14TH ANNUAL

HEALTHCARE FRAUD & ABUSE REVIEW

2025

BASS BERRY SIMS

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EXECUTIVE SUMMARY

Bass, Berry & Sims is pleased to bring you our 14th 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 did the arrival of a new administration in Washington, D.C., have on enforcement efforts concerning the healthcare industry? Have we seen 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 initiatives of the new administration, the future of the False Claims Act, developments regarding the Anti-Kickback Statute, Controlled Substances Act & drug diversion enforcement trends, enforcement challenging medical necessity, and cybersecurity issues confronting the healthcare industry.

NOTEWORTHY SETTLEMENTS

In FY 2025, healthcare fraud cases accounted for $5.7 billion (83%) of the $6.9 billion in FCA recoveries. This marks the 17th 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

$6.9B

Highest total recovery since DOJ began reporting such statistics

1,297

FCA *Qui Tam* Lawsuits Filed by Relators in FY 2025

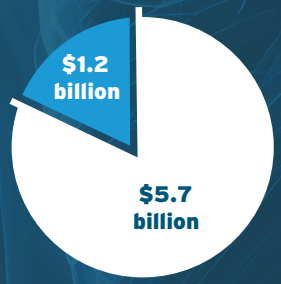
78%

Civil Fraud Recoveries Associated with *Qui Tam* Lawsuits

Comparison of Recoveries

FY 2025

Healthcare Recoveries v. All Other Recoveries

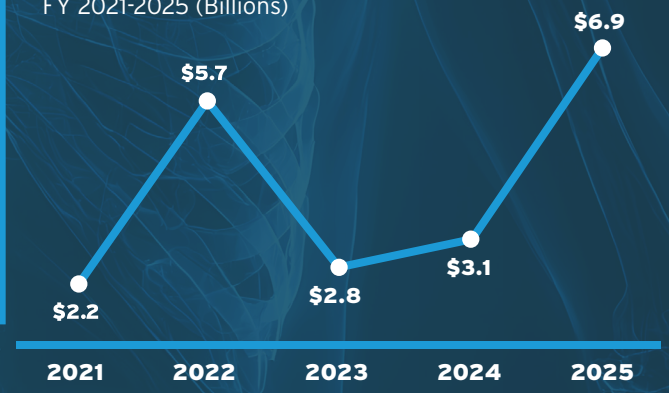


Healthcare Recoveries

All Other Recoveries

Civil Fraud Recoveries

FY 2021-2025 (Billions)



A LOOK BACK … A LOOK AHEAD

We are pleased to bring you our 14th annual Healthcare Fraud & Abuse Review. Our Review covers 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 at what we can expect in the coming year.

CIVIL HEALTHCARE FRAUD ENFORCEMENT

Commitment to civil healthcare fraud enforcement has enjoyed strong bipartisan support for decades. This is largely because of the massive amounts of annual spending associated with government healthcare programs and the significant amount of dollars lost to healthcare fraud each year. Whether considered purely as lost dollars or more broadly as a significant negative impact on the delivery of healthcare within the United States, there has been little debate that efforts to combat healthcare fraud must remain a high priority for any administration in power. That certainly has been the case with the new administration, which has stressed a continued commitment to healthcare fraud enforcement, and in particular, civil enforcement through the use of the False Claims Act (FCA), since its earliest days.

With the new administration also came new leadership within the U.S. Department of Justice (DOJ), which has brought a fresh perspective to key FCA issues, while at the same time reaffirming its commitment to defending the constitutionality of the FCA's *qui tam* provision. The federal government also announced a renewed working group combining the resources of DOJ with those of the U.S. Department of Health and Human Services (HHS) to combat healthcare fraud. Such developments signify an expanded use of civil fraud enforcement tools by the government to advance key initiatives while combating healthcare fraud.

Within the bipartisan commitment to healthcare fraud enforcement, government regulators often enjoy broad discretion as to how to utilize sometimes limited resources and may identify priorities that can change from one administration to the next. While announcing its commitment to pursuing civil healthcare fraud enforcement, the Trump administration also wasted little time in announcing that it would use traditional civil fraud enforcement tools to advance policy initiatives aimed at targeting diversity, equity and inclusion (DEI) programs under the guise of addressing illegal discrimination and other policy priorities.

DOJ's announced civil fraud recoveries for FY 2025 include several important points.[1] The $6.9 billion in civil fraud recoveries reported by DOJ is the highest total recovery since DOJ began reporting such statistics. That amount dwarfed FY 2024's (adjusted) recovery of $3.1 billion, which was the fourth-lowest recovery since 2010 and reflected only a modest increase over FY 2023's (adjusted) recovery of $2.78 billion. Total recoveries associated with filed *qui tam* lawsuits of $5.3 billion also more than doubled 2024's total of $2.6 billion.

While last year we noted that annual total recoveries for FY 2024 involving the healthcare industry were the lowest in more than a decade at $1.67 billion, FY 2025's recoveries from the healthcare industry more than tripled, coming in at $5.72 billion. This reversed the trend that we noted last year, in which four of the past five fiscal years (2020, 2022, 2023 and 2024) had seen recoveries under $2 billion within the healthcare industry.

Civil fraud recoveries involving the healthcare industry amounted to approximately 83% of total recoveries (compared with 57% of the total recoveries last year). The 83% of total recoveries is more in line with prior years in which recoveries involving the healthcare industry have hovered around 80%. Indeed, the average civil fraud recoveries involving the healthcare industry over the last five years has been just over 77%.

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 the relators last year. In FY 2025, a staggering 1,297 new *qui tam* lawsuits were filed by relators with 458 of those newly-filed lawsuits involving the healthcare industry.

Not surprisingly, recoveries associated with *qui tam* lawsuits continue to drive overall civil fraud recoveries. Nearly 78% of the civil fraud recoveries, or nearly $5.35 billion of the $6.9 billion in total recoveries resulted from settlements and judgments associated with *qui tam* lawsuits. With nearly 3,000 new *qui tam* lawsuits filed during the last three fiscal years alone, such lawsuits undoubtedly will remain the driving force for years to come.

We have previously 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. That percentage has continued to drop, with only 35% of the *qui tam* lawsuits filed last year involving the healthcare industry. Nearly 800 *qui tam* lawsuits filed last year did not involve either the healthcare or the defense industry. Because *qui tam* lawsuits are filed under seal, the exact nature of those lawsuits remains to be seen, but it is safe to assume that a large number of those lawsuits continue to be associated with pandemic-related fraud schemes.

Finally, it is worth noting that the total share of awards that relators obtained from *qui tam* actions ($330 million) was well below the average of such awards over the last five years ($438 million).

CRIMINAL HEALTHCARE FRAUD ENFORCEMENT

Despite the change in administration, DOJ made clear its continued commitment to focusing on criminal enforcement involving the healthcare industry. In June 2025, DOJ announced its annual healthcare fraud enforcement takedown involving more than $14.6 billion in intended fraud loss and 324 defendants charged across 50 federal judicial districts.[2] Traditional fraud schemes involving telemedicine and genetic testing ($1.17 billion in allegedly fraudulent claims), the prescribing and distributing of opioids (74 defendants charged across 58 cases) and wound care ($1.1 billion) remained a key focus.

1 https://www.justice.gov/opa/pr/false-claims-act-settlements-and-judgments-exceed-68b-fiscal-year-2025.

2 https://www.justice.gov/criminal/criminal-fraud/2025-national-health-care-fraud-takedown.

> ***We expect that managed care and the pharmaceutical industry will continue to be the subject of the government's enforcement efforts and relators pursuing qui tam lawsuits. That should come as no surprise, given the significant government spending associated with those sectors of the healthcare industry.***

Beyond those schemes, DOJ's takedown notably included a focus on transnational criminal organizations. DOJ announced that 29 defendants were charged for their roles in submitting over $12 billion in fraudulent claims to government health insurance programs. Described, in part, as "Operation Gold Rush," DOJ charged individuals involved in submitting more than $10 billion in fraudulent claims for urinary catheters and other durable medical equipment (DME) by exploiting stolen identities of more than one million people and laundering the stolen proceeds by the transfer of funds into cryptocurrency and shell companies located abroad. DOJ announced that its Health Care Fraud Unit's Data Analytics Team detected the fraudulent billing through data analytics.

In addition to the results of the takedown, DOJ highlighted the continued efforts of the Health Care Fraud Data Fusion Center, which brings together the expertise of DOJ's Health Care Fraud Unit's Data Analytics Team and other agencies to leverage cloud computing, artificial intelligence (AI) and advanced analytics to identify emerging healthcare fraud schemes.

LOOKING AHEAD

There can be little doubt that disruption within DOJ and local U.S. Attorney's Offices since the beginning of the second Trump administration has impacted and will continue to impact the federal government's efforts when it comes to civil and criminal healthcare fraud enforcement. Departures and a hiring freeze have strapped the resources of many U.S. Attorney's Offices and have necessarily required those Offices to focus their remaining resources on the most pressing cases. With the huge number of newly-filed *qui tam* lawsuits in recent years, there remains an open question regarding how DOJ will undertake its obligation to investigate the allegations in those lawsuits under the FCA. DOJ has touted its reliance on data analysis and AI as key tools in fighting healthcare fraud, and it may be that DOJ's reliance on such tools increases as a means of more efficiently investigating fraud allegations.

We expect that managed care and the pharmaceutical industry will continue to be the subject of the government's enforcement efforts and relators pursuing *qui tam* lawsuits. That should come as no surprise, given the significant government spending associated with those sectors of the healthcare industry. It remains to be seen, however, whether those enforcement efforts will pay dividends as the fraud theories pursued by regulators and relators involving those industries often face significant factual and legal challenges.

Finally, there is little doubt that enforcement efforts in the coming year will be impacted by court challenges seeking to pare back 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.

We expect that 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.

DOJ RELEASES RECORD-SETTING CIVIL FRAUD RECOVERY STATISTICS AND RESULTS… A CLOSER LOOK BEHIND THE NUMBERS

Our key observations behind DOJ's annual report on civil fraud recoveries (settlements and judgments) for FY 2025 include:

1. **Total Recoveries Set All-Time Record.** DOJ's announced settlements and judgments of nearly $6.9 billion eclipsed its prior record by more than $700 million and more than doubled its recoveries from last year.
2. **Recoveries Paced by Rare FCA Trial Outcomes.** High-dollar judgments following relatively rare FCA trials last year drove the record-setting recoveries, including a $948.8 million judgment against Omnicare, a $290 million judgment against CVS Caremark and a more than $1.6 billion judgment against Janssen Pharmaceuticals.
3. **Healthcare Industry-Related Recoveries Reverse Downward Trend.** After several years of recoveries involving the healthcare industry coming in below $2 billion, FY 2025's recoveries involving the healthcare industry hit an all-time high of more than $5.7 billion.
4. **Percentage of Total Recoveries Involving the Healthcare Industry Returned to Historic Levels.** Recoveries involving the healthcare industry rebounded to 83%, well up from last year's 57.3%.
5. **Number of Newly-Filed *Qui Tam* Lawsuits Smashes Prior Record (Again).** An astonishing 1,297 *qui tam* lawsuits were filed in FY 2025, with more than 4,200 such lawsuits filed in the last five years.
6. **Recoveries Stemming from *Qui Tam* Lawsuits Remain High.** Recoveries stemming from *qui tam* lawsuits ($5.34 billion or 77% of total recoveries) continued to drive overall civil fraud recoveries.
7. **Large Judgment Drives Record-Setting Recoveries in Declined Healthcare *Qui Tam* Matters.** The $1.6 billion judgment against Janssen contributed to the highest ever recoveries associated with matters initiated by the filing of *qui tam* lawsuits, but where the United States declined to intervene (nearly $2.3 billion).
8. **Percentage of *Qui Tam* Lawsuits Involving Healthcare Industry Continues Downward Trend.** The total number of new *qui tam* lawsuits involving the healthcare industry increased to 458 lawsuits, up significantly from the 370 such lawsuits filed in FY 2024. As a percentage of total *qui tam* lawsuits, however, such lawsuits comprised only 35% of the total lawsuits filed last year, which was down significantly from the average percentage over the last five years (53%).
9. **Relator Share Awards.** Although DOJ announced a record-setting year of FCA recoveries in matters arising from *qui tam* lawsuits, relator share awards amounted to only $330 million, well below the 10-year average of $438 million, which almost certainly resulted from the fact that relator shares have not yet been awarded in matters where judgments totaling over $2.8 billion remain pending on appeal.
10. **Non-*Qui Tam* Matters.** DOJ announced more than 400 new non-*qui tam* matters, which is a number that remains consistent with totals from the last five years (and is the third highest number since the 1986 FCA amendments). What stood out about that announcement, however, was the fact that 183 of those matters involved the healthcare industry, which was nearly 100 more new matters involving the healthcare industry than had been reported in FY 2024.
11. **MA/Pharma, AKS & Medical Necessity.** Significant areas of focus remained the Medicare Advantage (MA) and pharmaceutical sectors of the healthcare industry, along with matters involving alleged violations of the AKS and medically unnecessary services.

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

Consideration of the FCA's future has become an annual part of our Review. For the last decade, the Supreme Court has considered how key elements of FCA claims should be construed, such as materiality, falsity and scienter, as well as how key FCA procedural provisions should be interpreted, such as the United States' dismissal authority as it relates to *qui tam* lawsuits in which the United States initially declined to intervene.

Constitutional Questions

None of the cases we have previously covered has stood to upend FCA litigation as much as the issue of the constitutionality of the FCA's *qui tam* provision, which is currently winding its way through federal courts. Since Justice Thomas' dissent in ***U.S. ex rel. Polansky v. Executive Health Resources***, there have been cracks in what was previously a consistent rejection of constitutional challenges to the FCA's *qui tam* provision by courts considering the issue, which suggests rising judicial skepticism as to what most considered a settled issue just a few years ago.

Late last year, the Eleventh Circuit considered an appeal of the district court's conclusion that the FCA's *qui tam* provision violated the Appointments Clause of Article II of the Constitution by vesting relators with executive authority without proper appointment to that position. If the Eleventh Circuit were to affirm the district court's holding, it would result in a seismic circuit split, and the issue would almost certainly have to be addressed by the Supreme Court.

While no other court has reached the same conclusion as the district court in *Zafirov*, there has been an increasingly loud drumbeat of judges eager to take up Justice Thomas' invitation to consider this constitutional issue, even in circuits where precedent upholding the constitutionality of the FCA's *qui tam* provision has been in place for years. As a means of sidestepping that precedent, judges have looked to Justice Thomas' dissent as grounds for taking a fresh look at the issue.

For example, in ***U.S. ex rel. Gentry v. Encompass Health Rehabilitation Hosp. of Pearland, LLC***, Judge Ho of the Fifth Circuit authored a concurring opinion making his concerns clear: "[Qui tam relators] presume to represent the United States government in federal court, and to defend the interests of the United States Treasury against fraud. But like federal civil servants, they are neither appointed by, nor accountable to, the President. So it's not surprising that many members of the federal judiciary have expressed repeated constitutional concerns about the *qui tam* provisions of the False Claims Act."[3]

And, in ***U.S. ex rel. Murphy v. TriHealth, Inc.***, the district court certified the question of the constitutionality of the FCA's *qui tam* provision for interlocutory appeal, notwithstanding binding precedent within the Sixth Circuit rejecting such a constitutional challenge, finding

that there were now substantial grounds for difference of opinion given Justice Thomas' dissent.[4] In contrast, other courts have continued to hew to the settled case law within their particular circuit and have rejected the constitutional challenges advanced by the defendants.[5]

Until it is ultimately resolved by the Supreme Court, there is little doubt that the constitutionality of the FCA's *qui tam* provision will be the most closely watched legal issue impacting FCA litigation for the foreseeable future.

What Constitutes a "Claim?"

As we previewed last year, the Supreme Court addressed a significant question about the scope of FCA liability in ***Wisconsin Bell, Inc. v. United States***, in which the Court considered whether claims submitted to the Universal Service Fund (Fund)—an entity created by Congress that subsidizes telecommunications services for schools and libraries—under the E-Rate subsidies program meet the FCA's definition of a "claim." 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 had reached the opposite conclusion. We explained that the case was noteworthy because of its potential broad implications regarding whether FCA liability would be triggered where government funds were administered through public-private partnerships.

3 157 F.4th 758 (5th Cir. 2025).

4 2025 WL 2104279 (S.D. Ohio July 28, 2025).

5 *See U.S. ex rel. McCullough v. Anthem Ins. Cos.*, 2025 WL 2782576 (S.D. Ind. Sept. 30, 2025); *U.S. ex rel. Travis v. Gilead Sciences, Inc.*, 2025 WL 2627686 (E.D. Pa. Sept. 11, 2025); *U.S. ex rel. Stenson v. Radiology Ltd., LLC*, 2025 WL 1785266 (D. Ariz. June 27, 2025); *U.S. ex rel. Publix Litig. Partnership, LLP v. Publix Super Markets, Inc.*, 2025 WL 1381993 (M.D. Fla. May 13, 2025); *U.S. ex rel. Kenley Emergency Med. v. Schumacher Group of Louisiana, Inc.*, 2025 WL 1359065 (N.D. Cal. May 9, 2025); *U.S. ex rel. Gonite v. UnitedHealthcare of Georgia, Inc.*, 785 F. Supp. 3d 1325 (M.D. Ga. 2025); *U.S. ex rel. Gordon v. Shiel Med. Lab'y*, 2025 WL 949432 (E.D.N.Y. Mar. 29, 2025).

By way of background, the relator, an auditor of telecommunications bills, believed that Wisconsin Bell had defrauded the E-Rate program by overcharging schools for services. The relator sued Wisconsin Bell under the FCA, arguing that the company's overcharges led to inflated reimbursement requests, which were alleged to qualify as "claims" under the FCA. Wisconsin Bell moved to dismiss the relator's suit, arguing that an E-Rate reimbursement request cannot qualify as a "claim" under the FCA because the money comes from private carriers, not the government. Both the district court and the Seventh Circuit rejected that argument, and the Supreme Court agreed to hear the case.

The Supreme Court unanimously concluded that a claim submitted to the Fund constituted a "claim" for purposes of the FCA. The Court explained that a request for money qualifies as a claim if the government "provides or has provided any portion of the money … requested." As a result, the Court held that reimbursement requests made to the Fund satisfy the FCA's definition of a "claim" because the government provided a "portion" of the money applied for.

Justice Thomas wrote separately in a concurring opinion, suggesting that if the Court were to adopt the government's broader theory that the FCA applied because the government requires private parties to fund the E-Rate program, the FCA could be expanded to include payments between private parties—and unbounded litigation could follow. Justice Thomas posited that if the FCA were held to reach private funds merely regulated by the government, the FCA would seem to reach a wide range of conduct, including false or fraudulent claims of child support payments, the enforcement of civil judgments or fraudulent claims to private health insurance companies for policies purchased due to the individual mandate of the Affordable Care Act (ACA). Justice Kavanaugh, joined by Justice Thomas, also filed a concurrence in which he echoed Justice Thomas' concerns from *Polansky* and questioned whether the FCA's *qui tam* provisions are constitutional under Article II.

With the FCA's treble damages and requirement of per claim penalties associated with any claims determined to be false, defendants often work to resolve FCA litigation short of trial if they are unsuccessful in obtaining dismissal or summary judgment. Notwithstanding the risk of significant loss, defendants pursued an unusual number of high-stakes FCA cases to verdict last year with mixed results.

FCA Trials

With the FCA's treble damages and requirement of per claim penalties associated with any claims determined to be false, defendants often work to resolve FCA litigation short of trial if they are unsuccessful in obtaining dismissal or summary judgment. Notwithstanding the risk of significant loss, defendants pursued an unusual number of high-stakes FCA cases to verdict last year with mixed results.

U.S. ex rel. Schutte v. SuperValu Inc. Following remand from the Supreme Court, the parties in this long-running FCA litigation tried issues of scienter, causation and damages to jury verdict in March 2025. The relators alleged that SuperValu had defrauded government healthcare programs by failing to accurately report the usual and customary prices for prescription drugs billed to federal healthcare programs as a result of the pharmacies' price-matching program. The jury determined that, while SuperValu knowingly submitted false claims to federal healthcare programs, the relators failed to establish that the conduct caused the government to suffer any damages. This was a significant win for the defendants with respect to FCA litigation stemming from a *qui tam* lawsuit that had been filed more than a decade ago. After disposition of post-trial motions by the district court, the matter is on appeal to the Seventh Circuit.

