unaccounted.[186]	**$110,000**
2/15/2024	OU Medicine Inc. d/b/a OU Health	Pharmacy agreed to pay $140,000 to resolve allegations that it violated CSA recordkeeping regulations by accepting blank-signed DEA Forms 222 from purchasers.[187]	**$140,000**
2/27/2024	Dr. Mary C. Watson	Physician agreed to pay $60,000 to resolve allegations that she wrote prescriptions for a controlled diet drug and did not maintain any patient files for those prescriptions. The doctor surrendered her DEA registration in October 2023.[188]	**$60,000**
3/25/2024	Shrieve Chemical Company, LLC	Chemical importer and distributor agreed to pay $300,000 to resolve allegations that it: (1) violated recordkeeping requirements; (2) manufactured a List I chemical by repackaging and relabeling registering as a manufacturer; and (3) drop shipped a List I chemical to a customer without first importing it through the distributor's registered location.[189]	**$300,000**

183 https://www.justice.gov/usao-vt/pr/ebay-pay-59-million-settle-controlled-substances-act-allegations-related-pill-presses.
184 https://www.justice.gov/usao-wdva/pr/kroger-harris-teeter-pharmacies-charlottesville-pay-us-13-million.
185 https://www.dea.gov/press-releases/2024/02/07/dea-announces-settlement-morris-dickson-co-llc.
186 https://www.justice.gov/usao-mdal/pr/samson-alabama-pharmacy-liable-110000-penalty-recordkeeping-violations-controlled.
187 https://www.justice.gov/usao-wdok/pr/oklahoma-pharmacy-pays-140000-settle-civil-penalty-claims-stemming-allegations.
188 https://www.justice.gov/usao-ndfl/pr/tallahassee-physician-agrees-pay-60000-settle-allegations-she-violated-controlled.
189 https://www.justice.gov/usao-wdtx/pr/chemical-importer-pay-300000-civil-penalties-alleged-violations-controlled-substances.

DATE	ENTITY	CSA ALLEGATIONS	AMOUNT
4/22/2024	Cornerstone Pharmacy, Inc. d/b/a Whalley Drug Yong Kwon	Pharmacy and its owner agreed to pay $120,000 to resolve allegations that they filled prescriptions for controlled substances that were issued without a legitimate medical purpose, including prescriptions that displayed red flags of addiction and abuse and were in dangerous combinations or unsafe or excessive amounts. The owner agreed to surrender the DEA license for the pharmacy.[190]	**$120,000**
4/25/2024	Dr. James K. Robberson	Physician agreed to pay $200,000 to resolve allegations that he failed to maintain proper records of DEA Forms 222 for the purchase of Schedule II controlled substances.[191]	**$200,000**
4/25/2024	Dr. Ronnie Keith	Physician agreed to pay $60,000 to resolve allegations that he failed to comply with recordkeeping violations, including maintaining invoices for purchases of certain controlled substances and conducting the required biennial inventory.[192]	**$60,000**
5/2/2024	Palm Care Pharmacy	Pharmacy chain agreed to pay $350,000 to resolve allegations that it: (1) failed to control its inventory of controlled substances; (2) improperly sold pseudoephedrine chemical products; and (3) failed to maintain a complete record of controlled substances and their transactions. As part of the resolution, the pharmacy entered into a MOA with the DEA.[193]	**$350,000**
5/2/2024	State of Franklin Healthcare Associates, PLLC	Operator of a multi-specialty medical group agreed to pay $200,000 to resolve allegations that it failed to keep and produce records documenting: (1) the transfers of Schedule III and Schedule IV controlled substances between its supply warehouse and physicians; (2) transfers to unregistered clinics; and (3) the loss or theft of a Schedule III controlled substance.[194]	**$200,000**
5/9/2024	Smith Family Pharmacy Stephanie Smith	Pharmacy and its pharmacist-in-charge agreed to pay $215,000 to resolve allegations that they filled controlled substances prescriptions without a valid medical purpose; those prescriptions allegedly exhibited red flags for diversion or abuse including high dosages of controlled substances and patients traveling to out-of-state physicians to obtain prescriptions. As part of the resolution, the pharmacy entered into a four-year MOA with DEA and hired a different pharmacist-in-charge.[195]	**$215,000**
6/4/2024	First Choice Surgical Center	Ambulatory surgical center agreed to pay $125,000 to resolve allegations following the discovery of fentanyl diversion by an employed nurse. The center allegedly failed to maintain accurate and complete records by allowing employees to batch sign witness records for waste of controlled substances and failed to timely report the fentanyl theft to DEA.[196]	**$125,000**