U.S. ex rel. Bassan v. Omnicare, Inc. In April 2025, a jury determined that Omnicare was liable under the FCA for illegally dispensing drugs to elderly and disabled individuals in long-term care facilities without legitimate prescriptions. The jury's verdict included nearly $136 million in damages against Omnicare for submitting over three million false claims, and determined that CVS, which had acquired Omnicare in 2015, caused just over 30% of those claims to be submitted. Following trial, the district court trebled the damages for a total of nearly $407 million and imposed $542 million in penalties on Omnicare. The district court also determined that CVS was jointly and severally liable for 30.4% of the penalties imposed on Omnicare, in an amount of just over $164 million. This matter is on appeal to the Second Circuit.

U.S. ex rel. Behnke v. CVS Caremark Corp. In June 2025, the district court entered a $95 million judgment against the defendants following a bench trial, concluding that a pharmacy benefit manager (PBM) overbilled the government for Medicare Part D sponsored drugs. In the underlying *qui tam* complaint, the relator had alleged that the PBM violated the FCA by causing Medicare Part D plan sponsors to misrepresent amounts paid for prescription drugs on behalf of Medicare beneficiaries. The district judge eventually trebled the damages and added nearly $5 million in penalties for a total judgment of nearly $290 million. This matter is on appeal to the Third Circuit.

U.S. ex rel. Taylor v. Healthcare Assocs. of Texas, LLC. In late 2024, a jury reached a verdict that the defendant medical provider violated the FCA by engaging in fraudulent billing practices associated with services rendered by non-credentialed providers, incident to services and medically unnecessary services. In reaching that verdict, the jury also determined that the defendant was liable for more than $2.7 million in actual damages resulting from more than 21,000 false claims, leading to a proposed civil penalty of nearly $450 million.

Following the jury verdict, the district court considered the constitutionality of the imposition of FCA penalties and concluded that imposing such penalties would violate the Eighth Amendment's Excessive Fines Clause, which prohibits "grossly disproportional" fines relative to the offense. The district court evaluated the nature of the FCA violation at issue, the magnitude of the harm and the ratio of penalties to damages, and after doing so, concluded that the imposition of statutory penalties would be unconstitutional. As a result, the district court reduced the civil penalty to three times the actual damages for a total liability of just over $16.5 million. This matter is on appeal to the Fifth Circuit.

U.S. ex rel. Penelow v. Janssen Products, LP. Finally, the appeal of a 2024 FCA trial that resulted in a $1.64 billion judgment—the largest in FCA history—will be considered by the Third Circuit in the coming year. That judgment resulted from a jury verdict that federal healthcare programs paid claims seeking reimbursement associated with HIV medications that were ineligible for reimbursement because of off-label marketing of those medications. On appeal, Janssen is challenging the sufficiency of the trial evidence supporting the jury verdict as to the FCA elements of falsity, causation and scienter; the constitutionality of the FCA *qui tam* provision; and the constitutionality of the civil penalties awarded. As to the constitutionality of the civil penalties, Janssen noted that the penalties amounted to more than ten times the compensatory damages award. In connection with the appeal, the United States intervened to support the constitutionality of the FCA's *qui tam* and civil penalty provisions.

HHS-DOJ FCA Working Group

In July 2025, DOJ announced the renewal of the DOJ-HHS False Claims Act Working Group as a means of strengthening the government's approach to combating healthcare fraud.[6] The Working Group announced several areas of priority including:

- Medicare Advantage;
- Drug, device or biologics pricing, including arrangements for discounts, rebates, service fees, and formulary placement and price reporting;
- Barriers to patient access to care, including violations of network adequacy requirements;
- Kickbacks related to drugs, medical devices, DME and other products paid for by federal healthcare programs;
- Materially defective medical devices that impact patient safety; and
- Manipulation of Electronic Health Records (EHR) systems to drive inappropriate utilization of Medicare-covered products and services.

The Working Group announced that it would seek to "maximize cross-agency collaboration to expedite ongoing investigations in these priority areas and identify new leads, including by leveraging HHS resources through enhanced data mining and assessment of HHS and HHS-OIG [Office of Inspector General] report findings." Furthermore, it also announced that it would "discuss considerations bearing on whether HHS should implement a payment suspension pursuant to 42 C.F.R. § 405.370 *et seq*. or whether DOJ shall move to dismiss a *qui tam* complaint under 31 U.S.C. § 3730(c)(2)(A)."

The Working Group announced several areas of priority including:

- **Medicare Advantage;**
- **Drug, device or biologics pricing, including arrangements for discounts, rebates, service fees, and formulary placement and price reporting;**
- **Barriers to patient access to care, including violations of network adequacy requirements;**
- **Kickbacks related to drugs, medical devices, DME and other products paid for by federal healthcare programs;**
- **Materially defective medical devices that impact patient safety; and**
- **Manipulation of Electronic Health Records systems to drive inappropriate utilization of Medicare-covered products and services.**

We expect to see more developments from the Working Group in the coming year, which likely will continue to shape the way healthcare fraud enforcement is pursued across the federal government.

Other FCA Enforcement Initiatives

With the new administration and its new enforcement priorities, DOJ has explored using the FCA to pursue recovery for fraud committed against the government, particularly through customs and trade-related enforcement, as well as policy-driven enforcement targeted at what it has described as illegal discrimination stemming from DEI programs.

Customs Enforcement. Over the past decade, DOJ has steadily ramped up customs enforcement activity, with notable FCA settlements involving misrepresentations related to country of origin or product classification. In 2023, DOJ announced one of the first FCA settlements involving underpayment of customs duties allegedly owed on imported vitamins and other supplements.

6 www.hhs.gov/press-room/hhs-doj-false-claims-act-working-group.html.

Most recently, in December 2025, DOJ announced a $54.4 million settlement with Ceratizit USA LLC, a Charlotte, North Carolina-based distributor of tungsten carbide products, based on alleged customs violations. From August 2020 through March 2024, Ceratizit allegedly imported tungsten carbide rods manufactured in China but falsely declared them as originating from Taiwan to evade tariffs applicable to Chinese products. As a result of this false information, DOJ claimed that duties were substantially underpaid.

Similarly, in November 2025, Harman International Industries, Inc., a leading audio electronics company, agreed to pay $11.8 million to resolve FCA allegations related to evading customs duties. Harman allegedly imported "heat sinks" (thermal-management components used in electronics) containing extruded aluminum from China from June 2011 through March 2023. DOJ also alleged that when confronted, Harman "concealed and decided not to disclose its knowing avoidance" of those required duties.

DOJ's theory of liability in these cases has arisen under the FCA's "reverse false claim" provision, which arises when a party knowingly avoids paying money owed to the government. Of particular relevance here is that courts have held that an importer's failure to pay duties on imported products, as required under the Tariff Act of 1930, is sufficient to give rise to a reverse false claim since the FCA imposes liability on those who knowingly conceal or knowingly and improperly avoid or decrease an obligation to pay or transmit money or property to the government.[7]

Policy-Driven FCA Enforcement Initiatives. On January 21, 2025, President Trump rescinded Executive Order No. 11246, signed by former President Lyndon B. Johnson in 1965, by issuing Executive Order 14173 entitled "Ending Illegal Discrimination and Restoring Merit-Based Opportunity." Executive Order No. 11246 had imposed affirmative action obligations and non-discrimination requirements on certain federal contractors. Executive Order 14173 now provides that preferences based on race or sex may violate civil rights laws and mandates a streamlined contracting process that emphasizes compliance with anti-discrimination laws.

The implications of this shift are profound. Under Executive Order 14173, federal contracts and grants are now required to include a clause mandating that the contractor or grant recipient certify that they comply "with applicable Federal anti-discrimination laws." Executive Order 14173 provides that such a certification is a term "material to the government's payment decisions" for purposes of the FCA. Contractors and grant recipients must also certify that they do "not operate any programs promoting DEI that violate any applicable Federal anti-discrimination laws."

Executive Order 14173 has far-reaching implications; namely, in that FCA liability may apply should a contractor or grant recipient fail to comply with its requirements. In furtherance of that initiative, on May 19, 2025, DOJ launched the Civil Rights Fraud Initiative, explicitly encouraging whistleblowers to come forward and file *qui tam* complaints on this basis. Although there have been no public FCA resolutions or cases to date, reports indicate that DOJ is currently investigating several companies and universities for potential FCA violations related to their DEI practices.

THE FUTURE OF THE ANTI-KICKBACK STATUTE

Courts have continued to wrestle with the question of causation in FCA claims based on alleged violations of the federal AKS. As a result of an amendment made to the AKS as part of the ACA enacted in 2010, a claim "resulting from" an AKS violation constitutes a false or fraudulent claim under the FCA.[8] Prior to the amendment, courts applied a "false certification" theory when determining FCA liability based on alleged AKS violations. That theory required that providers implicitly certified compliance with the AKS when submitting claims to federal healthcare programs, thereby rendering claims false if the provider violated the AKS. In other words, if a provider were to have violated the AKS by offering or receiving a kickback to induce referrals, the government or relators had argued that claims tainted by the AKS violation should be deemed false because the provider misrepresented compliance with the AKS by implicit certification.

Since the amendment, however, courts have grappled with the meaning of the "resulting from" language, with the defendants typically arguing that the government or a relator must demonstrate "but-for" causation to show that a false claim *resulted from* an alleged kickback.

The First Circuit was the most recent federal appellate court to have addressed this issue in ***United States v. Regeneron Pharmaceuticals, Inc.***[9] There, Regeneron argued that a false claim "results from" an AKS violation if it includes "items or services" that would not have been paid for by the government absent the AKS violation. Regeneron asserted that if a doctor would have purchased (and sought reimbursement for) the product at issue regardless of any alleged inducement, then the subsequent Medicare claim could not have "resulted from" Regeneron's allegedly illicit payments. The government argued that it need only demonstrate "a sufficient causal connection" between the donations and the resulting claims. But the district court rejected that argument and held the government must plead and prove "but-for" causation. In reaching this decision, the district court expressed its view that the standard articulated by the Third Circuit in *U.S. ex rel. Greenfield* was "fraught with problems," "divorced from the actual language of the statute and from basic principles of statutory interpretation" and "disconnected from long-standing common-law principles of causation."

Despite its adoption of the "but-for" causation standard, which was a clear win for the defense, the First Circuit made clear that the government could still bring FCA claims based on alleged AKS violations through a false certification theory, where it is not the AKS violation itself that would render the claim false. Rather, as the First Circuit explained "it is false representation that there is no AKS violation" that would render the claim false.

7 *See U.S. ex rel. Customs Fraud Investigations, LLC v. Victaulic Co.*, 839 F.3d 242 (3d Cir. 2016).

8 42 U.S.C. 1320a-7b(g).

9 128 F.4th 324 (1st Cir. 2025).

> ***Since launching its Civil Cyber-Fraud Initiative in 2021, DOJ has announced 14 CCFI settlements, nearly half of which were announced in 2025. This is likely due in part to the slow-moving nature of FCA investigations, which can take years to resolve—meaning, many of the cyber-related FCA lawsuits initiated soon after the CCFI announcement are only now becoming public.***

Following *Regeneron*, the First Circuit reiterated its views on the appropriate causation standard in ***U.S. ex rel. Flanagan v. Fresenius Med. Care Holdings, Inc.***[10] There, the district court dismissed the relator's complaint for failing to meet the heightened pleading standard of Federal Rule of Civil Procedure 9(b), noting that the complaint did not adequately allege specific false claims or provide representative samples of such claims. On appeal, the First Circuit upheld the district court's decision and also emphasized that for a claim to be actionable under the FCA based on alleged AKS violations, the alleged kickback must be the "but-for" cause of the claims submitted to the government.

Although precedent on this issue continues to evolve, the consensus is increasingly favoring the application of a "but-for" causation standard. To that end, the First, Sixth and Eighth Circuits have aligned on applying a "but-for" causation standard, while the Third Circuit remains the outlier with its application of a more lenient "causal link" standard.[11]

CYBERSECURITY

Since launching its Civil Cyber-Fraud Initiative (CCFI) in 2021, DOJ has announced 14 CCFI settlements, nearly half of which were announced in 2025. This is likely due in part to the slow-moving nature of FCA investigations, which can take years to resolve—meaning, many of the cyber-related FCA lawsuits initiated soon after the CCFI announcement are only now becoming public. It is also a sign that cybersecurity remains a priority for FCA enforcement across administrations.

To date, enforcement has been focused on government contractors, with a particular focus on defense contractors that are granted access to certain classified and unclassified information. Recent settlements continued that trend, with high-profile settlements including DOJ's $11 million settlement with Centene Corporation in February,[12] its back-to-back $8.4 million settlement with Raytheon[13] and $4.6 million settlement with MORSE Corp Inc. in May,[14] and its $1.75 million settlement with Aero Turbine Inc. in July.[15]

In perhaps the biggest news for the healthcare industry, DOJ announced a first-of-its-kind CCFI settlement with Illumina, a medical device company that paid $9.8 million to resolve allegations that it sold genomic sequencing systems with cybersecurity vulnerabilities to federal agencies, despite certifying to the Food and Drug Administration (FDA) that its products complied with applicable cybersecurity requirements.[16] Two aspects of this settlement are particularly noteworthy. First, the action was initiated by a former Illumina employee, who received $1.9 million of the settlement as the relator's share. Second, it comes at a time when the FDA has just heightened its regulatory expectations for cybersecurity relating to medical devices. Taken together, this is a clear indication that more relator-initiated FDA cybersecurity actions are on the way.

CONTROLLED SUBSTANCES ACT & DIVERSION ISSUES

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 requirements under the CSA and its implementing regulations include: (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.

Federal and state regulators continued aggressive enforcement of CSA requirements, targeting entities across the controlled substances supply chain—including pharmacies, hospitals, physicians, research institutions and other healthcare facilities. These actions underscore emerging areas of legal risk for healthcare organizations.

FCA Actions Based on Alleged CSA Violations

We have previously commented on the continued use of CSA violations as the basis for pursuit of significant FCA cases as a notable trend. This approach gained traction in recent years with the $400 million settlement of an intervened *qui tam* FCA case against Rite Aid in

10 142 F.4th 25 (1st Cir. 2025).
11 The Seventh Circuit acknowledged the growing circuit split in *Stop Illinois Health Care Fraud, LLC v. Sayeed*, 100 F.4th 899 (7th Cir. 2024), but ultimately did not reach the issue.

12 https://www.justice.gov/opa/pr/health-net-federal-services-llc-and-centene-corporation-agree-pay-over-11-million-resolve.
13 https://www.justice.gov/opa/pr/raytheon-companies-and-nightwing-group-pay-84m-resolve-false-claims-act-allegations-relating.
14 https://www.justice.gov/opa/pr/defense-contractor-morsecorp-inc-agrees-pay-46-million-settle-cybersecurity-fraud.
15 https://www.justice.gov/opa/pr/california-defense-contractor-and-private-equity-firm-agree-pay-175m-resolve-false-claims.
16 https://www.justice.gov/opa/pr/illumina-inc-pay-98m-resolve-false-claims-act-allegations-arising-cybersecurity.
17 *Gonzales v. Raich*, 545 U.S. 1 (2005).

2024 based on allegations that the company billed federal healthcare programs for opioids dispensed in violation of CSA requirements.[18] DOJ intervention in a *qui tam* lawsuit against CVS Pharmacy with respect to similar allegations remains in active litigation, with a hearing on CVS's motion to dismiss set for early 2026.[19]

In April 2025, DOJ announced a $300 million settlement with Walgreens to resolve similar allegations.[20] The government claimed Walgreens submitted reimbursement claims for prescriptions not issued in the usual course of professional practice or for a legitimate medical purpose. The settlement also resulted in the dismissal of Walgreens' civil action challenging the Drug Enforcement Administration's (DEA) authority to impose liability on pharmacists for failing to address "red flags" under their corresponding responsibility obligations.[21]

Cases where the government declined to intervene were less successful for relators. In ***U.S. ex rel. Publix Litig. Partnership, LLP v. Publix Super Markets, Inc.***, the district court dismissed claims by two former pharmacists alleging a corporate-wide scheme to fill improper opioid prescriptions.[22] The district court emphasized that under an implied false certification theory, the relators must identify the source of corresponding responsibility obligations and link them to specific representations made to the government—which the relators had failed to do.

Enforcement extended beyond large pharmacy chains to individual prescribers and their employers. For example, DOJ announced a $650,000 settlement with three physicians and their hospital employer for allegedly issuing prescriptions without a legitimate medical purpose or outside the usual course of professional practice.[23] This action signals a growing willingness to hold healthcare facilities liable under the FCA for the prescribing practices of employed physicians—particularly when the facility bills for those services.

The financial exposure from combined CSA/FCA actions can be severe, as the settlements above demonstrate. As another example, in ***United States v. Hernandez***, the district court entered a default judgment exceeding $30 million against a physician and his clinic stemming from roughly 2,000 fraudulent prescriptions.[24] The district court not only tripled the actual damages paid for the prescriptions ($257,715) under the FCA, but also tripled the per-prescription statutory penalties, leading to a staggering penalty-to-damages ratio of nearly 114-to-1. This highlights the potential for extraordinary liability from what might seem like a relatively small number of violations.

18 https://www.justice.gov/archives/opa/pr/rite-aid-corporation-and-affiliates-agree-settle-false-claims-act-and-controlled-substance/.
19 https://www.justice.gov/usao-ri/pr/nationwide-lawsuit-filed-rhode-island-alleging-cvs-knowingly-dispensed-controlled.
20 https://www.justice.gov/opa/pr/walgreens-agrees-pay-350m-illegally-filling-unlawful-opioid-prescriptions-and-submitting.
21 *Walgreen Co. v. DEA*, Civ. No. 25-cv-00019 (E.D. Tex.).
22 2025 WL 2468832 (M.D. Fla. Aug. 27, 2025).
23 https://www.justice.gov/usao-co/pr/southern-colorado-hospital-and-doctors-agree-pay-650000-resolve-allegations-they.
24 2025 WL 2222742 (W.D. Tex. Aug. 1, 2025).

> ***Federal and state regulators continued aggressive enforcement of CSA requirements, targeting entities across the controlled substances supply chain—including pharmacies, hospitals, physicians, research institutions and other healthcare facilities. These actions underscore emerging areas of legal risk for healthcare organizations.***

Telehealth Prosecutions

Federal authorities also pursued prosecutions related to telehealth prescribing of controlled substances. In November 2025, a jury convicted the founder and clinical president of Done Global for conspiring to distribute controlled substances and to commit healthcare fraud tied to online Adderall and other stimulant prescribing.[25] DOJ alleged a model that leveraged deceptive advertising, constrained clinical discretion and enabled refills without clinician interaction through an "auto-fill" feature.

According to the government, evidence showed that the defendants arranged for prescriptions exceeding 40 million stimulant pills and generated over $100 million, including approximately $14 million from Medicare, Medicaid and commercial insurers based on allegedly false statements and prior authorization submissions. DOJ highlighted internal directives capping appointment length, limiting follow-up care and paying nurse practitioners up to $60,000 per month to refill prescriptions without clinical interaction, which in some instances resulted in prescriptions for deceased patients.

Weeks later, a federal grand jury returned corporate indictments for Done Global and Mindful Mental Wellness P.A. for conspiracies to illegally distribute Adderall, commit healthcare fraud and obstruct justice—the first criminal drug distribution prosecutions involving a digital health company.[26] The government alleged a subscription model that enabled stimulant access without a legitimate medical purpose or adequate examination and concealment of prescription illegality to secure dispensing and reimbursement. Such enforcement efforts show heightened scrutiny of telehealth platforms under CSA and fraud theories.

25 https://www.justice.gov/opa/pr/founderceo-and-clinical-president-digital-health-company-convicted-100m-adderall.
26 https://www.justice.gov/opa/pr/digital-health-company-and-medical-practice-indicted-100m-adderall-distribution-scheme.

NOTEWORTHY SETTLEMENTS

As in recent years, resolutions in healthcare fraud cases accounted for the vast majority of all FCA recoveries in FY 2025. Of the nearly $6.9 billion total in settlements and judgments, recoveries from matters involving the healthcare industry amounted to $5.72 billion (83%).