190 https://www.justice.gov/usao-ct/pr/new-haven-pharmacy-and-owner-agree-pay-120000-settle-controlled-substances-act.
191 https://www.justice.gov/usao-wdok/pr/lexington-physician-pays-200000-settle-civil-penalty-claims-stemming-his-alleged.
192 https://www.justice.gov/usao-wdok/pr/norman-doctor-pays-60000-settle-civil-penalty-claims-stemming-allegations.
193 https://www.justice.gov/usao-sdca/pr/san-diego-pharmacy-pays-350000-mishandling-controlled-substances.
194 https://www.justice.gov/usao-edtn/pr/state-franklin-healthcare-associates-agrees-resolve-potential-controlled-substances.
195 https://www.justice.gov/usao-edky/pr/barbourville-pharmacy-and-its-pharmacist-charge-pay-215000-resolve-alleged-0.
196 https://www.justice.gov/usao-ndia/pr/iowa-surgical-center-agrees-pay-125000-resolve-allegations-it-violated-controlled.

DATE	ENTITY	CSA ALLEGATIONS	AMOUNT
6/6/2024	Palomar Health	Public healthcare district agreed to pay $250,000 to resolve allegations that over a five-month period, numerous vials of fentanyl were diverted from its automated dispensing machines and unused fentanyl was not properly disposed of. As part of the resolution, the company entered into a MOA with DEA.[197]	**$250,000**
6/27/2024	OptumRx Inc.	Prescription drug benefit provider agreed to pay $20 million to resolve allegations that it improperly filled certain opioid prescriptions in dangerous combinations with other drugs, including "trinity" prescriptions consisting of an opioid, a benzodiazepine and a muscle relaxant. Numerous prescriptions allegedly raised red flags, but the provider filled many of them without first resolving the issues.[198]	**$20 million**
7/16/2024	Conifer Park Inc.	Maintenance and detoxification facility that treats individuals for substance use disorder agreed to pay $300,000 to resolve allegations that DEA inspections over a five-year period identified ongoing failures to maintain accurate records of its controlled substance inventory. The facility also allegedly had not performed the required biennial inventory and was co-mingling controlled substances between different registrants. As part of the resolution, the company entered into a MOA with DEA.[199]	**$300,000**
7/17/2024	Professional Pharmacy & Convalescent Products, Ltd.	Pharmacy agreed to pay $150,000 to resolve allegations that it improperly dispensed controlled substances, including oxycodone, that were not prescribed for a legitimate medical purpose and/or in the usual course of professional practice. As part of the resolution, the pharmacy surrendered its DEA registration.[200]	**$150,000**
7/22/2024	Dr. David L. Mattingly	Osteopathic doctor agreed to pay $72,000 to resolve allegations that he improperly prescribed opioids outside the usual course of professional practice. The settlement agreement permanently prevents the doctor from prescribing almost all controlled substances in the future. He also entered into an administrative agreement with DEA that includes additional compliance and education measures.[201]	**$72,000**
8/13/2024	Thackerville Pharmacy Dana Sprott	Pharmacy and its nurse practitioner owner agreed to pay $115,000 to resolve allegations that they used a rubber stamp of a doctor's signature to prescribe drugs without that doctor's knowledge or approval.[202]	**$115,000**
8/23/2024	Dexter Prescription Center a/k/a Dexter Pharmacy	Pharmacy agreed to pay over $141,000 to resolve allegations that it failed to maintain accurate records related to its purchases and sales of controlled substances and billed federal healthcare programs for medications it never dispensed.[203]	**$141,727**

197 https://www.justice.gov/usao-sdca/pr/palomar-hospital-pays-250000-diverting-fentanyl.
198 https://www.justice.gov/opa/pr/optumrx-agrees-pay-20m-resolve-allegations-it-filled-certain-opioid-prescriptions-violation.
199 https://www.justice.gov/usao-ndny/pr/glenville-narcotic-treatment-program-pays-300000-penalty-controlled-substances-act.
200 https://www.justice.gov/usao-edpa/pr/area-pharmacy-agrees-resolve-civil-allegations-improper-dispensing-controlled.
201 https://www.justice.gov/usao-edpa/pr/philadelphia-area-doctor-agrees-resolve-civil-allegations-improper-prescribing.
202 https://www.justice.gov/usao-edok/pr/thackerville-pharmacy-agrees-pay-115000-resolve-allegations-illegally-dispensing.
203 https://www.justice.gov/usao-wdny/pr/buffalo-pharmacy-pays-more-140000-settle-record-keeping-and-misbilling-allegations.

DATE	ENTITY	CSA ALLEGATIONS	AMOUNT
8/27/2024	Dr. Tuan Alex Nguyen	Physician agreed to pay $165,000 to resolve allegations that he dispensed prescriptions for Schedule III controlled substances without the required registration from the state's Bureau of Narcotics, in violation of the CSA's requirement that a practitioner be authorized to prescribe the substance at issue by the jurisdiction in which he or she is licensed.[204]	**$165,000**
9/5/2024	Dr. John Ross	Urologist agreed to pay $65,000 to resolve allegations that he failed to: (1) maintain records for certain purchases of a Schedule III controlled substance; (2) report his workplace as a practice location; and (3) properly document an instance of the destruction of a controlled substance.[205]	**$65,000**
9/10/2024	Dr. Edgar Ross	Physician agreed to pay $25,000 to resolve allegations that he prescribed opioids outside the usual course of professional practice, with one patient experiencing an overdose in connection with those prescriptions. As part of the resolution, the doctor entered into a three-year MOA with DEA.[206]	**$25,000**
9/11/2024	Dr. Donald Lyle Gates	Physician who operates weight-loss clinics agreed to pay $100,000 to resolve allegations that he failed to maintain complete records for prescription weight-loss drugs at his clinics and that he failed to keep certain controlled substances at registered locations, instead transferring them to his home. The physician also entered into an agreement that includes a two-year term of increased oversight by DEA.[207]	**$100,000**
9/26/2024	Sacred Heart Rehabilitation Center, Inc. Paula Nelson Dr. Janis Romanik	Behavioral health and addiction treatment services network, along with its president and chief executive officer, and medical director, agreed to a consent order that imposes a $1 million civil penalty, monitoring and compliance obligations to resolve allegations that they violated recordkeeping and dispensing requirements. The government had alleged that one of the company's treatment centers routinely dispensed controlled substances to patients before a qualified practitioner had evaluated them.[208]	**$1 million**
10/17/2024	Dr. Steven Shifreen Christopher Norval, PA Multicare Musculoskeletal Medicine and Pain Management Associates, P.C.	Physician assistant and his medical practice, along with a doctor practicing with him, agreed to pay $300,000 to resolve allegations that they prescribed controlled substances to patients who exhibited signs of diversion and drug abuse through inconsistent UDTs. As part of the resolution, the doctor and physician assistant surrendered their DEA registrations and agreed not to re-apply for five years.[209]	**$300,000**

204 https://www.justice.gov/usao-wdok/pr/oklahoma-city-physician-pays-165000-settle-civil-penalty-claims-stemming-his-alleged.
205 https://www.justice.gov/usao-wdok/pr/edmond-doctor-pays-64000-settle-civil-penalty-claims-stemming-allegations.
206 https://www.justice.gov/usao-ma/pr/boston-physician-resolves-allegations-improper-prescribing-practices-involving.
207 https://www.justice.gov/usao-sdga/pr/civil-settlement-resolves-allegations-record-keeping-violations-against-savannah-area.
208 https://www.justice.gov/usao-wdmi/pr/2024_0926_Sacred_Heart_Consent_Decree.
209 https://www.justice.gov/usao-ct/pr/berlin-physician-physician-assistant-and-practice-pay-300k-resolve-controlled-substances.