Newly filed *qui tam* complaints accounted for the majority of the new civil fraud matters initiated in FY 2025, in line with past years, although the number of government-initiated and data-driven FCA actions continues to rise. Whistleblowers filed a record-breaking 1,297 *qui tam* lawsuits in FY 2025, and recoveries from these and earlier filed lawsuits accounted for $5.34 billion of the $6.9 billion recovered. Settlements associated with *qui tam* lawsuits where the government intervened or otherwise pursued the allegations comprised more than $4.5 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 AND HEALTH SYSTEMS

Most of the settlements with hospitals and health systems in FY 2025 involved allegations of violations of the Stark Law and/or AKS. This included the year's largest settlement, wherein a health system and physician network agreed to pay $31.5 million to resolve allegations that the entities provided multiple forms of benefits to physicians to induce and reward referrals, including expensive wine, liquor and cigars; EHR software and maintenance subsidies; and bonuses for alleged work on clinical integration activities that were actually designed to reward referrals.[27] As part of the settlement, the hospital entered into a five-year corporate integrity agreement (CIA) with HHS-OIG. Another hospital agreed to pay nearly $7 million to resolve Stark and AKS allegations that it paid millions of dollars to an affiliated oncology practice to induce referrals under agreements for which the underlying work was not performed and/or not documented.[28]

In the year's second largest settlement with a health system, the system agreed to pay $29 million to resolve allegations that it knowingly retained and concealed the existence of mistakenly inflated payments for healthcare services received from the Department of Defense for retired military members and their families.[29] The government alleged that after learning errors had been made in the calculation of the capitated rates paid to the hospital, the hospital took steps to conceal the existence of the overpayments, continued to submit invoices at the inflated payment rates and conspired to avoid paying the money back.

The government also entered into substantial settlements with hospitals alleged to have made materially false statements to obtain Paycheck Protection Program (PPP) loans during the pandemic[30] and in grant applications for cancer research funding.[31]

27 https://www.justice.gov/usao-edca/pr/fresno-based-community-health-system-agree-pay-315-million-resolve-allegations-false.
28 https://www.justice.gov/usao-sdny/pr/us-attorney-announces-68-million-settlement-new-york-presbyterian-hudson-valley.
29 https://www.justice.gov/opa/pr/saint-vincents-catholic-medical-centers-new-york-agrees-pay-29m-resolve-alleged-false-claims.
30 https://www.justice.gov/usao-edca/pr/carson-tahoe-health-system-agrees-pay-over-88-million-settle-allegations-over-pandemic.
31 https://www.justice.gov/opa/pr/dana-farber-cancer-institute-agrees-pay-15m-settle-fraud-allegations-related-scientific.

LONG-TERM CARE

After a shift away from settlements involving typical theories of liability against home health, hospice and skilled nursing facilities (SNF) in 2024, last year saw a return to the majority of settlements in this sector involving allegations of substandard care[32] or medically unnecessary services and admissions,[33] with notable states' Attorneys General offices participation in cases involving substandard care allegations. One notable settlement involved a SNF and acute care hospital that agreed to pay over $6.5 million to resolve allegations that they billed for services that were not medically necessary or were not part of a documented plan of care and charged for more time than was actually spent with patients.[34]

Other significant settlements involving long-term care providers included a SNF chain that agreed to pay $18 million to resolve allegations related to the submission of falsified information in PPP loan and loan forgiveness applications,[35] a hospice company and executive who agreed to pay $9.2 million to resolve allegations that they paid kickbacks to medical directors in exchange for patient referrals,[36] and two home health providers who agreed to pay over $300,000 and $500,000, respectively, to resolve allegations that they billed for services provided by unqualified staff.[37]

Finally, the largest home health settlement of the year involved allegations that the agency sought Medicaid reimbursement while failing to comply with wage parity requirements.[38] The agency agreed to pay $10 million to resolve these allegations and will also pay nearly $45 million to compensate former and current home health aides for unpaid wages.

PHARMACEUTICAL AND DEVICE

In line with past years, most of the largest settlements in the pharmaceutical and device sector involved alleged AKS violations.[39] In one instance, a pharmaceutical manufacturer agreed to pay $202 million to resolve allegations that it violated the AKS by paying for travel, expensive meals and honoraria to physicians who were part of its speaker program to induce

32 https://oag.maryland.gov/News/Pages/Attorney-General%e2%80%99s-Medicaid-Fraud-and-Vulnerable-Victims-Unit-Secures-a-$1%2c289%2c679-Settlement-and-Corporate-Oversight.aspx; https://www.justice.gov/opa/pr/ohio-based-nonprofit-and-affiliated-nursing-homes-agree-pay-361m-resolve-false-claims-act; https://www.michigan.gov/ag/news/press-releases/2025/07/02/attorney-general-nessel-announces; https://oag.maryland.gov/News/Pages/Attorney-General%E2%80%99s-Medicaid-Fraud-and-Vulnerable-Victims-Unit-Secures-a-$200,000-Settlement-and-Corporate-Oversight-of-Pata.aspx.
33 https://www.justice.gov/opa/pr/saad-healthcare-agrees-pay-3m-settle-false-claims-act-allegations-it-billed-medicare.
34 https://www.justice.gov/usao-wdtx/pr/skilled-nursing-facility-and-acute-care-hospital-pay-65-million-settle-civil-false.
35 https://www.justice.gov/usao-cdca/pr/south-bay-based-nursing-facilities-chain-and-owner-agree-pay-18-million-resolve-0.
36 https://www.justice.gov/usao-ndga/pr/mahlega-abdsharafat-and-creative-hospice-settle-health-care-kickback-claims-92-million.
37 https://www.justice.gov/usao-edmi/pr/home-health-care-provider-pay-334807-settle-false-claims-act-allegations; https://www.justice.gov/usao-edmo/pr/missouri-home-health-care-company-agrees-pay-534475-false-claims-act-settlement.
38 https://ag.ny.gov/press-release/2025/attorney-general-james-secures-45-million-underpaid-home-health-aides.
39 E.g., https://www.justice.gov/usao-edpa/pr/aesculap-implant-systems-agrees-pay-385-million-resolve-false-claims-act-allegations.

prescriptions of its HIV drugs.[40] Another pharmaceutical company agreed to pay nearly $60 million to resolve similar AKS allegations that it used benefits conferred on prescribing physicians through its speaker programs to induce prescriptions of one of its drugs.[41] In another settlement, a medical device and supply company agreed to pay $17 million to resolve allegations that it provided free samples and discounts to induce urology practices to use the medical device company's form to prescribe intermittent catheters, in violation of the AKS.[42]

There were also several significant settlements in this sector resolving allegations that pharmaceutical and device companies caused the submission of claims for non-reimbursable or medically unnecessary services, or for unapproved uses of products.[43] In one such settlement, a medical device company agreed to pay over $29 million, and related companies agreed to pay over $7 million to resolve allegations that they caused the submission of claims to Medicare for diagnostic tests performed by devices that were not approved for that use, contrary to the company's representations.[44] As part of the settlement, the medical device company entered a five-year CIA with HHS-OIG.

In another notable settlement, a biotechnology and medical device company agreed to pay $9.8 million to resolve allegations that it sold government agencies genomic sequencing systems with software that had cybersecurity exposures after falsely representing that the software followed all required cybersecurity standards.[45] Another biopharmaceutical company agreed to pay over $4 million to resolve allegations that it failed to disclose and report allegations of research misconduct to the National Institutes of Health (NIH) and HHS's Office of Research Integrity in grant applications and grant award progress reports.[46]

LABORATORY AND DIAGNOSTIC SERVICES

AKS allegations continued to underpin a significant share of settlements with laboratory and diagnostic companies as well. In the year's largest resolution in this space, a diagnostic laboratory paid $9.62 million to resolve allegations that it improperly paid volume- and value-based commissions to independent sales representatives and marketing firms, and billed medically unnecessary respiratory pathogen panels.[47] Two genetic testing marketing companies and their executives paid $6 million for allegedly engaging in kickback schemes utilizing independent contractors, physicians and telemedicine providers to generate orders for genetic cancer (CGx) and pharmacogenetic (PGx) tests.[48] A laboratory CEO paid $4.25 million to resolve allegations that he orchestrated kickbacks disguised as management services, organization distributions, consulting and processing fees and copay and deductible waivers to induce testing referrals.[49] A remote patient monitoring company agreed to pay up to $4.9 million for allegedly purchasing Medicare beneficiary referrals from a marketing service.[50]

Separate from the kickback-driven settlements discussed in this section, the government also pursued standalone medical necessity cases involving alleged unnecessary testing. A toxicology laboratory and its owners paid $4.43 million to resolve allegations that they billed for medically unnecessary presumptive and definitive urine drug testing and hormone tests, including by improperly billing hormone levels as specimen validity tests.[51] A molecular diagnostics company paid at least $3.25 million (potentially more upon the sale of the company) to resolve claims that orders for breast cancer genomic testing were medically unnecessary, even absent allegations of illegal remuneration.[52] Urgent care operators also

40 https://www.justice.gov/usao-sdny/pr/us-attorney-announces-202-million-settlement-gilead-sciences-using-speaker-programs.
41 https://www.justice.gov/opa/pr/pfizer-agrees-pay-nearly-60m-resolve-false-claims-allegations-relating-improper-physician.
42 https://www.justice.gov/usao-ndga/pr/cr-bard-inc-and-affiliates-pay-17-million-resolve-allegations-healthcare-kickbacks.
43 https://www.justice.gov/usao-wdmi/pr/2025_0326_Prometheus_Settlement; https://www.justice.gov/usao-nj/pr/diopsys-inc-agrees-pay-1425-million-resolve-alleged-federal-false-claims-act-and-state; https://www.justice.gov/usao-dc/pr/pharmaceutical-manufacturer-assertio-therapeutics-inc-pay-36-million-resolve-allegations; https://www.justice.gov/usao-edpa/pr/rst-sanexas-inc-and-its-owners-agree-pay-15-million-resolve-allegations-they-caused.
44 https://www.justice.gov/opa/pr/semler-scientific-inc-and-bard-peripheral-vascular-inc-pay-nearly-37m-resolve-false-claims.
45 https://www.justice.gov/opa/pr/illumina-inc-pay-98m-resolve-false-claims-act-allegations-arising-cybersecurity.
46 https://www.justice.gov/opa/pr/athira-pharma-inc-agrees-pay-4m-settle-false-claims-act-allegations-related-scientific.
47 https://www.justice.gov/usao-md/pr/diagnostic-laboratory-agrees-pay-more-9-million-settle-alleged-false-claims-act.
48 https://www.justice.gov/usao-edpa/pr/genetic-testing-marketing-companies-genexe-llc-and-immerge-inc-and-two-executives.
49 https://www.justice.gov/opa/pr/laboratory-ceo-marketers-and-physicians-pay-over-6m-settle-allegations-management-service.
50 https://www.justice.gov/usao-mdfl/pr/livecare-inc-agrees-pay-49-million-resolve-false-claims-act-allegations.
51 https://www.justice.gov/usao-wdmi/pr/2025_0103_physicians_toxicology_laboratory_settlement.
52 https://www.justice.gov/usao-edtn/pr/agendia-inc-knoxville-comprehensive-breast-center-pllc-and-knoxville-0.

resolved allegations tied to testing and coding practices, including a $3 million settlement involving unnecessary respiratory testing and upcoding during the COVID-19 pandemic[53] and a $2.81 million settlement involving unbundled panel testing.[54]

The government also continued to pursue enforcement actions based on alleged failures to comply with program-specific billing requirements. A healthcare screening company paid $8 million to resolve allegations that it billed the COVID-19 Uninsured Program for patients who had active insurance, contrary to program eligibility rules.[55] A laboratory group and a health system paid $388,667 to resolve allegations that they delayed submission of physician orders to circumvent Medicare's Date of Service rule.[56]

Two notable radiology settlements in FY 2025 addressed risk-adjustment coding and pandemic-era relief programs. One radiology group paid $2.35 million to resolve allegations that, in coordination with an affiliated physician group, it caused the submission of unsupported diagnosis codes to inflate MA payments.[57] Another radiology group paid $2.88 million to resolve allegations that it misreported payroll costs to obtain full forgiveness of a PPP loan.[58]

PHARMACY SERVICES

Settlements involving pharmacy services accounted for several of the year's largest recoveries. A national pharmacy chain and its subsidiaries agreed to pay up to $350 million in a matter alleging that they filled invalid opioid and other controlled substance prescriptions, and then sought reimbursement from federal healthcare programs. The resolution also required multi-year compliance obligations, including ongoing DEA oversight and a CIA with HHS-OIG.[59]

Another national pharmacy chain resolved multiple billing-related matters. The chain paid $37.76 million in connection with allegations that it improperly billed for insulin pens by seeking premature refills, dispensing quantities larger than prescribed and understating days' supply.[60] The same chain separately paid $18.28 million in a case involving allegations that it failed to confirm and document required diagnoses for certain Medi-Cal prescriptions and, in some instances, billed for drugs dispensed for unapproved diagnoses without the required justification.[61] In another significant pharmacy settlement, a pharmacy agreed to pay $17.07 million after allegedly billing Medicare for over-the-counter COVID-19 tests that were not provided or were shipped months after claims were submitted, despite internal acknowledgments of the issue.[62]

PHYSICIAN PRACTICE GROUPS AND INDIVIDUAL PROVIDERS

Settlements involving physician practice groups and individual providers spanned risk-adjustment coding, medical necessity violations and improper billing practices. In the year's most significant settlement in this category, a primary care and specialist physician provider group and its subsidiary paid $60.5 million to resolve allegations that they caused the submission of unsupported diagnosis codes for two spinal conditions to inflate MA payments, including by arranging for radiology reports to appear to substantiate the diagnoses.[63]

Significant enforcement activity also involved pain management practices. An interventional pain management practice and its founder paid $13.62 million in a matter alleging the billing of concurrent presumptive and definitive urine drug tests on the same date without a medical necessity determination and the unbundling of definitive testing through separate analyte codes.[64] A pain medicine practice paid $3.5 million over allegations involving medically unnecessary and duplicative laboratory testing and the use of pre-signed opioid prescriptions. The resolution included DEA monitoring and a three-year integrity agreement (IA).[65] DOJ also secured a $3.5 million settlement with a physician accused of billing higher-level evaluation and management (E&M) services that were not performed by appropriate healthcare professionals at COVID-19 testing sites and of billing E&M codes for patient test result notifications that were ineligible for reimbursement from the COVID-19 Uninsured Program.[66]

DOJ continued its multi-year focus on the alleged misbilling of surgically implanted neurostimulators when patients instead received external electroacupuncture devices. An anesthesiologist and pain medicine physician paid over $2 million in connection with such alleged conduct.[67] Similar resolutions included a pain management physician who paid $390,082 and another physician who paid $600,000 for allegedly billing the disposable device as a surgically implanted neurostimulator.[68]

53 https://www.justice.gov/usao-id/pr/urgent-care-operator-pays-3-million-dollars-resolve-alleged-violations-false-claims-act.
54 https://www.justice.gov/usao-edwa/pr/tri-cities-urgent-care-clinic-agrees-pay-28-million-resolve-claims-overbilling.
55 https://www.justice.gov/usao-nj/pr/vault-agrees-pay-8-million-settle-allegations-billing-false-claims-covid-19-uninsured.
56 https://www.justice.gov/usao-edtn/pr/labcorp-and-university-health-system-agree-pay-388667-resolve-alleged-false-claims-act.
57 https://www.justice.gov/opa/pr/medicare-advantage-provider-seoul-medical-group-and-related-parties-pay-over-62m-settle.
58 https://www.justice.gov/usao-edva/pr/medical-group-agrees-pay-28m-settle-false-claims-act-allegations.
59 https://www.justice.gov/usao-mdfl/pr/walgreens-agrees-pay-350m-illegally-filling-unlawful-opioid-prescriptions-and.
60 https://www.justice.gov/usao-sdny/pr/us-attorney-announces-3776-million-settlement-cvs-over-dispensing-insulin-pens.
61 https://www.justice.gov/usao-edca/pr/cvs-pharmacy-inc-pays-182-million-resolve-alleged-false-claims-act-violations.
62 https://www.justice.gov/usao-mdfl/pr/vra-enterprises-agrees-pay-over-17-million-allegedly-billing-medicare-over-counter.
63 https://www.justice.gov/opa/pr/medicare-advantage-provider-seoul-medical-group-and-related-parties-pay-over-62m-settle.
64 https://www.justice.gov/usao-wdtx/pr/austin-pain-management-doctor-and-pain-medicine-practice-pay-13625000-settle-civil.
65 https://www.justice.gov/usao-ndga/pr/pain-management-doctor-and-medical-practice-pay-35-million-resolve-false-claims-act.
66 https://www.justice.gov/usao-edtx/pr/collin-county-physician-agrees-pay-35-million-resolve-false-claims-act-allegations.
67 https://www.justice.gov/usao-sdtx/pr/houston-doctor-agrees-pay-over-2-million-settle-allegations-fraudulent-billing-federal.
68 https://www.justice.gov/usao-sdtx/pr/houston-doctor-pays-six-figures-settle-false-claims-act-liability-involving; https://www.justice.gov/usao-sdoh/pr/ohio-doctor-agrees-pay-600000-settle-false-claims-act-allegations.

Outside of pain management, an ophthalmology practice paid $615,000 in a case involving medically unnecessary transcranial Doppler ultrasounds that were allegedly based on false diagnoses and tainted by a volume-based arrangement with a third-party testing supplier, in violation of the AKS and Stark Law.[69] Another eye care practice paid $790,000 for billing E&M visits on the same day as bilateral eye injections, contrary to Medicare billing rules.[70]

OTHER PROVIDERS

Some of the year's largest recoveries arose from DOJ's continued focus on wound care services. A group of wound graft company owners agreed to pay nearly $310 million to resolve civil allegations involving medically unnecessary wound graft claims and related kickbacks, in parallel with related criminal proceedings that resulted in guilty pleas, sentencing and forfeiture for healthcare fraud and kickback conspiracies.[71] A specialty wound care provider and its physician owner agreed to pay $45 million and enter into a five-year CIA based on allegations involving: (1) unnecessary or unperformed procedures; (2) upcoding to more profitable excisional services; and (3) improper EHR-based billing logic that defaulted procedures to higher reimbursed excisional codes and generated documentation to support those claims.[72]

Behavioral health and addiction providers also accounted for several significant settlements, often centered on alleged documentation failures, improper coding practices and services not provided as billed. An addiction treatment provider paid $18.5 million to resolve allegations involving double-billed or unprovided intensive outpatient services and AKS violations tied to payments made to Medicaid beneficiaries.[73] A nonprofit operator of residential and day programs for individuals with developmental disabilities paid more than $5 million to address allegations that day habilitation services failed to meet applicable program requirements and that the operator avoided returning overpayments from Medicaid for those services.[74] Additional behavioral health resolutions addressed psychotherapy coding and documentation issues, including a: (1) $2.75 million settlement involving improper Current Procedural Technology (CPT) add-on coding;[75] and (2) $1.9 million settlement with a state's largest behavioral health practice and certain former officers to resolve allegations that they billed Medicare for psychotherapy and medication management services without required documentation of separate and distinct psychotherapy time and disregarded repeated internal warnings.[76]

Transportation-related settlements reflected significant enforcement activity by states' Attorneys General—as opposed to DOJ—in cases involving Medicaid-funded services. A group of sixteen medical transport companies collectively paid more than $13 million to resolve allegations involving fabricated trips, inflated mileage and tolls, unlicensed drivers and kickbacks tied to ride requests.[77] Two ambulance companies and their owners paid $6 million and agreed to independent compliance monitoring in connection with alleged improper emergency billing, medically unnecessary transports and deficient ownership disclosures.[78]

Finally, enforcement activity extended beyond traditional providers to health technology vendors. A medical software company paid approximately $529,000 to resolve allegations that it caused providers to bill for breast cancer screenings that were medically unnecessary by sometimes configuring the company's risk assessment software contrary to recommended guidelines.[79]

69 https://www.justice.gov/usao-mdfl/pr/florida-ophthalmology-practice-agrees-pay-615000-resolve-allegations-fraudulent-claims.
70 https://www.justice.gov/usao-mdpa/pr/eye-consultants-pennsylvania-pc-agrees-pay-79000000-settle-false-claims-act.
71 https://www.justice.gov/opa/pr/wound-graft-company-owners-sentenced-12b-health-care-fraud-and-agree-pay-309m-resolve-civil.
72 https://www.justice.gov/opa/pr/vohra-wound-physicians-and-its-owner-agree-pay-45m-settle-fraud-allegations-overbilling.
73 https://www.justice.gov/usao-mn/pr/nuway-alliance-agrees-pay-18500000-settlement-medicaid-kickbacks-scheme-false-claims-act.
74 https://www.justice.gov/usao-sdny/pr/acting-us-attorney-announces-5-million-false-claims-act-settlement-providers-programs.
75 https://www.justice.gov/usao-ndca/pr/california-behavioral-medicine-provider-agrees-pay-275-million-resolve-alleged-false.
76 https://www.justice.gov/usao-ednc/pr/largest-north-carolina-behavioral-health-practice-agrees-pay-19-million-resolve.
77 https://ag.ny.gov/press-release/2025/attorney-general-james-secures-more-13-million-sweeping-takedown-transportation.
78 https://www.mass.gov/news/ag-campbell-secures-6-million-settlement-with-weymouth-based-ambulance-companies-for-masshealth-false-claims.
79 https://www.justice.gov/usao-ma/pr/medical-software-company-agrees-pay-500000-resolve-allegations-causing-medically.

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 government 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

Materiality remains an important and frequently contested element in FCA litigation. In the years since the Supreme Court's decision in *Universal Health Services, Inc. v. U.S. ex rel. Escobar*,[80] courts have continued to emphasize that FCA liability turns not on regulatory or contractual noncompliance by itself, but on whether the alleged violation actually affected, or would have affected, the government's payment decision. In *Escobar*, the Supreme Court characterized the materiality element as "rigorous" and "demanding," while identifying several factors for courts to weigh. In 2025, courts have continued wrestling with these factors, particularly focusing on the government's payment practices and the significance of alleged violations to the underlying contractual relationship.

Government Payment Practices

The government's track record of paying or refusing payment after learning of alleged noncompliance remains perhaps the most important materiality consideration. For example, in ***U.S. ex rel. McCullough v. Anthem Ins. Companies, Inc.***, the district court granted a motion to dismiss where the Indiana Medicaid program had demonstrably deemphasized enforcement with respect to the kinds of violations at issue.[81] The district court determined that the state's decision to let the alleged overpayments stand "indicate[d] a conscious choice to no longer emphasize correct payments," and provided "further evidence that the Government is not concerned with the alleged violations." This decision underscores the continued viability of materiality defenses grounded in the government's own payment decisions and enforcement choices.

Nonetheless, continued payment may not always be dispositive on its own. In ***U.S. ex rel. Streck v. Eli Lilly & Co.***, for instance, the Seventh Circuit affirmed a verdict in favor of a relator who challenged a pharmaceutical manufacturer's Medicaid Drug Rebate Program calculations, which allegedly excluded roughly $600 million in price adjustments.[82] The defendant contended that its prior communications with Centers for Medicare & Medicaid Services (CMS) established government knowledge and continued payment sufficient to defeat materiality. But the Seventh Circuit disagreed, clarifying that *Escobar* does not treat government knowledge as an automatic materiality bar. While continued payment with "actual knowledge" constitutes strong evidence against materiality, the Seventh Circuit found that genuine questions remained about what CMS actually knew, since the manufacturer's disclosures had not fully explained the financial impact of its pricing methodology.

> ***Courts have emphasized that plaintiffs must plead specific, non-conclusory facts demonstrating that the challenged conduct was significant in scope or substance, and they have rejected attempts to satisfy this requirement through generalized assertions or conclusory labels.***

The "Essence of the Bargain" Analysis

Courts have also continued to refine the inquiry into whether alleged noncompliance went to the "essence of the bargain," or was instead "minor or insubstantial," another materiality factor identified in *Escobar*. Courts have emphasized that plaintiffs must plead specific, non-conclusory facts demonstrating that the challenged conduct was significant in scope or substance, and they have rejected attempts to satisfy this requirement through generalized assertions or conclusory labels.

In ***Manley v. HCA Holdings, Inc.***, the district court dismissed FCA claims premised on allegations concerning false HITECH Act meaningful use attestations involving a single patient, rejecting the relator's conclusory assertion that the conduct was widespread or went to the "essence of the bargain."[83] The district court emphasized that isolated incidents, without factual allegations showing a broader scope or significance, "cannot be sufficiently significant or major to establish materiality."

At the same time, courts have cautioned against unduly narrow definitions of the "bargain" itself. In ***U.S. ex rel. Gonite v. UnitedHealthcare of Georgia, Inc.***, the district court held that alleged violations of Medicare marketing regulations could be material even though they did not directly affect the provision of medical services, reasoning that the requirements influenced beneficiary choice and protected program integrity.[84] Courts have likewise looked to contractual obligations—such as those found in provider agreements—that expressly tie compliance to payment or identify a requirement as material, reasoning that such provisions may go to the core of the parties' bargain even when the conduct at issue did not independently violate a statute or regulation.[85]

80 579 U.S. 176 (2016).
81 2025 WL 2782576 (S.D. Ind. Sept. 30, 2025).
82 152 F.4th 816 (7th Cir. 2025).
83 2025 WL 1707678 (D.D.C. June 17, 2025).
84 785 F. Supp. 3d 1325 (M.D. Ga. 2025).
85 *See U.S. ex rel. Conrad v. Rochester Reg'l Health*, 2025 WL 1651787 (W.D.N.Y. June 11, 2025) (concluding that a requirement was "essential" and went "to the heart" of the parties' bargain because a provider agreement "specifically address[ed] this issue and linked it to payment" and expressly characterized the requirement as "material").

Government statements and guidance may also inform the "essence of the bargain" analysis when they directly address the importance of the challenged conduct.[86] Still, courts have remained reluctant to infer materiality from more generalized agency statements, reinforcing that the inquiry remains highly context specific.

In sum, recent decisions continue to confirm that *Escobar*'s materiality standard may operate as a significant limitation on FCA liability. Courts remain focused, however, on whether alleged noncompliance had practical significance to the government's payment decisions, was substantial rather than isolated or insignificant, and went to the core of the parties' bargain. These considerations are likely to remain central to FCA litigation involving healthcare providers.

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.

Rule 9(b) does not require plaintiffs to prove their case in a complaint, but in order to survive a motion to dismiss, courts agree that Rule 9(b) requires factual specificity regarding the alleged fraud scheme. Courts have consistently held that the mere potential for fraud will not suffice to support an inference that such fraud actually occurred under the particularity requirements set forth in Rule 9(b).

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, courts agree that Rule 9(b) requires factual specificity regarding the alleged fraud scheme. Courts have consistently held that the mere potential for fraud will not suffice to support an inference that such fraud actually occurred under the particularity requirements set forth in Rule 9(b).

For example, in ***U.S. ex rel. Collado v. Bracco USA, Inc.***, the Third Circuit affirmed dismissal of a complaint alleging a fraudulent scheme where a manufacturer of imaging products entered into agreements with medical facilities for free machinery in exchange for a guaranteed 90 percent purchase volume of their imaging agents.[87] The Third Circuit held that the relator had not met the pleading requirements under Rule 9(b), and that although he had described how the free products *could have been used* to defraud the government, a "mere opportunity for fraud will not suffice." The Third Circuit highlighted that the relator had not pleaded any reliable indicia of fraud, and that his reliance on the medical facility agreements attached to his complaint did not meet Rule 9(b)'s requirements where those agreements could have a legal or illegal explanation.

Likewise, in ***U.S. ex rel. Jensen v. Genesis Lab.***, the district court dismissed the relators' complaint, finding that the relators failed to plead with particularity the "when" and "how" of the purported fraudulent scheme.[88] In their amended complaint, the relators alleged that the defendant provided clinical testing and diagnostic labs and submitted claims for services that were medically unnecessary by bundling necessary and unnecessary tests, along with other alleged schemes. The district court found the relators' allegations regarding marketing materials for unnecessary medical testing only established the potential for fraud, which did not suffice under Rule 9(b). The district court further determined that it was insufficient for the relators to state that the fraud ran through February 2020, without specifying a time period when they believed the fraud began or how long it lasted.

Courts also emphasized Rule 9(b)'s requirements that claims must be pleaded with particularity as to each defendant and that group pleading is insufficient to meet the more stringent standard of Rule 9(b). In ***U.S. ex rel. Nicholson v. Clarksville Pain Inst., LLC***, the government intervened in an underlying *qui tam* action alleging FCA violations with respect to certain allergy, urine drug and psychological testing rendered by a pain clinic operated by two distinct entities that eventually merged and were allegedly managed by the individual defendants.[89] Applying Sixth Circuit precedent, the district court dismissed the government's claims asserted against both the individual and the entity defendants, emphasizing that Rule 9(b) bars "group pleading," and requires each defendant's role to be distinctly pleaded. With respect to the individual defendants, aside from alleging broad oversight and control of the entity defendants and a close tracking of the financial performance of the company, the district court found that the allegations were too conclusory and lacked specific facts to

86 *See U.S. ex rel. Aharon v. Nuvance Health, Inc.*, 2025 WL 968583 (S.D.N.Y. Mar. 31, 2025) (concluding that "statements made by CMS in connection with [a National Coverage Determination] strongly suggest[ed] that CMS view[ed]" a particular requirement "as an important part of the procedure").

87 2025 WL 1261779 (3d Cir. May 1, 2025).
88 2025 WL 615480 (D.N.J. Feb. 26, 2025).
89 2025 WL 727901 (M.D. Tenn. Mar. 6, 2025).

show how the individual defendants caused the submission of false claims. Regarding the entity defendants, the district court found that the complaint failed to allege with particularity the existence of fraudulent schemes or a causal connection between the alleged schemes and the submission of false claims and instead fatally relied on "vague and ambiguous communications the context for which is not explained."

Conversely, in ***U.S. ex rel. McCullough v. Anthem Ins. Companies, Inc.***, the district court found that the relators had adequately pleaded their claims against a number of hospital defendants and had not engaged in impermissible group pleading under Rule 9(b).[90] The district court highlighted that the relators had alleged violations by each of the hospital defendants separately, and that even though the complaint referred to them as a collective, the substance of the complaint itself detailed specific violations by each individual hospital defendant, how many claims they allegedly submitted and how much money each received due to their respective violations. The district court ultimately granted the motions to dismiss for failure to plead materiality, but provided leave to amend for certain of the claims.

In addition to group pleading, courts have found that complaints fail to meet the particularity standard set forth under Rule 9(b) when they fail to identify a nexus between the purported fraudulent conduct and the submission of false claims. For example, in ***U.S. ex rel. Winnon v. Lozano***, the district court dismissed a complaint that alleged a skilled nursing home, its operators and providers had engaged in two distinct fraudulent schemes.[91] The district court found allegations suggesting that payments by the defendants in the forms of bonuses, "sham" medical directorships and marketing gifts were made in exchange for patient referrals to skilled nursing facilities fell short of what was required by Rule 9(b). The district court emphasized that the relator failed to provide a nexus between the medical directorship agreements and the claims submitted. Although the district court found the relator's allegations regarding marketing gifts closest to meeting the requirements of Rule 9(b) and conceded that the relator provided some details in her complaint about those gifts, the district court found the relator's failure to connect those details to the submission of false claims fatal.

In ***U.S. ex rel. Gordon v. Shiel Medical Laboratory***, the district court emphasized that the Second Circuit employs a relaxed interpretation of Rule 9(b) where the relators "mak[e] plausible allegations … that lead to a strong inference that specific claims were indeed submitted" and where the particular facts are otherwise within the opposing party's knowledge.[92] Despite this, the district court found that the relators had failed to plead any facts to show that the invoices or bills at issue were uniquely within the knowledge or control of the defendants and that where the relator held a senior position and could identify examples of false claims, he "must do so at the pleading stage."

Moreover, courts have consistently struck down claims that are conclusory in nature and fail to connect the dots as to how alleged conduct amounts to a kickback. For instance, the relators in ***U.S. ex rel. Amine v. Team Health Holdings, Inc.***, alleged that a physician and Team Health engaged in a fraudulent medical billing scheme to increase Team Health's revenue, which led to higher bonuses for the physician.[93] The district court dismissed the relators' FCA claims where the relators failed to identify a specific false claim that was presented to any governmental agency and likewise failed to plead sufficient facts to create a strong inference. The relators argued that the amended complaint's inclusion of patient forms, which contained attestations by patients that they were not seen by the physician despite charts of those patients containing unidentified medical notes, was sufficient to create an inference that false claims were submitted. The district court disagreed, finding that the relators had provided no information as to how a note on the patient chart would lead to the submission of a false claim.

In ***U.S. ex rel. Omni Healthcare, Inc. v. Exagen, Inc.***, the relator and medical professional group Omni filed a *qui tam* lawsuit against Exagen—a developer of testing products for autoimmune diseases—alleging a scheme to induce physicians to refer patients for their autoimmune testing products, in violation of the AKS.[94] The United States intervened and entered into a settlement agreement with Exagen pertaining to certain "Covered Conduct." The relator, in its proposed amended complaint, alleged that Exagen's illicit scheme went beyond its physicians and extended to certain contractors, such as phlebotomists and laboratories. The district court, however, denied the relator's leave to amend, finding that the allegations were conclusory in nature and failed to explain how the reimbursements to contractors amounted to kickbacks, or how the alleged "scheme with third-party contractors relate[d] to the unlawful physician referrals."

Courts remain skeptical when complaints seek to extrapolate specific alleged conduct to a nationwide scheme. In ***U.S. ex rel. Wheeler v. Acadia Healthcare Co., Inc.***, the Fourth Circuit reversed a district court decision dismissing a relator's complaint alleging that Acadia and its subsidiaries engaged in fraudulent activities by creating false therapy notes for methadone assisted treatments that did not occur.[95] The Fourth Circuit found the relator's allegations tying the conduct she witnessed at the Asheville location to other North Carolina facilities were sufficient to allege a scheme, where the state-wide clinical director for Acadia affirmed that fraudulent group notes were being used across the state. The Fourth Circuit, however, found that the relator's complaint fell short of extending the allegations about the North Carolina practices to a nationwide scheme and that the relator's reliance on corporate policies in order to do so was insufficient under Rule 9(b).

In ***U.S. ex rel. Wilkerson v. Allergan Ltd.***, the relators alleged that a pharmaceutical company engaged in a nationwide scheme to provide illegal kickbacks to doctors to increase the prescribing rate of two of its drugs.[96] The relators alleged that this was done through a sham speaker program that allowed Allergan to ply doctors with cash, food and other gifts to incentivize them to increase prescription rates. The district court, applying Seventh Circuit precedent, recognized that while Rule 9(b) allows for some inferences supported

90 2025 WL 2782576 (S.D. Ind. Sept. 30, 2025).
91 146 F.4th 1197 (D.D.C. Aug. 12, 2025).
92 2025 WL 949432 (E.D.N.Y. Mar. 29, 2025).
93 2025 WL 760038 (E.D. Mich. Mar. 10, 2025).
94 2025 WL 959460 (D. Mass. Mar. 31, 2025).
95 127 F.4th 472 (4th Cir. 2025).
96 782 F. Supp. 3d 658 (N.D. Ill. Apr. 23, 2025).

> ***Like the Sixth Circuit, the Eleventh Circuit has dismissed FCA claims where relators failed to allege that a fraudulent scheme actually led to false claims being submitted to the government.***

by factual allegations, the relators' claims regarding an increase in prescribing rates for certain doctors after receiving payments from Allergan were insufficient to show that the submission of false claims "resulted from" the unlawful kickbacks. The district court further held that the relators failed to plead with particularity that physicians and pharmacies falsely certified compliance with the AKS, and that Allergan falsified attendance records for its physician-speaker presentations.

Pleading the Presentment of False Claims

Courts continued to emphasize the demanding nature of Rule 9(b), dismissing numerous FCA claims on presentment grounds. These cases underscore that alleging the submission of false claims with the requisite particularity remains a substantial hurdle, even under various formulations of a relaxed pleading standard.

The Sixth Circuit reiterated that it is not enough for the relators to allege a fraudulent scheme; they must also allege that a false claim was actually submitted and they may not rely on speculation to do so. In ***U.S. ex rel. O'Laughlin v. Radiation Therapy Servs., P.S.C.***, a former employee of a radiation and chemotherapy service provider brought FCA claims alleging that the defendants falsely represented that their services were supervised or performed by qualified physicians when billing Medicare and other federal healthcare programs.[97] For example, the relator alleged that the defendant billed for chemotherapy services at physician rates when no physicians were present. The relator attempted to use a "triangulating" method—comparing employment practices, master schedules and billing records—to argue that only two physicians were spread across three centers, making it impossible for a physician to be present at all times. But the Sixth Circuit was unpersuaded, affirming the district court's conclusion that the relator's claims were a "house built on sand," and finding that the master schedules were unreliable indicators of a physician's actual location and that the relator did not account for several locum physicians who worked at the centers.

The relator also cited testimony from other witnesses who alleged a "practice" of administering chemotherapy services without a physician present, but the Sixth Circuit found these statements insufficient to meet Rule 9(b) because they did not state how often this occurred, specify any dates or identify any patients who received chemotherapy services without a physician present. Ultimately, the Sixth Circuit held that "[s]peculation cannot support an FCA violation," and the relator failed to show that any false claims were submitted.

In yet another case, the Sixth Circuit made clear that the relators must allege meaningful insider knowledge of the alleged fraud to avoid dismissal. In ***U.S. ex rel. Olsen v. Tenet Healthcare Corp.***, current and former employees of Detroit-area hospitals brought FCA claims alleging their hospitals' parent company fraudulently billed the government for inpatient care that patients did not and could not receive.[98] The relators argued that, even without identifying the submission of specific false claims, they could rely on personal knowledge to satisfy their pleading requirements. The Sixth Circuit contrasted the relators' case with others where courts had determined that detailed personal knowledge of the payment scheme was sufficient. For example, the Sixth Circuit previously held that a relator's knowledge of the billing and treatment documentation related to the submission of requests for final payment to Medicare was sufficient to overcome her failure to identify the submission of a representative false claim.[99] In contrast, the relators in the case before the Sixth Circuit admitted they did not know which entity even keyed the bills, and thus fell well short of alleging the level of personal knowledge required to satisfy their Rule 9(b) burden.

In ***U.S. ex rel. VIB Partners v. LHC Grp., Inc.***, the relators brought an FCA claim alleging that the defendant submitted false patient data to exaggerate patient needs, thereby inflating Medicare reimbursement rates.[100] To satisfy their Rule 9(b) burden, the relators urged the district court to apply a relaxed Rule 9(b) standard because the defendant controlled key billing records. The Sixth Circuit, noting the "limited flexibility" of such an approach, held that the relators failed to present sufficient factual support for their claims because they failed to identify the dates of any claims or the amounts of those claims. Even when "relaxing" the Rule 9(b) standard, the Sixth Circuit held that relators still must identify the documents containing evidence of the false claims and that those documents are exclusively in the defendant's control.

Like the Sixth Circuit, the Eleventh Circuit has dismissed FCA claims where relators failed to allege that a fraudulent scheme actually led to false claims being submitted to the government. In ***U.S. ex rel. Vargas v. Lincare, Inc.***, the relators, former employees of a DME supplier, brought FCA claims alleging multiple fraudulent schemes, including systematic upcoding, routine waiver of copays and automatic shipments of unordered supplies.[101] The Eleventh Circuit found that only the upcoding scheme was pleaded with sufficient particularity because the relators identified specific claims with dates, amounts and billing codes. The Eleventh Circuit dismissed the relators' claims related to co-pay waivers and automatic shipments, noting that the relators failed to identify any specific false claims, claim numbers, billing codes, dates or reimbursement amounts.

97 148 F.4th 791 (6th Cir. 2025).

98 2025 WL 1166894 (6th Cir. Apr. 22, 2025).
99 *U.S. ex rel. Prather v. Brookdale Senior Living Cmtys., Inc.*, 838 F.3d 750 (6th Cir. 2016).
100 2025 WL 1103997 (6th Cir. Apr. 14, 2025).
101 134 F.4th 1150 (4th Cir. 2025).

Similarly, in ***U.S. ex rel. Senters v. Quest Diagnostics, Inc.***, the relator attempted to support her claim with personal knowledge of the alleged fraud, but the Eleventh Circuit found that her access to Quest's billing system did not translate to knowledge of actual false claims submitted to the government.[102] The relator, a former HR generalist who had worked in compliance, said her role included ensuring that Quest's billing to Medicare and Medicaid was for tests that were eligible for reimbursement. But the Eleventh Circuit concluded that her complaint "failed to provide any specific details regarding either the dates on or the frequency with which the defendants submitted false claims, the amounts of those claims, or the patients whose treatment served as the basis for the claims."

The Eleventh Circuit rejected a relator's request to proceed under a relaxed pleading standard in ***U.S. ex rel. McKoy v. Atlanta Primary Care Peachtree***.[103] The relator argued that she was entitled to a relaxed pleading standard because her position working at the front desk gave her sufficient insider knowledge about the alleged schemes and submissions of false claims to excuse her from providing representative claims. Specifically, the relator contended she had a "physical vantage" that let her see "many occurrences." The relator additionally alleged that she had "extensive conversations" with her mother, who was the former office manager and told her of "improper practices" with respect to Medicare and Medicaid billing. The Eleventh Circuit was unpersuaded, finding that the relator "isn't anything like" previous relators who were entitled to the relaxed standard because they either provided the services billed or knew of or worked in the defendant's billing department.