DATE	ENTITY	CSA ALLEGATIONS	AMOUNT
10/30/2024	Covetrus North America, LLC	Veterinary pharmaceutical distributor agreed to pay over $1 million to resolve allegations that it, among other things, failed to provide adequate explanation to DEA for distributing certain opioid orders that its own internal system had flagged as suspicious. As part of the resolution, the company entered into a one-year MOA with DEA. An employee of the veterinary office that placed those orders was convicted after admitting she diverted drugs from the orders for her own personal use.[210]	**$1.13 million**
11/4/2024	Cerebral, Inc.	Online mental health company entered into a non-prosecution agreement and agreed to pay more than $3.6 million to resolve allegations that it engaged in practices that encouraged the unlawful distribution of controlled substances, including: (1) encouraging and incentivizing providers to issue stimulant medication for ADHD patients; and (2) failing to maintain adequate operational controls against drug diversion.[211]	**$3.65 million**
12/6/2024	Elk Pharmacy Inc.	Pharmacy agreed to be bound by a $500,000 consent decree to resolve allegations that it dispensed prescription opioids while disregarding various red flags including dangerous drug combinations and evidence of doctor or pharmacy shopping.[212]	**$500,000**
12/10/2024	Monica Preston, N.P.	Nurse practitioner agreed to pay $90,000 to resolve allegations that she wrote prescriptions for controlled substances that were in dosages, at frequencies and in combinations with other controlled substances that were not for a legitimate medical purpose. As part of the resolution, the nurse agreed to permanently forgo her DEA registration.[213]	**$90,000**
12/20/2024	Dr. Donald J. Dinello	Dentist agreed to pay $120,000 to resolve allegations that he failed to comply with multiple recordkeeping requirements related to the CSA, including failing to maintain a biennial inventory and use required DEA Forms 222.[214]	**$120,000**
12/20/2024	Dr. Stephen R. Holuk	Physician agreed to pay $220,000 to resolve allegations that he prescribed controlled substances outside the usual course of professional practice, including by failing to check the state administered drug monitoring program before prescribing Schedule II controlled substances.[215]	**$220,000**

210 https://www.justice.gov/usao-ma/pr/covetrus-agrees-pay-1125000-failing-adequately-address-suspicious-opioid-orders-and.
211 https://www.justice.gov/usao-edny/pr/telehealth-company-cerebral-agrees-pay-over-36-million-connection-business-practices.
212 https://www.justice.gov/opa/pr/court-orders-north-carolina-pharmacy-pay-500000-penalty-and-enters-injunction-prevent.
213 https://www.justice.gov/usao-co/pr/colorado-springs-nurse-practitioner-agrees-pay-90k-resolve-allegations-improper.
214 https://www.justice.gov/usao-mdpa/pr/dr-donald-j-dinello-dmd-agrees-pay-120000-civil-penalties-violations-controlled.
215 https://www.justice.gov/usao-ma/pr/physician-resolves-allegations-improper-prescribing-practices-involving-controlled.

ABOUT BASS, BERRY & SIMS

The Bass, Berry & Sims Healthcare Fraud & Abuse Task Force represents healthcare providers in responding to inquiries and investigations by DOJ, HHS-OIG, various states' Attorneys General offices, and other federal and state agencies, and in related litigation.

We have a proven track record of representing healthcare providers throughout the United States in civil and criminal investigations and healthcare fraud-related litigation. We have successfully defended healthcare providers in FCA litigation in trial and appellate courts, secured dismissals of FCA allegations in numerous cases and have negotiated favorable resolutions on behalf of our clients where appropriate. Furthermore, we routinely counsel healthcare providers on implementing state-of-the-art compliance programs and assist clients in navigating self-disclosures and other compliance-related matters.

Our team includes former members of DOJ and HHS-OIG with significant experience handling healthcare fraud matters on behalf of the government. Our attorneys are frequent speakers on healthcare fraud and abuse topics, and three of our members serve as Adjunct Professors of Law teaching Healthcare Fraud and Abuse at both Vanderbilt Law School and Belmont University College of Law.

For more information, please visit our website at www.bassberry.com/healthcare-fraud.

Our Healthcare Fraud & Abuse Resource Center provides a central location for healthcare leaders to access tools and information, including:

- An innovative, searchable database featuring nearly 2,500 significant FCA settlements from the last decade.
- Content from our Inside the False Claims Act blog.
- Current and past editions of the Healthcare Fraud & Abuse Annual Review.
- A video library with presentations from conferences and webinars highlighting the latest compliance and enforcement developments.

Access the Healthcare Fraud & Abuse Resource Center at fraudinhealthcare.com.