Beyond the Sixth and Eleventh Circuits, the Third Circuit examined whether the "possibility of a legitimate explanation undermine[d] the strength of the inference of illegality" in ***U.S. ex rel. Hunter v. Fillmore Capital Partners, LLC***.[104] The relator alleged that the defendant, an operator of nursing homes across the country, overbilled Medicare and Medicaid by intentionally admitting high acuity patients that required intensive care, while simultaneously understaffing facilities. The relator alleged that the defendant did not provide adequate care to residents, thus rendering claims for payment fraudulent. In support of his claim, the relator cited expert reports, personal experience and affidavits identifying understaffing and inadequate patient care. But the Third Circuit rejected his argument, finding this only indicated an *opportunity* for fraud, not that it was probable. Moreover, the Third Circuit explained that the nursing homes had a legitimate business reason for its low staffing decisions, which militated against any "strong inference" of fraud. Further, the relator's personal experience did not support his claim, either, because "overwork alone does not equate to false claims being submitted."

102 2025 WL 1951196 (11th Cir. July 16, 2025).
103 2025 WL 1823269 (11th Cir. July 2, 2025).
104 2025 WL 971668 (3d Cir. Apr. 1, 2025).

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

DEVELOPMENTS REGARDING FALSITY

FCA plaintiffs must plead and prove that claims were actually false to successfully state a claim for relief. As a result, defendants facing FCA claims often challenge the legal viability of theories of falsity asserted by the government or *qui tam* relators. Both appellate and district courts have continued to issue notable opinions concerning the FCA element of falsity.

With respect to factual falsity, courts continue to highlight the boundary between objective falsity and normative wrongdoing, and insist that factual falsity remain anchored to something verifiably untrue. In ***U.S. ex rel. King v. Harper's Pharmacy, Inc.***, the district court found that the relators adequately pleaded factual falsity where they identified specific examples with respect to an alleged scheme whereby the defendant pharmacy would bill for a particular drug but dispense another brand or formula.[105] With respect to additional schemes raised by the relators, the district court was unpersuaded and found that the relators did not adequately allege false certification because they failed to allege specific representations about goods or services provided.

In ***U.S. ex rel. McCullough v. Anthem Ins. Companies, Inc.***, the district court likewise found that the relators sufficiently alleged factual falsity. There, the relators alleged that Anthem, and other managed care and hospital entities, violated the FCA by wrongfully receiving and retaining Indiana Medicaid funds through improper payments and billing practices.[106] The district court cited that the defendants allegedly "submitted claims that violated basic hospital billing rules, were clearly not payable, and contravened Medicaid billing requirements" and highlighted that the second amended complaint "specifically states the applicable Medicaid billing requirements, . . . describes the algorithms used by IBM and what those algorithms were looking for . . . and then tied those violations back to each Defendant." The defendants challenged the IBM audit upon which the relators had relied to identify overpayments, arguing that the claims were merely "potentially false." The district court, however, held that the relators were not required to conclusively prove that overpayments occurred at the motion to dismiss stage of litigation, and that it was sufficient that the relators explained each billing

105 2025 WL 2684277 (C.D. Cal. Aug. 12, 2025).
106 2025 WL 2782576 (S.D. Ind. Sept. 30, 2025).

requirement they allege was violated, how the report was compiled regarding each alleged violation and identified a specific number of claims coinciding with the specific dollar amount that the defendants alleged to have misused.

Courts also continued to evaluate whether allegations regarding medical necessity satisfied the FCA's falsity element. In ***U.S. ex rel. Oak Bull, LLC v. Cedar-Sinai Medical Ctr.***, the relator alleged that Cedar-Sinai submitted or caused the submission of false claims under two theories of liability: (1) that the defendant physicians performed concurrent surgeries in violation of Medicare regulations and without obtaining adequate informed consent; and (2) that Cedar-Sinai submitted false claims for medically unnecessary artificial disc replacement surgeries.[107] The district court dismissed those allegations with prejudice, noting that the relator failed to specify whether the allegedly falsified operative reports were submitted to CMS or whether CMS paid any portion of the relevant claims. The district court further noted that although the conduct at issue may violate Medicare guidance, the relator failed to allege that a materially false claim was submitted to CMS.

In evaluating medical necessity claims, courts have continued to require that the allegations contain facts sufficient to explain what makes a particular service medically unnecessary. In ***U.S. ex rel. Shannon v. BHG Holdings, LLC***, the district court granted a motion to dismiss the relator's allegations that the defendant had engaged in fraudulent schemes to illegally bill Medicare and Medicaid for unnecessary and duplicative drug tests and utilized unlicensed counselors to perform services.[108] The district court held that the relator had not adequately pleaded falsity with respect to the alleged schemes. The district court found that the relator failed to plead facts indicating what made the drug tests medically unnecessary, had overlooked a statutory provision allowing for the use of unlicensed counselors in a substance abuse facility and lastly, had not pleaded any reverse false claims because the relator had not identified any payments that the defendant owed the government or that payment was obligated.

In ***U.S. ex rel. Devarapally v. Ferncreek Cardiology, P.A.***, the relator alleged that a cardiology practice and its physicians performed and billed for medically unnecessary procedures, such as cardiac catheterizations and stent placements, which were not reasonable or necessary according to expert testimony, and that the defendants knowingly submitted false claims by certifying medically unnecessary procedures as necessary.[109] The district court denied both parties' motions for summary judgment, finding a genuine dispute as to the falsity of the defendants' claims.

Courts have also continued to evaluate FCA theories of falsity premised on alleged express and implied false certifications. In ***U.S. ex rel. Streck v. Eli Lilly & Co.***, the relator alleged that Eli Lilly falsely reported lower average manufacturer prices (AMP) to the government for its drugs covered by Medicaid, resulting in underpayments from 2005 to 2017.[110] The district court granted the relator's motion for summary judgment, in part, as to the falsity of the AMPs and related certifications under the FCA, and denied the defendant's motions for summary judgment as a matter of law and for a new trial. On appeal, Eli Lilly argued that its AMP calculations were the result of a reasonable interpretation of the relevant legal framework, and thus, reasonable interpretations of the law cannot be "false." The Seventh Circuit rejected that argument, however, noting that Eli Lilly's manipulation of its AMPs and the corresponding rebate to the government, through its subsequent pre-planned claw-backs, were not objectively reasonable since it contradicted the plain text of the law, regulations, the underlying agreement and its purpose.

In ***U.S. ex rel. Carter v. Emergency Staffing Solutions, Inc.***, the district court rejected the defendants' argument that they could not be held liable under the FCA because a third-party billing vendor submitted claims on their behalf, holding that the submission of reimbursement claims by the third party was "reasonably foreseeable or anticipated as a natural consequence of Defendants' conduct."[111] The district court emphasized that the defendants staffed client hospitals with contracted physicians to provide billable services, marketed to those hospitals the increased revenue they could generate by utilizing the defendants' services, incentivized physicians to perform those services and then furnished the resulting incentivized documentation to a third-party billing company, which submitted Medicare claims on the defendants' behalf. Viewing the evidence of the defendants' business model—including cash incentives to physicians for referrals, rounds and discharges; internal correspondence; billing data; and other record evidence—in the light most favorable to the relator, the district court found a genuine dispute of material fact as to whether the

107 2025 WL 3035111 (C.D. Cal. Sept. 9, 2025).
108 2025 WL 958226 (D.D.C. Mar. 31, 2025).
109 2025 WL 871616 (E.D.N.C. Mar. 20, 2025).
110 152 F.4th 816 (7th Cir. 2025).
111 2025 WL 2432662 (N.D. Tex. Aug. 22, 2025).

defendants submitted, or caused to be submitted, legally false claims. The district court further concluded that this evidence, together with the requisite CMS form certifications, was sufficient to withstand summary judgment as to FCA claims premised on false certifications of compliance with the AKS.

The district court likewise denied the defendants' motion for summary judgment in ***U.S. ex rel. Butler v. Shikara***, where the defendant physician owned a primary care practice with ten offices specializing in servicing MA beneficiaries.[112] The defendant also owned and operated a Field Marketing Organization that contracted with insurance agents who sold MA plans and a Management Services Organization that contracted with and provided administrative services to primary care providers. The relators alleged that the defendant physician and the entities he owned received patient referrals that were tainted by kickbacks in the form of contractual commission payments and inflated provider rates, which violated Medicare marketing regulations. Denying the defendants' motion for summary judgment, the district court held that although the commissions and payments at issue may ordinarily be permitted if paid at fair market value, commissions paid to the physician's entities could constitute unlawful "remuneration" under the AKS because the physician owned those entities, and the AKS prohibits paying something of value "directly or indirectly" to providers for referral activity.

Relators have also survived challenges to pleading legal falsity. In ***U.S. ex rel. Conrad v. Rochester Reg'l Health***, a former physician assistant alleged that Rochester Regional Health violated the FCA by failing to report adverse events to the Vaccine Adverse Event Reporting System when submitting claims for payment under the COVID-19 vaccination program.[113] The district court held that the relator had not alleged factual falsity, but had sufficiently pleaded legal falsity under a false certification theory of liability as to requirements in the applicable provider agreements that required the disclosure of adverse events, which Rochester Regional attested compliance with when it submitted claims.

In ***U.S. ex rel. Aharon v. Nuvance Health, Inc.***, the relators alleged that the defendants failed to meet a National Coverage Determination (NCD) as to transcatheter aortic valve replacement (TAVR), which required joint coordination between a cardiologist and cardiac surgeon.[114] The relators alleged that the cardiac surgeons were relegated to minor roles or did not participate at all while cardiologists took the primary position, rendering any claims associated with TAVR procedures to be expressly and implicitly false. The district court denied the defendants' motion to dismiss, concluding that the relators adequately alleged falsity based upon their pleadings that there was no joint participation in the surgeries, and thus any certifications by the defendants to the contrary were "likely false."

In ***U.S. ex rel. Gonite v. UnitedHealthcare of Georgia, Inc.***, the relator alleged that the defendant submitted claims for MA beneficiaries who were not "validly enrolled" in the MA plan because the defendant violated Medicare marketing and HIPAA rules to enroll those patients in the plan.[115] The defendant argued that the relator failed to plead falsity because the relator did not challenge the accuracy of enrollment information or any information provided to CMS about the beneficiaries, and that the only cases allowing an FCA claim to proceed on the regulation at issue involved falsifying risk adjustment data. The district court rejected that argument, holding that the certification of "valid enrollment" was separate and in addition to the certification that the information provided was accurate, complete and truthful, and that the relator adequately pleaded falsity based on the valid enrollment certification.

In ***U.S. ex rel. Harrison v. Valley's Best Hospice, Inc.***, the relators alleged that the hospice company had a practice of admitting ineligible Medicare beneficiaries, which resulted from the company's aggressive targets for new patients by accessing medical records of patients of the non-hospice defendants and directly contacting patients without a physician referral, among other things.[116] The district court denied the defendants' motion to dismiss, holding that the relators sufficiently alleged facts to assert a claim of implied false certification for hospice eligibility.

In ***U.S. ex rel. Nunnelly v. Regeneron Pharmaceuticals, Inc.***, the government alleged that Regeneron fraudulently reported an inflated average sales price of a prescription drug by failing to deduct the credit card processing fees from the average sales price reimbursed to third-party distributors.[117] The district court found that the government adequately alleged falsity under an implied false certification theory as to compliance with applicable Medicare requirements.

In other cases, however, courts found a variety of instances where legal falsity was not adequately pled at the pleading stage. For example, in ***U.S. ex rel. O'Laughlin v. Radiation Therapy Servs., P.S.C.***, the relator alleged that the defendants falsely certified their compliance with Medicare rules by falsely representing that radiation services were either supervised or performed by qualified physicians.[118] The Sixth Circuit affirmed dismissal of the relator's claims because the relator failed to identify any requirement that the defendants violated with respect to the physicians' qualifications. The Sixth Circuit noted that the Medicare Claims Processing Manual provides that any physician may perform radiation services "regardless of the specialty of the physician who performs the service," and the relator failed to identify any statutory or regulatory violation that rendered the claims false.

Courts also found that failure to comply with certain policies was insufficient to constitute legal falsity, reflecting the view that implied false certification requires allegations of specific representations about goods or services provided. In ***U.S. ex rel. Hunter v. Fillmore Capital Partners, LLC***, the relator alleged that an operator of nursing homes overbilled Medicare and Medicaid by intentionally admitting high acuity patients who required intensive care while simultaneously understaffing facilities, leading to substandard care, inflated billing and billing for worthless services.[119] The Third Circuit dismissed the relator's amended complaint,

112 2025 WL 2506617 (S.D. Fla. Aug. 11, 2025).
113 2025 WL 1651787 (W.D.N.Y. June 11, 2025).
114 2025 WL 968583 (S.D.N.Y. Mar. 31, 2025).
115 785 F. Supp. 3d 1325 (M.D. Ga. 2025).
116 2025 WL 2043304 (C.D. Cal. July 10, 2025).
117 780 F. Supp. 3d 336 (D. Mass. Apr. 29, 2025).
118 148 F.4th 791 (6th Cir. 2025).
119 2025 WL 971668 (3d Cir. Apr. 1, 2025).

finding that it failed to allege express false certification where the complaint did not identify who submitted the fraudulent claims, what those fraudulent claims said, the locations where the claims occurred or which patients were impacted. The Third Circuit likewise found that the relator's conclusory and generalized language about failures to comply with certain policy violations was insufficient to allege implied false certification or identify a condition material to payment.

In ***U.S. ex rel. Wilkerson v. Allergan Ltd.***, the relators alleged that Allergan engaged in a nationwide scheme to provide illegal kickbacks to doctors in exchange for prescribing more of its drugs.[120] The relators alleged, among other things, that Allergan's payment of kickbacks to doctors resulted in false claims for prescriptions being presented to the government for payment and that the defendant violated the FCA by causing others to falsely certify compliance with the AKS as to those prescriptions. The district court partly granted the defendant's motion to dismiss because the relators' express certification theory allegations were insufficient in connecting certain form certifications necessary for physicians to be paid for providing physician services and claims for reimbursement for specific prescriptions. The district court noted that Rule 9(b) requires relators to explain "the who, what, when, where, and how" of their false certification theory, which the relators failed to do.

In ***Hall v. Abington Memorial Hospital***, the relators alleged that the defendant failed to obtain informed consent from its patients regarding the use of recalled sleep machine devices.[121] The relators argued that claims for services provided in relation to those machines were predicated on a false certification that such services were necessary. The district court granted the defendant's motion to dismiss and held that failure to obtain informed consent did not render claims false. The district court explained that the presence or adequacy of informed consent "sounds more in medical malpractice than it does in the FCA."

> ***Scienter is an essential element under the FCA. To establish scienter, the government or a* qui tam *relator must show that the defendant acted with actual knowledge, deliberate ignorance or reckless disregard that its claims were false.***

DEVELOPMENTS REGARDING KNOWLEDGE & SCIENTER

Scienter is an essential element under the FCA. To establish scienter, the government or a *qui tam* relator must show that the defendant acted with actual knowledge, deliberate ignorance or reckless disregard that its claims were false.

Two years ago, the Supreme Court decided ***U.S. ex rel. Schutte v. SuperValu Inc.***, which clarified that scienter turns on "what the defendant thought when submitting the false claim."[122] *Schutte* overruled several previous federal appellate court decisions granting dismissal to defendants who relied on an objectively reasonable interpretation of a particular legal rule to justify their conduct. Under *Schutte*, however, a defendant may not rely on an objectively reasonable interpretation as a defense, if that defendant subjectively believed its conduct violated the rule (or acted in conscious disregard of a substantial and unjustifiable risk that it could violate the rule) "when submitting the claim."

The impact of *Schutte* has been most felt by defendants at the motion to dismiss stage, where scienter needs only to be "plausibly" pleaded under the more general standards of Rule 8(a) of the Federal Rules of Civil Procedure.

Knowledge from Internal Complaints

Several courts considered allegations that relators, while employed by the defendants, personally raised concerns regarding false or fraudulent conduct.

For example, in ***U.S. ex rel. Olhausen v. Arriva Medical***, the district court considered a renewed motion to dismiss after the case was remanded for reconsideration from the Supreme Court in light of its intervening *Schutte* decision.[123] The relator, a former vice president at Arriva, alleged that the defendants submitted false claims by sending medical supplies to Medicare beneficiaries without collecting signed assignment of benefits forms from the patients. Arriva argued that under its "reasonable" interpretation of the applicable rules, it was allowed to submit mail-order supplies without collecting assignments because it was a "participating supplier" of the goods. The district court found that "participating supplier" was a "genuinely ambiguous" term, but applying *Schutte*, held that whether Arriva's interpretation was objectively reasonable was no longer dispositive. Instead, the district court looked to allegations about Arriva's subjective belief that it did not have to collect assignments. Although the district court ultimately dismissed the complaint on other grounds, it held that the relator's allegations that he personally told Arriva they needed to collect assignments, but that Arriva nonetheless instructed its sales staff not to discuss assignments on sales calls, were enough to allege scienter at the pleading stage.

120 782 F. Supp. 3d 658 (N.D. Ill. 2025).
121 2025 WL 777638 (E.D. Pa. Mar. 10, 2025).
122 598 U.S. 739 (2023).
123 787 F. Supp. 3d 1308 (S.D. Fla. 2025).

Similarly, in ***U.S. ex rel. Murphy v. TriHealth, Inc.***, the district court held that the defendants' former chief financial officer plausibly alleged scienter, where he alleged that the defendants' physician compensation arrangements took referrals into account despite his repeated warnings and the defendants' own internal policies requiring compliance with the AKS and Stark Law.[124] The district court found these to be plausible allegations that the defendants, "at minimum, recklessly disregarded whether their claims or certifications were false."

Knowledge from "Motive and Opportunity"

Courts also held that a defendant's knowledge could be pleaded through allegations that the defendant had both the "motive and opportunity" to submit false claims.

For example, in ***U.S. ex rel. Aharon v. Nuvance Health, Inc.***, a group of cardiac surgeons alleged that the defendants violated an NCD regarding TAVRs because they did not allow the surgeons to meaningfully participate in TAVRs—while interventional cardiologists performed "most, if not all, of the work."[125] According to the relators, the defendants allowed cardiologists to control the TAVR program and paid them lucrative work relative value units for the procedures in furtherance of a referral scheme that violated the Stark Law, and when the relators raised concerns about the TAVRs, they were threatened with termination. The district court held that, taken together, the defendants' actions against the relators and their financial "motive and opportunity" to disregard the NCD plausibly suggested that they acted with requisite scienter.

Likewise, in ***U.S. ex rel. Conrad v. Rochester Reg'l Health***, a physician assistant employed by the defendants alleged that they submitted thousands of COVID-19 vaccine claims without reporting adverse events as required for program participation. The relator alleged that after learning of the non-reporting, she took it upon herself to report the adverse events until the defendants prevented her from doing so and eventually fired her. In their motion to dismiss, the defendants argued that the relator's allegations amount to nothing more than differences in medical opinions and differences in interpreting reporting obligations. But the district court found that the relator's specific allegations—that the defendants' leaders knew reporting was a material requirement of their provider agreements, but told her to "dial back" her reporting—amount to "strong circumstantial evidence of recklessness." In addition, the district court found the relator's allegations that the defendants had removed vaccine information from a patient's death certificate, paired with alleged comments about prioritizing high vaccine numbers over safety monitoring, suggested "motive and opportunity" to commit fraud. Together, this was enough to plausibly plead scienter.

Knowledge from Outside Sources

In addition to internal complaints and financial motivation, courts also accepted allegations that defendants obtained requisite knowledge from outside sources, such as customers and industry publications and conferences.

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For example, in ***U.S. ex rel. Nunnelly v. Regeneron Pharmaceuticals, Inc.***, allegations regarding the customers' treatment of alleged discounts helped to show scienter. The government alleged that Regeneron fraudulently reported the average sales price of one of its drugs to CMS because Regeneron did not deduct the amounts it was reimbursing distributors for credit card processing fees, which acted as a price concession to providers purchasing the drug.[126] In seeking dismissal, Regeneron argued that, like shipping fees, the credit card fees did not need to be deducted and that the government's complaint failed to allege that Regeneron knew they must be deducted. The district court disagreed. The government alleged that Regeneron knew providers conducted "profitability" calculations that factored in credit card processing fees and that those providers considered the fee reimbursement a "discount." It also alleged that Regeneron received, but ignored, a Deloitte report indicating that the card processing fees were different from shipping fees in terms of price concessions. According to the district court, such allegations were enough to plead scienter.

Regeneron also argued that, even if it was required to deduct the reimbursement from the average sales price, it should not be held liable because its calculation was based on "reasonable assumptions," which is all that would be required by CMS guidance. The district court viewed the Supreme Court's decision in *Schutte* as foreclosing such an argument in light of the allegations about what Regeneron knew.

Industry knowledge was relevant in both ***Stenson v. Radiology Ltd.*** and ***U.S. ex rel. McCullough v. Anthem Ins. Companies, Inc.*** In ***Stenson***, the relator alleged that a radiology practice submitted claims for readings performed on consumer-grade monitors, which "did not meet minimum efficacy standards" and "were not 'reasonable and necessary' under the general Medicare statute."[127] The practice argued that there were no allegations that any of its physicians or employees knew that use of the consumer-grade monitors was not "reasonable and necessary," but the district court found the relator's allegations—that the practice attended industry conferences marketing diagnostic-grade devices, that its IT leadership tracked technology standards across the industry and that FDA approval of

124 2025 WL 2104279 (S.D. Ohio July 28, 2025).
125 2025 WL 968583 (S.D.N.Y. Mar. 31, 2025).
126 780 F. Supp. 3d 336 (D. Mass. 2025).
127 2025 WL 89751 (D. Ariz. Jan. 14, 2025).

equipment functioned as a baseline for the medical community—showed a substantial and unjustifiable risk that claims for readings on consumer-grade monitors were not "reasonable and necessary."

Likewise, in ***McCullough***, the relator, who was a director of Indiana Medicaid's Program Integrity Unit, alleged that the defendants were aware of their compliance obligations through his trainings and industry-wide bulletins.[128] The district court found that knowledge could be inferred from these circumstances at the motion to dismiss stage, where all the relator must allege within the Seventh Circuit is that the defendant "had reason to know of facts that would lead a reasonable person to realize that [they were] causing the submission of a false claim," or that the defendant "failed to make a reasonable and prudent inquiry into that possibility."

Scienter at Summary Judgment

Although it has become more difficult to obtain dismissal on a motion to dismiss, courts continue to apply the strict scienter requirements under the FCA where appropriate, including at summary judgment.

For example, the First Circuit in ***U.S. ex rel. Omni Healthcare Inc. v. MD Spine Sols. LLC*** affirmed summary judgment for a defendant laboratory, where the relator's primary evidence of scienter was an email in which one of the defendant's co-founders proposed asking their region's Medicare contractor for guidance on the medical necessity of certain testing.[129] In the relator's view, the email showed knowledge of false claims because the defendant recognized that it had a duty to seek guidance on medical necessity, but never did. The First Circuit rejected the relator's characterizations of the email as "all foam and no beer," explaining that because one co-founder at one time proposed seeking guidance on medical necessity, this did not reflect the defendant's awareness of a substantial and unjustifiable risk that its claims were false. To the contrary, the First Circuit found it unlikely that the defendant would bring the Medicare contractor's attention to the issue if it believed the tests were medically unnecessary.

Likewise, the district court in ***United States v. The Renovo Ctr., LLC***, relied on *Schutte*'s holding regarding a defendant's subjective beliefs to grant summary judgment in the defendant's favor.[130] In *Renovo*, the defendant owned a counseling service that allegedly billed for procedures it was not licensed to provide. Because the defendant testified that she was unaware of the billing requirements and stopped billing the procedures once she learned they were improper, the district court granted summary judgment. The district court held that a reasonable jury could not conclude that the government's scienter evidence—the number of violations, the percentage of the defendant's clients who were government beneficiaries and the defendant's general awareness of an applicable billing manual—showed the defendant's deliberate ignorance or reckless disregard for the truth.

In contrast to *Renovo* and *Omni*, however, the Fifth Circuit affirmed summary judgment in favor of the relators on scienter in ***U.S. ex rel. Montcrief v. Peripheral Vascular Assocs., P.A.***[131] There, the defendant, a vascular surgery practice, allegedly submitted false claims for services before those services were completed. The relators proffered emails showing the defendant's awareness of the applicable Medicare billing requirements and its concerns about related audit requests. The Fifth Circuit found this evidence sufficient to show that the defendant either consciously avoided taking steps to learn whether its claims were false or took a substantial and unjustifiable risk that they may have been false.

Scienter at Trial

In ***U.S. ex rel. Streck v. Eli Lilly & Co.***, the Seventh Circuit reviewed a jury's determination that the defendant drug manufacturer acted with scienter by excluding price increases from the AWP reported to the government.[132] The Seventh Circuit affirmed the award, holding that a jury could reasonably find that the defendant disregarded an unjustifiable risk of violating the law by allowing a middle-management employee to make an objectively unreasonable decision without any oversight. In so holding, the Seventh Circuit observed that, even post-*Schutte*, the defendant's "objectively unreasonable interpretation of the relevant law is highly probative circumstantial evidence of a culpable state of mind."

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.

The FCA's reverse false claims provision was analyzed in ***U.S. ex rel. Poehling v. UnitedHealth Group, Inc.***, as part of that long-running FCA litigation, when the court-appointed Special Master recommended that UnitedHealth was entitled to summary judgment on the government's reverse false claims allegations.[133] At issue was UnitedHealth's chart review program, in which coders would review medical charts to identify diagnosis codes that were supported by information in those charts. UnitedHealth would then submit these diagnosis codes to CMS, in addition to the doctor's diagnosis codes that were previously submitted to

128 2025 WL 2782576 (S.D. Ind. Sept. 30, 2025).
129 2025 WL 3442574 (1st Cir. Dec. 1, 2025).
130 2025 WL 2664082 (N.D.W. Va. Sept. 17, 2025).
131 133 F.4th 395 (5th Cir. 2025).
132 152 F.4th 816 (7th Cir. 2025).
133 2025 WL 682285 (C.D. Cal. Mar. 3, 2025).

CMS. The government alleged that UnitedHealth violated the reverse false claims provision by retaining payments from CMS for diagnosis codes that were submitted by the doctor but were not identified by UnitedHealth's coders in the chart review program.

The Special Master found that the government failed to present any evidence on two elements of the reverse false claims cause of action. First, the government had not presented sufficient evidence that there were overpayments because the government assumed that a diagnosis code was not supported by the medical chart if the code was not identified by the coder. The government's theory relied "entirely on speculative assumptions," including assuming that the UnitedHealth coders never made mistakes and coded perfectly. The Special Master recommended that the government could not carry its burden of proof because, without comparing the submitted codes to the medical records, "a jury would be required to speculate as to whether the diagnosis codes were actually incorrect."[134]

The Special Master again ruled in UnitedHealth's favor when she recommended denying the government's motion for partial summary judgment. The government argued that materiality was not an element of the reverse false claims' second prong for textual reasons: the language of the statute includes "material" in the first prong but omits similar language in the second prong. The Special Master disagreed, concluding that a materiality element must apply to the second prong of the reverse false claims provision because the reverse false claims action, like the FCA as a whole, incorporates the common law fraud elements, including materiality.

Analysis of the FCA's reverse false claim provision often focuses on the provision's relationship to traditional FCA violations. Courts dismissed reverse false claims allegations that mirrored the defendant's alleged traditional violations of §§ 3729(a)(1)(A) or (a)(1)(B) of the FCA.[135] However, in ***U.S. ex rel. Harrison v. Valley's Best Hospice, Inc.***, the district court rejected the defendants' argument that the relator's claim for reverse false claims allegation was redundant of their FCA claims.[136] According to the district court, in addition to their FCA claim, which was sufficiently alleged under Rule 9(b) to survive a motion to dismiss, the relators alleged that the defendants caused false certifications of eligibility to be made to conceal and avoid overpayment obligations. Alleging this additional fact meant that the relator had sufficiently pleaded a reverse false claims cause of action.

In considering reverse false claim violations, courts often must evaluate whether certain alleged conduct amounts to an "obligation." In ***U.S. ex rel. La Frontera Ctr., Inc. v. United Behavioral Health, Inc.***, United Behavioral was instructed by New Mexico Human Services Department (HSD) to withhold payments to 15 providers after reporting suspicious billing

> ***"The contours of who qualifies as an "original source" under the exception to the public disclosure bar for individuals who "voluntarily" disclose information before the public disclosure or "materially add" to the disclosure were also considered.***

activity, which HSD was investigating.[137] United Behavioral withheld $15 million when these payments were suspended. The relator alleged that a letter from the New Mexico State Auditor to the state legislature, criticizing HSD's investigation into the 15 providers, triggered United Behavioral's obligation to pay the withheld funds to the state. The district court rejected this argument because, with the State Auditor's letter, which was not addressed to United Behavioral and did not conclude whether the fraud allegations were credible, United Behavioral's "obligation remained merely potential and contingent," rather than established.

An established obligation, however, does not have to be enforced to sustain a reverse false claims cause of action. In ***U.S. ex rel. Wheeler v. Acadia Healthcare Co., Inc.***, the Fourth Circuit reversed the district court's dismissal of the relator's reverse FCA claim.[138] The defendant entered into a CIA with HHS, and the relator sufficiently alleged violations of the CIA, which contained a provision requiring the payment of $2,500 for each day the defendant violated the CIA. The defendant argued that there was no obligation because the government had the discretion not to enforce the penalties, thus making the obligation contingent. The Fourth Circuit rejected this argument because a "contracting party's discretion to enforce an obligation does not eliminate the existence of that obligation." The Fourth Circuit noted that this holding was limited to the terms of this specific CIA and was not an opinion on whether liquidated damages remedies generally would constitute an obligation.

And, in ***U.S. ex rel. Thomas v. Touchstone Behavioral Health***, the district court considered whether an "indirect" reverse false claims allegation could survive summary judgment.[139] The relator alleged that Touchstone identified a deferred revenue obligation to Mercy Care, a managed care organization that Touchstone contracted with, to receive federal funding to provide behavioral health services to eligible individuals. The relator alleged that this deferred revenue made Touchstone liable under the FCA's reverse false claim provision, but Touchstone argued that it did not have an "obligation" to the government because Mercy Care was responsible for Medicaid payments and overpayments, thus making the reverse false claims an "indirect" allegation. Citing case law in other circuits and legislative intent

134 The government also argued that mere avoidance of an obligation to repay, without evidence of any deceptive conduct, was sufficient to prove that UnitedHealth "knowingly and improperly" avoided its obligation to pay. This argument, the Special Master recommended, undermines the purpose of the "reverse FCA as the fraud statute that it is."

135 *See U.S. ex rel. Gordon v. Shiel Med. Lab.*, 2025 WL 949432 (E.D.N.Y. Mar. 29, 2025) ("Relator's attempt to base its reverse false claim theory on the same underlying conduct establishing its other FCA claims is futile."); *U.S. ex rel. Thomas v. Premier Home Health Care Servs., Inc.*, 2025 WL 3002967 (S.D.N.Y. Oct. 27, 2025) ("Because [the relator's] reverse false claims mirror his false claims under § 3729(a)(1)(A) and (B), he fails to state a plausible cause of action.").

136 2025 WL 2043304 (C.D. Cal. July 10, 2025).

137 2025 WL 1046748 (D.N.M. Apr. 8, 2025) (rejecting the relator's motion for partial summary judgment); 2025 WL 2256890 (D.N.M. Aug. 7, 2025) (granting United Behavioral's motion for summary judgment).

138 127 F.4th 472 (4th Cir. 2025).

139 774 F.Supp.3d 1179 (D. Ariz. 2025).

of the 2009 FCA amendments, the district court rejected Touchstone's motion for summary judgment—Touchstone's actions *could have* caused Mercy Care to impair its obligations to the government, which was sufficient to establish an issue of fact for trial.

PUBLIC DISCLOSURE BAR

The FCA's "public disclosure bar" deters relators from filing lawsuits based on information already in the public eye, subject to an exception for the relators who qualify as an original source.[140] Courts typically ask three questions to determine whether a relator's claims must be dismissed under the bar: (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.

Courts continued to refine the FCA's public disclosure bar, with decisions on what it means to "infer fraud" from public sources, reliance on federal data repositories, what sorts of court filings or government actions trigger the bar and the line between "puzzle-piecing" and parasitic repackaging. The contours of who qualifies as an "original source" under the exception to the public disclosure bar for individuals who "voluntarily" disclose information before the public disclosure or "materially add" to the disclosure were also considered.

When Do Public Sources Disclose "Facts From Which Fraud Can Be Inferred?"

Two decisions from the Ninth Circuit reinforced what must be included in a public disclosure for it to disclose a "fraud" and be considered "substantially similar" to a relator's alleged scheme.

In ***U.S. ex rel. 3729, LLC v. Evernorth Health, Inc.***, the Ninth Circuit reversed a dismissal under the FCA's public disclosure bar, finding the disclosures did not contain "facts from which fraud can be inferred."[141] The relator alleged that Express Scripts' mail-order pharmacy automatically overfilled 90-day prescriptions every 60 days, resulting in "flagrant and persistent overutilization." The district court dismissed the claims based on an *Army Times* article containing complaints about Express Scripts' program, including a complaint that a servicemember received 90-day supplies after 60 days, resulting in nine months' oversupply each year. Yet, the Ninth Circuit held that, while this article may have suggested "some" oversupplying occurred, it did not disclose the "flagrant and persistent" overfilling that the relator had alleged. Express Scripts also pointed to *Federal Register* comments criticizing potential waste from auto-shipping policies when drugs are shipped after they are no longer needed. The Ninth Circuit found the comments about potential waste from auto-shipping were both too general and insufficiently similar to the relator's alleged scheme of routine overfilling needed prescriptions. Accordingly, the Ninth Circuit held that the public disclosure bar was never triggered.

Roughly six months later, in ***U.S. ex rel. Sam Jones Co., LLC v. Biotronik, Inc.***, the Ninth Circuit reversed another district court dismissal on public disclosure bar grounds, focusing on the "level of generality" to apply in interpreting a prior disclosure.[142] Biotronik argued that a series of *New York Times* articles describing its strategies to increase market share by paying "consulting" payments, per-patient study fees and hiring relatives barred the relator's allegations of a "nationwide scheme" to employ close family members of physicians, including an exemplar arrangement where Biotronik hired a high-volume physician's brother as a sales representative and then paid the brother based on the number of implants used by the physician. The Ninth Circuit held that the *New York Times*' reporting on "generalized fraud across a swath of an industry"—even when it referenced Biotronik's practice of hiring family members—was not "substantially the same" as the complaint's allegations because the reporting did not describe the specific type of arrangement alleged, it did not specifically reference any hospitals in Southern California and it did not accuse Biotronik of violating the AKS or the Stark Law. The Ninth Circuit again concluded the FCA's public disclosure bar was not triggered.

Government Datasets

There were divergent decisions from district courts within the Ninth Circuit in relation to federal data repositories. In ***U.S. ex rel. Relator LLC v. Erskine***, the district court treated PandemicOversight.gov as a "federal report," concluding that the combination of the defendants' publicly disclosed mortgage lending codes (X), plus the Small Business Administration (SBA) rules categorically excluding mortgage lenders from receiving PPP loans (Y), together constituted a public disclosure of a "transaction" from which the alleged fraud (Z) could be inferred.[143] The district court emphasized that the database included borrower identity, loan amount, forgiveness status and industry classification, which, paired with the complaint's theory about categorical ineligibility for lenders, supplied the material elements to put the government "on notice to investigate."

140 31 U.S.C. § 3730(e)(4).
141 2025 WL 383801 (9th Cir. Feb. 4, 2025).
142 152 F.4th 946 (9th Cir. 2025).
143 2025 WL 796621 (S.D. Cal. Feb. 25, 2025).

By contrast, in ***United States v. Baxter***, the district court held that data from the same site, PandemicOversight.gov, was too "innocuous" to disclose either an "allegation" or a "transaction" because it did not contain a misrepresented state of facts juxtaposed with a true state of facts.[144] The difference was that the relator in *Baxter* did not allege that the defendants were categorically excluded from receiving a loan, but that they made material misrepresentations about their need for the PPP loans, which were not among the data disclosed on the website. As a result, the district court explained that the dataset did not contain facts from which fraud could be readily inferred.

Like the district court in *Erskine*, in ***U.S. ex rel. Akeel & Valentine, PLC v. Napleton Auto Group***, the district court dismissed a *qui tam* complaint where PandemicOversight.gov loan data and contemporaneous news articles together placed the "critical elements" of the alleged fraud in the public domain.[145] The relator alleged that the defendant car dealerships applied for PPP loans while falsely claiming that no "Associate" was under felony indictment. The district court held that the government could infer fraud from public SBA PPP loan certifications combined with reporting that an indicted executive exercised control, qualifying him as an "Associate" under SBA rules.

Court Filings & Government Investigations

Several courts analyzed the impact of prior court filings and government investigations on the application of the FCA's public disclosure bar.

In ***U.S. ex rel. Winnon v. Lozano***, the D.C. Circuit affirmed dismissal of a relator's complaint, in part under the FCA's public disclosure bar.[146] The former executive assistant and controller of a skilled nursing facility operator alleged that a contracted therapy services provider (RehabCare) artificially inflated patient therapy hours and intensities in order to push patients into higher reimbursement categories under Medicare's Resource Utilization Group system. The district court dismissed the relator's allegations because they were "substantially similar" to those previously disclosed in *U.S. ex rel. Halpin & Fahey v. Kindred Healthcare*.

On appeal, the D.C. Circuit rejected Winnon's arguments that she identified eight specific facilities that were not among the nationwide scheme alleged in *Halpin* and that her allegations spanned seven more months beyond the scheme alleged in *Halpin*. Additionally, the D.C. Circuit pointed to a CIA between HHS and RehabCare addressing the same misconduct and the government's press release announcing a settlement in *Halpin*. The D.C. Circuit concluded, "The who, what, when, and where of Winnon's allegations are a retread of *Halpin*, minor differences notwithstanding" and thus did not lead to a new inference of fraud.

A few months earlier, an opposite conclusion was reached by the district court in ***U.S. ex rel. Shannon v. BHG Holdings, LLC***, finding the public disclosure bar did not apply to the relator's allegations of medically unnecessary drug testing against a network of outpatient opioid treatment and recovery clinics.[147] The defendant argued that the district court should dismiss the allegations under the public disclosure bar because they were substantially the same as industry-wide allegations in *U.S. ex rel. Ashton v. Logan Labs., LLC*. Notwithstanding the defendant's "side-by-side chart" comparing allegations "copied verbatim" from *Logan Labs.* action, the district court held that Shannon's allegations as against BHG specifically were not in the public domain, reasoning that the existence of "public [ ] industry-wide allegations is not enough to bar Relator's suit."

In ***U.S. ex rel. Schnupp v. Blair Pharmacy***, the district court closely parsed the sequencing and nature of numerous court filings and touchpoints with government investigators in a *qui tam* action against a compounding pharmacy.[148] The first four schemes alleged in the relator's original complaint related to overbilling for certain drugs and beneficiary inducements. "Scheme 5," added in an amended complaint related to alleged AKS violations for improper payments to independent marketers. The district court summarized the key timeline: (1) in August 2015, a third-party marketer sued Blair Pharmacy for breach of their distributorship agreement, disclosing allegations consistent with Scheme 5; (2) in July 2017, the government obtained a search warrant in its criminal investigation of Blair Pharmacy's owner, which reflected awareness of the 2015 lawsuit; (3) & (4) in August 2017, the relator filed this lawsuit and the associated disclosure memorandum; (5) beginning in October 2017, the relator had numerous meetings with the government; (6) in August 2019, Mr. Blair was criminally indicted; (7) in March 2020, a superseding indictment included facts pertinent to Scheme 5; and (8) in December 2021, Mr. Blair pleaded guilty based on conduct pertaining to Scheme 5. As to Schemes 1–4, the district court held that there was no qualifying public disclosure before the 2017 complaint, so the bar did not apply. Specifically, the district court held that the 2015 civil suit was not a public disclosure because the government was not a party to the dispute between private parties. And, the subsequent search warrant application materials were confidential criminal investigative records, not disclosures in the public domain. The parties agreed, however, that a qualifying public disclosure occurred as to Scheme 5 in March 2020 through the filing of the superseding indictment.

In ***U.S. ex rel. Sorgi v. Jazz Pharmaceuticals***, the district court dismissed a complaint on public disclosure bar grounds, finding that ex parte patent prosecution dockets are "other Federal . . . hearing[s]" under § 3730(e)(4)(A)(ii) and that FDA Adverse Event Reporting System (FAERS) data, labeling and safety communications and news coverage together disclosed both the allegedly misrepresented and true state of facts.[149] According to the district court, the complaint merely added color and did not materially augment public information. The district court also rejected the relator's argument that he qualified as an original source because he used industry expertise to synthesize scattered public disclosures into the alleged fraud scheme; absent non-public, insider knowledge, the relator's exclusive reliance on information in the public domain was insufficient to defeat the public disclosure bar.

144 2025 WL 1343076 (N.D. Cal. May 8, 2025).
145 2025 WL 2930796 (N.D. Ill. Oct. 15, 2025).
146 146 F.4th 1197 (D.C. Cir. 2025).
147 2025 WL 958226 (D.D.C. Mar. 31, 2025).
148 2025 WL 375927 (D. Md. Jan. 28, 2025).
149 2025 WL 2701928 (D. Mass. Sept. 23, 2025).