TOP-RANKED NATIONAL HEALTHCARE PRACTICE

AMERICAN HEALTH LAW ASSOCIATION

Ranked 3rd Largest Healthcare Law Firm in the U.S. (2024)

Chambers TOP RANKED USA 2024 Bass, Berry & Sims PLC

Healthcare & Healthcare Government Investigations and Fraud Attorneys Recognized (2024)

LAW360 PRACTICE GROUPS OF THE YEAR 2020

Named Healthcare Practice Group of the Year (2020)

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Denise Barnes counsels clients in high-stakes matters related to fraud allegations, including in healthcare, federal contract procurement and securities and financial services. A former trial attorney with DOJ, she has extensive experience handling issues related to compliance, white-collar and regulatory investigations and complex commercial litigation. Denise represents businesses in public and non-public investigations, regulatory inquiries and proceedings involving federal and state agencies. She frequently assists clients navigating government investigations related to allegations arising under the FCA, AKS, Stark Law and Financial Institutions Reform, Recovery, and Enforcement Act (FIRREA).

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Angie Bergman represents healthcare providers and companies facing claims of fraud, government investigations and Medicare administrative appeals. She represents a broad range of clients in all sectors of the healthcare industry including hospitals, long-term care facilities, ambulatory surgery centers, home health and hospice providers.

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Kristin Bohl blends her experience as a healthcare attorney in private practice and government service with first-hand knowledge of care delivery as a registered nurse. Kristin advises hospitals, health systems and other provider organizations on compliance and regulatory issues and fraud and abuse matters, with a focus on the wide range of Medicare payment models. Before she entered private practice, Kristin was the Technical Advisor in the Division of Technical Payment Policy at CMS. She was part of a team that developed the CMS Voluntary Self-Referral Disclosure Protocol and provided technical assistance in the creation of Stark Law waivers for ACO models and other payment initiatives of the Center for Medicare and Medicaid Innovation within CMS.

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Justin Brown focuses on solving complex healthcare regulatory issues, particularly those involving the Stark Law, AKS and state analogs. His clients include hospitals and health systems, post-acute providers, ambulatory surgery centers, physician practices, device and pharmaceutical manufacturers, healthcare technology companies and their strategic partners and investors.

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Taylor Chenery concentrates his practice on government compliance and investigations and related litigation, focusing on issues of healthcare fraud and abuse. Taylor has significant experience representing a wide variety of healthcare clients in relation to government inquiries and investigations by the HHS-OIG, U.S. Attorneys' Offices, DOJ and other federal and state agencies. Taylor regularly litigates lawsuits filed under the FCA and conducts internal investigations and compliance assessments for healthcare companies and providers, advising them on compliance-related issues. He also routinely represents healthcare clients defending claims denials in Medicare and Medicaid claims audits.

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John Eason represents clients in government enforcement actions, investigations and litigation, particularly involving the FCA. He has represented companies and individuals in responding to inquiries and investigations by DOJ, HHS-OIG, and other federal and state agencies regarding healthcare and procurement fraud issues.

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Lindsey Brown Fetzer is chair of the firm's multi-disciplinary Managed Care Practice Group and has a deep understanding of the managed care industry and partners with her clients to provide strategic guidance and solutions in this ever-evolving area. She has extensive experience working with healthcare plans, risk-bearing provider groups and vendors in litigation, investigations and compliance counseling matters. She represents clients in connection with government and internal investigations and litigation involving alleged violations of the FCA, AKS, Foreign Corrupt Practice Act (FCPA) and other criminal and civil regulations.

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Jeff Gibson has extensive experience representing clients in complex civil litigation and government investigations, including defending individuals and companies facing FCA investigations and litigation, white-collar criminal charges and regulatory violations. He leads internal investigations, addresses compliance issues and provides crisis management services, in addition to maintaining a business litigation practice. Jeff is also a Tennessee Supreme Court Rule 31 Listed General Civil Mediator.

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Anna Grizzle focuses her practice exclusively on helping healthcare clients address enforcement, fraud and abuse and compliance issues through the structuring of arrangements and in responding to potential legal and regulatory matters and government investigations. Anna routinely advises on the reporting and repayment of overpayments and in responding to payor audits and has advised a number of healthcare clients in self-disclosures, including disclosures made through the Stark Law and HHS-OIG disclosure protocols.