By statute, an "original source" is an individual who either:

- **Voluntarily disclosed the information to the government before the relevant public disclosure; or**
- **"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.**

At the same time, courts were careful not to overextend the FCA's public disclosure bar where later allegations differ in kind, time or theory from prior public materials. In ***U.S. ex rel. Permenter v. eClinicalWorks***, the district court declined to grant summary judgment under the public disclosure bar on the relators' core "false ONC certification" theory.[150] Distinguishing an earlier government settlement involving different software versions and standards, the district court found that the cited websites and prior case did not disclose the specific alleged vulnerabilities or fraudulent inducement theory tied to Merit-based Incentive Payment System (MIPS) incentives. Thus, the record did not establish that the relators' allegations were "in their entirety" substantially similar to public disclosures.

Reliance on Expertise

The Ninth Circuit in ***Silbersher v. Allergan*** addressed when it is appropriate for a relator to rely on "expertise" to piece together public disclosures and reveal a fraud scheme.[151] The Ninth Circuit emphasized a prior decision that, if "scattered" public disclosures each contain a "piece of the puzzle," but fail to "present the full picture" when pieced together, then a relator may rely on expertise to identify a critical *missing* fact. The Ninth Circuit further explained that such "expertise" arguments are considered under the "substantially the same" portion of the analysis, not under the original-source exception. This would mean that if the relator were to concede that the public disclosure already provided all the facts needed to infer the fraud, then reliance on expertise would not overcome the bar; it would amount to a simple repackaging of what would already be public. That was the case in *Silbersher*, where the relator conceded that the relevant public sources (patent prosecution histories) contained facts from which fraud could be inferred. The Ninth Circuit declined to consider whether the relator was nonetheless an original source.

In ***United States v. Nelson***, the district court discussed a similar issue where it held that CMS claims data alone did not trigger the public disclosure bar because the alleged "patient recycling scheme" was neither "directly claimed" nor "readily inferred" from the just raw data. The district court, however, found the relator's expert analysis, combined with interviews of former employees and patient-level investigations, supplied the "missing pieces" that transformed otherwise inert public data into a coherent fraud theory.[152] After denying the motion to dismiss, the defendants sought interlocutory appeal arguing that the relator may not merely apply expertise and analysis to publicly disclosed data and that the fraud need not be "obvious" from the public sources. In rejecting the request, the district court explained that in the Ninth Circuit, the relator may clear the public disclosure bar by "stitching together" pieces of the puzzle to fill in the gaps from "scattered qualifying public disclosures," if doing so were to reveal a new material fact.

Appellate Review of Public Disclosure Bar Decisions

In ***U.S. ex rel. Fiorisce, LLC v. Colorado Technical Univ.***, the Tenth Circuit dismissed an interlocutory appeal from the denial of a motion to dismiss under the public disclosure bar, holding that the bar is not within the collateral-order doctrine because it does not provide a right to avoid trial and is non-jurisdictional.[153] The Tenth Circuit emphasized that post-judgment review adequately protects any interests served by the bar, rejecting efficiency and separation-of-powers arguments for immediate appeal.

Whether a Relator Is an Original Source

Even where a prior public disclosure is substantially similar to a relator's allegations, a relator nevertheless may proceed if the relator qualifies as an "original source." By statute, 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 a pair of cases relating to cellular licenses, the D.C. Circuit addressed what information can qualify as "materially adding to" the previously publicly disclosed material. In ***U.S. ex rel. O'Connor v. USCC Wireless Inv., Inc.***, the D.C. Circuit held for the first time that a "material" addition to the previous public disclosure is one that "is sufficiently significant or essential" to influence the government's decision to prosecute the fraud, joining the First, Sixth and Tenth Circuits.[154] The D.C. Circuit found that the relator did not satisfy this standard when he merely alleged a continuation of the previously disclosed fraud.

In a continuation of this analysis, in ***U.S. ex rel. O'Connor v. U.S. Cellular Corp.***, the D.C. Circuit addressed concerns about whether a complaint that discloses "substantially similar" conduct that is the subject of a public disclosure can simultaneously provide information that

150 2025 WL 1762264 (M.D. Ga. June 25, 2025).
151 2025 WL 325761 (9th Cir. Jan. 29, 2025).
152 2025 WL 1165863 (C.D. Cal. Mar. 25, 2025).
153 130 F.4th 811 (10th Cir. 2025).
154 128 F.4th 276 (D.C. Cir. 2025).

"materially adds" to the allegations under this new definition.[155] The D.C. Circuit answered in the affirmative, finding that an alternative conclusion would render the second prong of the original source exception as surplusage. The relator alleged fraudulent misrepresentation and concealed relationships between cellular companies that should have disqualified it from receiving bid credits for licenses auctioned by the Federal Communications Commission (FCC). The D.C. Circuit found that despite public reports, the relator added allegations that one of the companies at issue never actually functioned as an independent business, and that it made an undisclosed agreement to transfer licenses to U.S. Cellular through a merger after the unjust enrichment period had ended. The D.C. Circuit also joined the First, Second, Eighth and Tenth Circuits in agreeing that the public disclosure bar post-2010 amendments is no longer jurisdictional, but merely an affirmative defense.

In ***U.S. ex rel. Schnupp v. Blair Pharmacy***, the district court analyzed whether the relator qualified as an original source.[156] Its analysis focused on whether the disclosure memorandum filed by the relator prior to the filing of the *qui tam* complaint could be considered a "voluntary" disclosure to the government. As to the first issue, the district court cited the Second, Seventh and Tenth Circuits in concluding that the disclosure memorandum cannot be considered a "voluntary" disclosure, but that the relator's subsequent sixteen government interviews could constitute such a disclosure. In reaching that conclusion, the district court distinguished between circumstances where a relator was subpoenaed for the information or provided it only in exchange for immunity. Despite the voluntary nature of his interactions with the government, however, the district court found that the government already had the information it needed relating to the relator's allegations. The relator's interviews, however voluntary, did not materially add to the information that the government already retained regarding the criminal kickback scheme at the heart of the matter.

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."[157] 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.

The FCA provides that "[w]hen a person brings an action under this subsection, no person other than the Government may intervene or bring a related action based on the facts underlying the pending action." This relatively straightforward provision nonetheless has led to significant litigation in certain cases.

The Fourth Circuit affirmed dismissal under the FCA's first-to-file bar in litigation alleging fraud in connection with certifying patients for hospice in ***U.S. ex rel. Rosales v. Amedisys North Carolina, LLC***.[158] The Fourth Circuit applied the "material elements test," which bars a later suit "if it is based upon the same material elements of fraud as the earlier suit, even though the subsequent suit may incorporate somewhat different details." Despite saying that the complaints should be analyzed "claim-by-claim," the Fourth Circuit emphasized whether the earlier filed lawsuit alerted the government to the essential facts of the fraudulent scheme and not necessarily the identities of the defendants named in the complaints. The Fourth Circuit noted that it was among a minority of circuits holding that the first-to-file rule is jurisdictional and acknowledged that the Supreme Court has hinted to the contrary.

The Fourth Circuit's jurisdictional approach to the first-to-file bar was crucial to the district court's conclusion in ***U.S. ex rel. Goebel v. Anchorage SNF, LLC***.[159] The lawsuit had been transferred to a district court outside of the Fourth Circuit, where the relator faced a motion to dismiss for failure to state a claim based on the FCA's first-to-file bar, and the complaint survived that challenge. When the case was returned to a district court within the Fourth Circuit, the motion to dismiss was renewed and granted on jurisdictional grounds. The district court broadly interpreted and applied Fourth Circuit precedent, emphasizing the "material elements test" and whether the government had been put on notice of the fraud that was described in the later action, even if it involved different named defendants.

In ***U.S. ex rel. Olhausen v. Arriva Medical***, the district court dismissed the relator's complaint under Rule 12(b)(6), citing the FCA's first-to-file bar and res judicata.[160] There, it was the relator's own previously filed complaint on the same issues that barred the relator's subsequent complaint. The relator's second complaint was filed during the appeal of the dismissal without prejudice of the first complaint and relied on the same underlying facts as the previous complaint. Since the first case remained pending during its appeal, the new filing created a second suit on the same subject matter, a scenario the FCA seeks to avoid.

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."[161] 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.

155 153 F.4th 1272 (D.C. Cir. 2025).
156 2025 WL 375927 (D. Md. Jan. 28, 2025); 2025 WL 316112 (D. Md. Jan. 27, 2025).
157 31 U.S.C. § 3730(b)(5).
158 128 F.4th 548 (4th Cir. 2025)
159 2025 WL 2898087 (D. Md. 2025).
160 781 F. Supp. 3d 1315 (S.D. Fla. 2025).
161 31 U.S.C. § 3730(c)(2)(A).

Since the Supreme Court's decision in ***U.S. ex rel. Polansky v. Executive Health Resources***, confirming the broad authority enjoyed by the government with respect to the ability to intervene and dismiss *qui tam* lawsuits, we have closely monitored instances in which the government has exercised that authority. It is fair to say that exercise of that dismissal authority continues to be a relatively rare event; when that authority is exercised, however, it provides insight into what factors may lead the government to that result.

In ***U.S. ex rel. Khoury v. Mountain West Anesthesia***, the government exercised its dismissal authority after concluding that continued litigation by the relator was not in the interest of the United States. The assertion of that position followed more than four years of litigation by the relator and the defendants, culminating in the defendants' discovery that the relator had disclosed an expert whose expert report and expert opinions relied upon fabricated testimony and documents created by AI, including fabricated testimony from CMS in the very case at issue. The defendants moved for sanctions against the relator and his counsel for offering the expert opinions based on fabricated evidence, arguing that the relator was no longer a suitable representative of the United States in FCA litigation and that his counsel should be sanctioned for violations of various rules of professional conduct. During the pendency of that motion, the United States exercised its dismissal authority under § 3730(c)(2)(A), moving to intervene for purposes of dismissal, which the district court granted and brought an end to the multi-year litigation.

Courts otherwise continued to recognize the broad authority of the government when it moves to intervene for purposes of seeking dismissal of FCA litigation in cases in which the relator opposes dismissal. Appellate courts readily affirmed district court decisions granting the United States' motions to intervene and subsequent dismissals.

In ***U.S. ex rel. Vanderlan v. HMA, LLC***, the Fifth Circuit rejected the relator's argument that a *qui tam* relator is entitled to the procedural protection of an evidentiary hearing when faced with a motion to intervene for purposes of dismissal filed by the United States.[162] The Fifth Circuit reasoned that § 3730(c)(2)(A) requires only a hearing on the parties' briefs and not a "live hearing."

And, in ***U.S. ex rel. USN4U, LLC v. Wolf Creek Fed. Servs., Inc.***, the Sixth Circuit affirmed the district court's decision granting the United States' motion to intervene for purposes of seeking dismissal.[163] The motion followed proceedings in the district court in which the defendants asserted that the relator had violated the FCA's seal provision, and the district court conducted an in-person hearing on the issue in which it expressed concerns regarding the credibility of individuals associated with the relator. Following the district court's invitation to the United States to "take over this case or to conclude it by settlement or dismissal," the United States moved to intervene for purposes of dismissal, which the district court granted. On appeal, the Sixth Circuit easily rejected the relator's objection to the district court's ruling, concluding that the reasons offered by the United States for dismissal, namely,

the resources required to continue to monitor the action and its doubt that the relator could prove the underlying FCA violations, were sufficient to support the motion to intervene and dismissal. As in *Vanderlan*, the Sixth Circuit also rejected the relator's argument that an in-person hearing was necessary before the district court could rule on the United States' motion for intervention.[164]

Given the clear Supreme Court precedent in *Polansky*, we expect relators will continue to face an uphill battle in challenging motions for intervention and dismissal filed by the United States.

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.[165] 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.

162 135 F.4th 257 (5th Cir. 2025).
163 34 F.4th 507 (6th Cir. 2025).

164 *See also U.S. ex rel. CMB Export, LLC v. Tonopah Solar Energy, LLC*, 2025 WL 2029831 (D. Nev. July 18, 2025) (granting United States' motion for intervention in order to dismiss FCA litigation because of undue burden on the government despite the relator's assertion that the evidentiary record before the district court did not support that United States' stated basis for seeking dismissal).
165 *Cochise Consultancy v. U.S. ex rel. Hunt*, 587 U.S. 262 (2019).

In ***U.S. ex rel. Southard v. Kipper Tool Co.***, the district court focused very narrowly on the phrase "known by the official of the United States charged with responsibility to act in the circumstances."[166] The district court did not analyze the particular action for which the official had to have responsibility, but rather, it assumed that the necessary action was the filing of a fraud or FCA lawsuit or giving notice to DOJ so that it could do so. In this case, the 10-year limitation was not applicable because the requisite knowledge was not held by the General Services Administration (GSA) OIG, which could have alerted DOJ about a potential fraud and FCA lawsuit, but by the GSA Industrial Operations Analysts. In reaching that conclusion, the district court noted that some courts have held that only individuals within DOJ, rather than those within other agencies, qualify as responsible officials.

> ***Identifying the specific claims at issue during fact discovery can be critical to defending against FCA allegations, as relators and the government often seek to postpone that disclosure until expert discovery, creating the risk of late-stage disputes that can prejudice defendants.***

DISCOVERY DEVELOPMENTS

Discovery disputes remained front and center in FCA litigation. Court decisions scrutinized privilege assertions in multiple contexts, addressed when a relator must identify the false claims at issue, evaluated the temporal and substantive scope of discovery based on a relator's well-pled allegations and weighed defendant's challenges regarding the government's preservation of relevant evidence and the scope of civil investigative demand (CID) requests.

Assertions of Privilege

In a significant privilege ruling, the Sixth Circuit in ***In re FirstEnergy Corp.*** reversed a district court order that had compelled production of the results of two internal corporate investigations, holding that both the attorney-client privilege and work-product doctrine applied.[167] At issue were materials and information stemming from two criminal investigations that a company undertook in response to criminal bribery charges. Soon after the investigations concluded, shareholders sued the company in a securities class action and sought the fruits of those investigations. The district court ordered production of the materials from the investigations finding that: (1) the attorney-client privilege did not apply because the company initiated the investigations for business advice, not legal advice, and later used the fruits of the investigations for business decisions; and (2) the work-product doctrine did not apply because employment decisions and business concerns prompted the investigations.

In reversing the district court's decision, the Sixth Circuit criticized the district court's "substantial departures from bedrock privilege and work-product principles." The Sixth Circuit explained that there is no way to affirm the district court's ruling "without abandoning" nearly a half-century of jurisprudence since the Supreme Court's decision in *Upjohn*. Assessing attorney-client privilege, the Sixth Circuit found that the communications at issue were protected because they "all involved requested legal advice." Regarding the work-product doctrine, the Sixth Circuit noted that the district court overlooked "the realities of litigation" and concluded that the doctrine applied because the company "anticipated" it "would face government investigations, civil litigation, and regulatory proceedings," and that "anticipated legal risk became an actual legal risk."

The shareholders also made two waiver arguments. First, they argued that the company waived privilege by disclosing portions of the internal investigation in a deferred prosecution agreement and during civil litigation. The Sixth Circuit disagreed, explaining that even though the company "disclosed some information that also appears in the internal investigation, most of it was non-privileged," and parties do not waive attorney-client privilege or work-product protection by disclosing non-privileged material. Second, the shareholders argued that the company waived privilege by sharing thousands of documents from the internal investigation with its third-party auditor. The Sixth Circuit rejected this argument because: (1) the auditor's own memoranda noted that responsive documents had been withheld from the auditor on the basis of privilege; and (2) "[o]nly disclosures to an adversary would waive work product protection," and the shareholders had not established any adversarial relationship between the auditor and the company.

In ***U.S. ex rel. Langer v. Zimmer Biomet Holdings, Inc.***, the district court granted the defendant's motion to compel production of the relator's prefiling disclosure statements to DOJ, which the relator relied on to satisfy the original source exception to the FCA's public disclosure bar.[168] The relator argued that the statements were protected from discovery by the work-product and common interest doctrines. The district court first noted that the disclosures were "highly relevant" to evaluating both the applicability of the public disclosure bar and whether the relator qualified as an original source. In rejecting the relator's work-product arguments, the district court found that the relator failed to carry his burden to show the statements were protected opinion work-product and, at most, they constituted ordinary work-product subject to disclosure upon a showing of substantial need and undue hardship, which the defendant established after multiple unsuccessful attempts to obtain

166 2025 WL 2557211 (N.D. Ga. 2025).
167 154 F.4th 431 (6th Cir. 2025).
168 2025 WL 2529827 (D. Mass. July 31, 2025).

the substantial equivalent through other discovery. Because work-product protection was unavailing, the relator could not invoke a common-interest privilege, which presupposes a valid underlying privilege.

Identification of False Claims

Identifying the specific claims at issue during fact discovery can be critical to defending against FCA allegations, as relators and the government often seek to postpone that disclosure until expert discovery, creating the risk of late-stage disputes that can prejudice defendants.

In ***U.S. ex rel. Everest Principals, LLC v. Abbott Laboratories***, a magistrate judge compelled the relator to provide a complete list of allegedly false claims by the close of fact discovery, rejecting the relator's argument that expert analysis was a prerequisite and emphasizing that "the requested list of allegedly false claims is factual information that should be produced during fact discovery."[169] The magistrate judge further noted that the "[r]elator has not explained why it cannot identify all allegedly false claims" by the close of fact discovery, "despite receiving significant extensions to the discovery schedule" and possessing most claims data for many months. Regarding the need for experts, the district court stressed that the relator "has had sufficient time to provide" this information in response to the defendant's interrogatory requests, "with or without the assistance of experts" and "even if expertise is needed," the relator failed to explain "why its experts have not made sufficient progress on this work, considering it began receiving claims data" almost a year earlier. After the relator objected to this ruling, the district court affirmed the magistrate judge's decision.[170]

Scope of Discovery

In ***U.S. ex rel. Ashley Mothershed v. Mayo Clinic Ambulance***, the district court examined the temporal and substantive scope of discovery in a declined *qui tam* case where the relator alleged multiple ambulance billing upcoding theories.[171] As to temporal scope, the district court declined the relator's request to reach back the full ten-year limitations period and instead set discovery from two years before the relator's employment began through the date the relator filed the complaint, explaining that "[c]ursory or superficial references to ongoing or systemic fraud do not warrant discovery of fraudulent claims for an extended period." The district court invited a later motion to expand the period if discovery revealed earlier misconduct.

On the substantive scope of discovery, the district court reached differing conclusions in analyzing the two alleged schemes. First, concerning the alleged scheme of upcoding non-emergency transports to emergency transports, the district court concluded that discovery should not be limited to hospital-to-hospital transports, as the defendant argued, because the complaint described a wider pattern supported by specific examples and tied those allegations to the relator's personal knowledge and experience. Conversely, as to upcoding Basic Life Support (BLS) services to Advanced Life Support (ALS) services, the district court limited the scope to instances where the defendant "billed for an ALS service when an EMT-Basic assessed the patient *and* neither an ALS assessment nor an ALS intervention was performed," noting that beyond two representative examples, the complaint offered only conclusory assertions and no additional specifics—warranting a narrower, proportional scope.

Spoliation

The district court addressed a defendant's spoliation motion in ***United States v. Novo Nordisk, Inc.***, after it emerged, following fact discovery, that the state of Washington failed to preserve key records concerning reviews of patient prescriptions.[172] The government argued that the defendant was speculating about the "existence of certain notes" and that even if the documents did exist, they were legally irrelevant and "unlikely…subject to retention." The district court disagreed, finding that the government was "culpable in failing to timely preserve this evidence" for several years after issuing its first litigation hold because it "knew or should have known" that the documents "were relevant to potential litigation," and that the defendant was prejudiced because it lost the opportunity to prove that the government viewed the prescriptions as medically necessary, which would have been relevant to causation, materiality and damages. The district court, therefore, granted an adverse-inference jury instruction favorable to the defendant about the medical necessity of the prescriptions at issue.

Civil Investigative Demands

In ***Life Chiropractic Ctr., P.A. v. United States***, the district court denied a motion to quash or modify two CIDs served on the petitioner company's physician and office manager after the company had already responded to a prior CID.[173] In seeking to quash the CIDs, the company argued that they appeared to seek the same information as the earlier CID served on the company, which the company had already produced to the government. In denying the company's motion, the district court reasoned that the government's discretion is broad at the investigatory stage, the information requested was relevant, and the government is "not required to provide the target of a CID with any more information about the scope of its investigation or potential topics and questions than what is statutorily required."

For healthcare entities, this case serves as a reminder that challenges to CIDs may face steep hurdles. Where feasible, negotiating scope and sequencing—rather than litigating to quash—may more effectively mitigate burden while maintaining a constructive posture with the government.