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Brian Irving represents businesses and individuals in government investigations and enforcement actions, focusing on healthcare fraud and controlled substances enforcement and diversion. Brian's clients span a variety of industries, including healthcare, pharmacy and government contracting. Brian is the editor of the firm's Inside the False Claims Act blog and the co-chair of the firm's Controlled Substances Enforcement & Diversion Practice.

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Travis Lloyd focuses on complex healthcare regulatory matters. He represents a broad range of healthcare industry clients, including hospitals and health systems, ambulatory surgery centers, post-acute providers, behavioral health providers and physician practices, as well as their strategic partners. A substantial portion of Travis's practice involves advising clients on fraud and abuse issues, including those that relate to AKS and the Stark Law. His experience includes guiding healthcare providers through thorny compliance issues, obtaining advisory opinions, managing internal compliance reviews and investigations and making voluntary disclosures to government entities.

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Bill Mathias is a healthcare regulatory attorney with a focus on fraud and abuse and Stark Law issues. He works with healthcare organizations to structure complex business arrangements, including joint ventures and strategic transactions, to manage risk while meeting their business objectives. Bill is a recognized leader on the federal AKS, the Stark Physician Self-Referral Law, Eliminating Kickbacks in Recovery Act (EKRA), and the federal Civil Monetary Penalty (CMP) regulations. He regularly assists with government investigations and defending FCA lawsuits and other enforcement actions.

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Jennifer Michael draws on her experience as the former Chief of the Industry Guidance Branch at HHS-OIG to help healthcare providers and life science companies avoid potential fraud and abuse landmines and defend them in fraud and abuse investigations. Jennifer helps her clients structure their arrangements to comply with the federal AKS, the federal CMP law and other state and federal fraud and abuse laws and navigate government investigations under the federal FCA. She also leads internal investigations for healthcare companies to identify and quantify potential overpayments from federal healthcare programs; advises on fraud risks of existing and proposed arrangements in connection with pending and proposed transactions; and designs, implements, and evaluates compliance programs.

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Brianna Powell provides healthcare regulatory counsel to a wide range of clients, including physician groups, hospices, hospital systems, long-term care providers and private equity firms. Brianna counsels clients on an array of complex regulatory issues including fraud and abuse, government enforcement and compliance, Emergency Medical Treatment and Labor Act (EMTALA) and transactions.

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Lisa Rivera is chair of the firm's Compliance & Government Investigations Practice Group and advises healthcare providers on matters related to compliance and internal investigations, as well as responding to government investigations and enforcement of civil and criminal healthcare fraud. Lisa previously served for 13 years as an Assistant U.S. Attorney, with 10 of those years spent in the U.S. Attorney's Office for the Middle District of Tennessee, where she was Civil and Criminal Healthcare Fraud Coordinator and responsible for the review and coordination of all criminal and civil healthcare fraud investigations, as well as handling her own civil and criminal healthcare cases. She is an adjunct professor teaching Healthcare Fraud & Abuse and Litigation at Belmont University College of Law.

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Brian Roark is co-chair of the Bass, Berry & Sims Healthcare Fraud & Abuse Task Force and concentrates his practice on representing healthcare clients in responding to government investigations and defending FCA lawsuits. He has successfully litigated and resolved numerous healthcare fraud matters and frequently represents clients in connection with Medicare audits and overpayment disputes. Brian is an adjunct professor at Vanderbilt Law School, teaching Healthcare Fraud & Abuse.

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Molly Ruberg represents clients in connection with internal investigations, government enforcement actions and civil and criminal proceedings, particularly involving matters of alleged fraud and abuse in the healthcare sector. She has successfully litigated and resolved matters for a variety of global, national and regional clients, including hospitals and health systems, health insurers, life sciences companies, hospice and home health providers, behavioral health providers and physician groups.

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Julia Tamulis provides guidance on government investigations of healthcare providers concerning potential fraud and abuse matters under the AKS, Stark Law and the FCA. She assists healthcare companies with internal compliance reviews and investigations, including on Medicare Advantage and risk adjustment issues, and advises healthcare providers on Medicare appeals related to government audits. Julia previously was an attorney-advisor for HHS's Departmental Appeals Board.

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