169 2025 WL 1194078 (S.D. Cal. Apr. 24, 2025).
170 Everest, No. 20-cv-286 (S.D. Cal.), Dkt. 182 (Aug. 6, 2025 Order).
171 2025 WL 3043342 (D. Minn. Oct. 31, 2025).
172 2025 WL 1696881 (W.D. Wash. June 17, 2025).
173 2025 WL 1883734 (D. Idaho July 7, 2025).

FCA DAMAGES

Defendants held liable under the FCA face mandatory treble damages and per-claim civil penalties, which can yield extraordinary awards, particularly when violations involve large numbers of claims. The Constitution, however, provides a check on penalties through the Eighth Amendment's Excessive Fines Clause. Civil penalties 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 statutory penalties to actual damages.

Recent trials have resulted in extraordinarily high potential awards or damages and penalties. As a result, courts have undertaken the constitutional analysis of whether the Excessive Fines Clause should limit the civil penalties under the FCA in certain circumstances. Defendants have achieved only mixed results, as some courts have been willing to adjust penalties to well below the per-claim calculation associated with the FCA's statutory minimum, while others have approved sizeable FCA penalty awards.

In ***U.S. ex rel. Taylor v. Healthcare Assocs. of Texas, LLC***, the district court found that the statutory penalty of $450 million sought by the relator, based on the finding of 21,844 false Medicare claims, was excessive.[174] Indeed, the district court noted that the penalties would have been excessive even at the statutory minimum. Therefore, the district court adjusted the civil penalty down to $8.26 million, or a 3:1 ratio to the actual damages, which the district court said was the maximum permissible ratio under the Eighth Amendment in these circumstances. As to those circumstances, the district court emphasized that "this is not a case where the defendants billed for fictitious services," but rather concerned claims submitted "in violation of Medicare billing rules," which was similar to a "reporting offense." The district court ultimately entered a judgment of $16.5 million as a result of the FCA's statutory penalties and treble damages, greatly reduced from the $458 million sought.

On a larger scale, in ***U.S. ex rel. Bassan v. Omnicare, Inc.***, the district court approved a $542 million penalty that was well below the statutory minimum.[175] Because the per-claim amount applied to 3.34 million false claims, the civil penalty would have been at least $27 billion. Instead, the government proactively requested a reduced number, which reflected the 4:1 ratio of statutory penalties to actual damages that the Supreme Court has previously stated—in the punitive damages context—"might be close to the line of constitutional impropriety."[176] Although the district court noted that the statutory penalty was still "a very big number," it maintained that Congress clearly provided for both treble damages and an additional statutory penalty without a ceiling and emphasized that the violations were "both deliberate and egregious." Still, the district court noted that had the government not sought a reduced per-claim penalty on its own, the district court would have had to step in, as the $27 billion amount resulting from applying the per-claim minimum would have truly shocked the conscience and violated the Constitution.

Also noteworthy from *Bassan*, the district court held defendant CVS Health jointly and severally liable for a percentage of the per-claim penalties, reflecting the number of false claims submitted after CVS Health acquired defendant Omnicare, even though CVS Health was itself not found liable for any actual damages by the jury. The district court rejected the notion that this resulted in a penalties-to-actual-damages ratio that was "effectively infinite." Instead, it referred to the shared penalty as an "equitable solution" that held CVS Health liable for a share of the penalty where both defendants were found to have participated in the filing of roughly a third of the false claims. As a result, CVS Health was liable for $164 million in statutory penalties.

Not all courts this year were inclined to reduce awards based on the Excessive Fines Clause. In ***U.S. ex rel. Behnke v. CVS Caremark Corp.***, the defendants challenged not only the civil penalties ($4.87 million) but also the mandatory trebling of damages ($285 million) following a bench trial, as violating the Excessive Fines Clause.[177] In rejecting the defendants' arguments, the district court emphasized that treble damages under the FCA serve both remedial and punitive purposes and are expressly authorized by Congress to operate alongside per-claim penalties. The district court also stressed that the defendants' conduct was intentional and deceptive, involved the precise type of fraud the FCA is designed to prevent, and undermined public confidence in government programs. Viewing the combined award—approximately $290 million—as a whole, the district court concluded that it was not grossly disproportionate to the gravity of the offense and therefore did not violate the Excessive Fines Clause.

And in ***U.S. ex rel. Penelow v. Janssen Products, LP***, the district court approved a significantly larger statutory penalty of almost $1.3 billion.[178] The district court determined a per-claim amount of $8,000 and found no adjustment was necessary in applying that middle-

"Recent trials have resulted in extraordinarily high potential awards or damages and penalties. As a result, courts have undertaken the constitutional analysis of whether the Excessive Fines Clause should limit the civil penalties under the FCA in certain circumstances.

174 2025 WL 624493 (N.D. Tex. Feb. 26, 2025).
175 2025 WL 1865202 (S.D.N.Y. July 7, 2025).
176 *State Farm Mutual Automobile Ins. Co. v. Campbell*, 538 U.S. 408 (2003).
177 2025 WL 2404382 (E.D. Pa. Aug. 19, 2025).
178 2025 WL 937504 (D.N.J. Mar. 28, 2025).

of-the-statutory-range amount to the 159,574 demonstrated false claims. Similar to *Behnke*, the district court justified the penalty because the defendant's conduct was "deliberate and calculated" and "evidenced a pattern of misconduct." The district court noted that this penalty was more than a 10:1 ratio to the actual damages, but it maintained that the amount "both reflects the seriousness of the offense, and is not so grossly disproportionate to the jury's finding of actual damages that it would constitute excessive punishment or a breach of due process under the U.S. Constitution."

Because the number of false claims drives the magnitude of statutory penalties, defendants frequently challenge the claim count—particularly where claims were submitted by third parties rather than the defendant itself. These cases demonstrate, however, that such arguments face significant headwinds where the evidence shows that the defendant knowingly caused or substantially contributed to the submission of false claims. In *Taylor, Behnke and Penelow*, the defendants argued that many of the claims at issue were submitted by intermediaries or downstream actors, but those challenges failed based on fact-specific findings that the defendants designed, directed or benefited from conduct that predictably resulted in false claims. As the district court in *Penelow* put it, a defendant that "reaped significant benefits from its fraudulent conduct" cannot avoid liability by emphasizing that it was not the entity that physically submitted claims to the government.

FCA SETTLEMENT AGREEMENTS

An FCA action can be dismissed only if the district court and the U.S. Attorney General give written consent to the dismissal and state their reasons for doing so.[179] However, the statute is silent as to settlement agreements. To determine the effect of a settlement agreement on a relator's ability to bring FCA claims, courts examine the agreement's specific language and assess it in light of the FCA's dismissal requirements.

In ***United States v. Allen***, the district court reaffirmed the general rule that a post-filing release of *qui tam* claims is unenforceable.[180] The defendant argued that the relator had released all claims arising out of her employment—including FCA *qui tam* claims—by executing a severance agreement after filing an FCA action. In addition to releasing employment-related claims, the severance agreement provided that the relator waived "her right to receive any monetary relief from any action brought by her or on her behalf pursuant to the [FCA]." The district court rejected the defendant's argument. It acknowledged that some courts have enforced similar releases executed before a relator filed a *qui tam* action, when the government was already aware of the alleged fraud. The district court emphasized, however, that "such pre-filing releases do not implicate the same concerns" as post-filing releases, given the FCA's requirement that the government consent to dismissal of a pending *qui tam* action.

The district court also addressed the Sixth Circuit's decision in *State Farm Mutual Automobile Insurance Co. v. Angelo*, which "may have appeared to contemplate" the enforceability of a post-filing release.[181] The district court concluded, however, that *Angelo* was distinguishable because the relief sought there was narrow. In *State Farm*, the agreement required the defendant to "take all steps necessary" to dismiss the claims—language the district court interpreted as obligating the defendant to seek the government's consent, without which dismissal would have been impossible. By contrast, the severance agreement in *Allen* did not require the relator to take any steps to dismiss the *qui tam* action or any other proceeding.

In ***U.S. ex rel. Omni Healthcare, Inc. v. Exagen, Inc.***, the district court refused to prevent the relator from pursuing non-settled, non-intervened claims after the government settled the intervened claims.[182] The government had partially intervened and subsequently settled, releasing the defendant only with respect to conduct expressly covered in the settlement agreement. After the settlement, the defendant moved to dismiss claims in the amended complaint falling outside the defined Covered Conduct. The district court emphasized that the settlement agreement and dismissal order expressly limited the release to defined "Covered Conduct" and dismissed any remaining claims only without prejudice as to the government, thereby preserving the relator's ability to proceed on non-intervened claims. The district court further rejected the argument that the FCA categorically bars relators from continuing to litigate after a partial government settlement, noting that courts routinely permit relators to pursue non-released claims where the government has intervened solely for settlement purposes and otherwise declined intervention. Finding no authority to compel a different result, the district court allowed the relator to proceed on allegations beyond the settlement agreement's Covered Conduct.

ISSUES INVOLVING RELATORS

Constitutionality of the FCA's *Qui Tam* Provisions

As discussed in **Issues to Watch**, three current Supreme Court Justices have expressed skepticism about the constitutionality of the FCA's *qui tam* provisions, and the issue is currently winding its way through federal courts. In September 2024, the district court in ***U.S. ex rel. Zafirov v. Florida Medical Assocs., LLC***, held that the FCA's *qui tam* provisions violate the Constitution's Appointments Clause. Other district and circuit courts that previously considered this question uniformly found the FCA's *qui tam* mechanism to be constitutional.

The United States appealed the district court's decision to the Eleventh Circuit, making four core arguments: (1) relators do not exercise executive power but instead pursue a private interest in a share of the government's recovery, thus, they are not executive officers who need to be appointed; (2) the government retains authority over *qui tam* suits, even in declined cases, including the right to dismiss cases under 31 U.S.C. § 3730(c)(2)(A), providing

179 31 U.S.C. § 3730(b)(1).
180 2025 WL 1691628 (E.D. Ky. June 16, 2025).
181 95 F.4th 419 (6th Cir.), cert. denied, 145 S. Ct. 264 (2024).
182 2025 WL 959460 (D. Mass. Mar. 31, 2025).

> ***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.***

sufficient safeguards for relator-initiated suits; (3) relators are not "Officers of the United States" because they do not hold a "continuing position," rather, their role is limited and personal in nature, they receive no salary, have no access to government files and cannot be replaced by others if they withdraw; and (4) historically, Congress has enacted numerous statutes with *qui tam* devices, supporting the constitutionality of the FCA *qui tam* provisions.

Oral argument was held in December 2025. If the Eleventh Circuit were to affirm, the effects of such a ruling could be immediate and significant. Regardless of the outcome, the issue is likely bound for the Supreme Court. For now, DOJ continues to publicly encourage relators to bring FCA cases and there has been no slowing of relator-initiated FCA lawsuits.

Retaliation

The FCA protects whistleblowers from adverse employment actions related to their efforts to stop violations of the statute.[183] To establish a prima facie FCA retaliation claim, a plaintiff must show that: (1) they engaged in protected activity; (2) their employer knew that they engaged in 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 provide a legitimate, non-retaliatory reason for the adverse action, which the plaintiff can rebut by demonstrating it was pretextual.

Protected Activity and the Underlying Fraud

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.[184]

In ***Makela v. Apex Hospice & Palliative Care, Inc.***, a former hospice medical director brought an FCA retaliation action alleging she was terminated after only 43 days for refusing to certify certain prospective patients as eligible for hospice service.[185] In denying the defendant's motion to dismiss, the district court held that the plaintiff engaged in conduct intended and reasonably expected to prevent a suspected FCA violation by "repeatedly opposing Apex's attempts to admit patients who were ineligible for hospice care under Medicare" and "refusing to permit Apex to bill" by failing to provide the required certifications of eligibility. The district court further held that the plaintiff engaged in these refusals based on a "good faith belief" that the defendant was attempting to submit fraudulent claims for payment and focused on the close temporal proximity of the plaintiff's refusals and her termination in denying the defendant's motion to dismiss.

Similarly, in ***Zazzali v. VitalCore Health Strategies, LLC***, the district court found that the relator's refusal to engage in what they believed was a fraudulent scheme was enough to constitute protected activity.[186] The plaintiff brought a retaliation action after he was terminated from his job as the medical director of a healthcare provider contracted with the State of Vermont to provide services to incarcerated individuals. The termination occurred after the plaintiff refused to submit a signed version of a policy manual required by the state because of alleged violations of the policies he witnessed during his tenure. The defendant's motion to dismiss argued that the plaintiff failed to sufficiently plead protected activity but the district court found the plaintiff's complaints and refusal to sign the manual made it "difficult, or even impossible" for the provider to demand money from the State of Vermont under its contract and thus he had adequately pleaded protected activity and otherwise sufficiently stated a retaliation claim.

Courts generally review the question of protected activity with heightened scrutiny when the conduct constituting the protected activity is part of the employee's regular job duties. For example, in ***U.S. ex rel. Thomas v. Premier Home Health Care Servs., Inc.***, the relator alleged that he was terminated after repeatedly complaining to senior leaders about the need to disclose and repay various overpayments he uncovered in audits.[187] The district court granted the defendant's motion to dismiss the relator's retaliation claim, reasoning that the relator's discussions and presentations to leadership "were not directly aimed at uncovering fraud," and he failed to show his auditing and reporting activity went beyond the performance of his normal job responsibilities in his role of director of quality compliance.

In contrast, the district court denied the defendant's motion to dismiss the plaintiff's retaliation claim in ***Kirk v. Norton County Hosp.***, even though the alleged protected activity involved a hospital CEO reporting information he was duty-bound to report to the defendant's Board of Directors.[188] The district court reasoned that although some of the plaintiff's conduct could be viewed as flowing from his job duties, his decision to pursue remedies under the employee grievance procedure after the Board allegedly disregarded his complaints was reasonably viewed as outside the chain of command and thus would have put the Board on notice that he was not merely doing his job. The district court also noted the Board's

183 31 U.S.C. § 3730(h).
184 31 U.S.C. § 3730(h)(1).
185 2025 WL 343464 (N.D. Ill. Jan. 30, 2025).
186 2025 WL 1836968 (D. Vt. July 3, 2025).
187 2025 WL 3002967 (S.D.N.Y. Oct. 27, 2025).
188 765 F. Supp. 3d 1204 (D. Kan. Feb. 4, 2025).

response to the plaintiff's concerns was "telling," including alleged "social ostracism, a hostile work environment, mandatory training on disruptive behavior," all of which the court found to support knowledge the plaintiff was engaging in protected activity.

Employer Notice of Protected Activity

The second question in assessing FCA retaliation claims is whether an employer had knowledge that the plaintiff 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 protected activity occurred outside the scope of the employee's regular duties.

In ***Lewis v. AbbVie Inc.***, the plaintiff alleged that he informed his employer on multiple occasions that a program related to off-label use of an antipsychotic medication was "noncompliant," against "corp policy," and potentially illegal. The district court dismissed the case, and the Seventh Circuit affirmed on the grounds that the plaintiff's complaints did not "once suggest[] he feared defrauding the government," and thus his employer was not placed on notice of any protected activity.[189]

Relatedly, in ***Baier v. Community Home Health Care, Inc.***, the plaintiff, a registered nurse, was terminated after he reported to his employer that staff members were knowingly submitting false claims to the government for services not rendered by a registered nurse.[190] The district court agreed that at least one of the plaintiff's statements satisfied the standard for protected activity, but dismissed the case because the plaintiff failed to allege that he made any overt communication or otherwise gave reason for his employer to suspect that he intended to bring an FCA action or assist the government in an FCA investigation. The district court held, "[a]t bottom, the only conceivable notice of protective activity that . . . Defendant [received] was through a brief reference to 'defrauding the government' in one letter . . . that almost exclusively focused on ordinary workplace grievances. This is not enough to show that Defendant knew or had reason to suspect that Plaintiff was engaged in [] protected activity."

Several decisions also centered on whether defendant-employers were on notice of potential FCA liability when the protected activity arose in the context of a plaintiff-employee performing their assigned duties. In ***U.S. ex rel. Irizarry v. Innovative Technologies, Inc.***,[191] a case we discussed in 2024, the relator sought leave to file a second amended complaint after his original complaint was dismissed for failure to allege protected activity.[192] The CEO of the company tasked the plaintiff with conducting an audit of the company's compliance with certain labor laws. In denying the relator's request to amend, the district court held that

since the CEO had specifically tasked the relator with assessing compliance, his warnings of noncompliance, particularly since they never went outside his usual chain of command, could not have put the company on notice of potential fraud against the government.

The fact that a plaintiff-employee has regular auditing duties, however, is not always fatal to a retaliation claim. In ***Jefferson v. Sci. Applications Int'l Corp.***, the plaintiff, a cybersecurity professional tasked with ensuring compliance with security standards for a government defense contractor, alerted his management, corporate executives (including the CEO) and U.S. Air Force officials that his employer was engaging in "fraud, waste, and abuse" by falsely reporting compliance with internal security controls.[193] The employer argued that since the plaintiff's ordinary duties included reporting network security concerns, it was not put on notice that the plaintiff was engaging in a protected activity. In denying the motion to dismiss, the district court noted that although the plaintiff's position included an auditing component, his reports outside of traditional chains of command to executive leadership and U.S. Air Force personnel went "well beyond his normal duties," thus placing the company on notice he was engaging in protected activity.

Adverse Action Because of Protected Activity

The third element of FCA retaliation that plaintiffs must show is a causal connection between an adverse employment action and protected activity. If shown, the burden moves to the employer to articulate a nonretaliatory reason for the adverse action, which the plaintiff must then show is pretextual.

In ***Morgan-Lee v. Therapy Res. Mgmt., LLC***, the First Circuit upheld a jury verdict for the defendant where the defendant showed "multiple legitimate, nonretaliatory reasons" for the plaintiff's termination, emphasizing that a plaintiff "must establish that his or her activity

189 152 F.4th 807 (7th Cir. 2025).
190 2025 WL 2432399 (S.D. Ohio Aug. 22, 2025).
191 2025 WL 2298711 (D.D.C. Aug. 8, 2025).
192 2024 WL 4345827 (D.D.C. Sept. 30, 2024).

193 2025 WL 1305245 (D.D.C. May 6, 2025).

was a but-for cause of the alleged adverse action by the employer."[194] The First Circuit, along with the Third, Fourth, Fifth, Ninth, Tenth and Eleventh Circuits, requires "but-for" causation for FCA retaliation claims. Since the plaintiff failed to show by a preponderance of the evidence that her protected activity was a "but-for" cause of her termination, the First Circuit upheld the verdict.

Since retaliatory intent may not always be clear, courts sometimes find the temporal proximity of the protected activity to the adverse employment action to be determinative to the issue of causation, particularly where there are no intervening actions. In ***U.S. ex rel. Cooley v. ERMI, LLC***, the chief compliance officer agreed with company leadership to resign upon the end of the year after significant delays in obtaining a license to sell medical goods and services in Florida.[195] After the relator confided to the chief operating officer her intent to meet a lawyer to discuss a potential whistleblower suit, corporate leadership decided to accelerate the plaintiff's previously agreed-upon resignation date. In partially denying the defendant's motion for summary judgment, the district court noted that the acceleration of the impending resignation was enough to establish an inference of causation.

In contrast, the district court in ***Torres v. IAP Worldwide Servs., Inc.***, granted the defendants' motion for summary judgment when the plaintiffs could not show a direct causal link between the activity in question and the adverse action.[196] The plaintiffs, both engineers working for the United States government in Afghanistan, alleged they were terminated after complaining about fraudulent wage payments and equipment procurement. The district court granted summary judgment based on the failure to show a protected activity and, in the alternative, causation grounds, finding no reasonable jury could find that the defendants' decision to terminate the plaintiffs was retaliatory. The district court noted the existence of intervening events between the alleged protected activity and the plaintiffs' terminations, as well as a lack of evidence of temporal proximity between any protected activity and the terminations. Further, the district court noted that while the plaintiffs' briefs focused on asserting the defendants' rationale for their terminations was pretextual, they had failed to make the requisite prima facie case of retaliation to shift the burden to the defendants in the first place.

Employer-Employee Relationship

Modern healthcare companies often have layers of ownership and management. This year, multiple courts grappled with the question of who counts as an "employer" for purposes of the FCA's retaliation provisions. Courts generally find an "employment-like" relationship where corporate defendants have the capacity to exert some control over the plaintiff's continued employment.

In ***Nolan v. Post Acute Partners Mgmt., LLC***, the plaintiff brought an FCA action against a parent company that operated post-acute facilities and a healthcare management firm acquired by the parent company that owns and operates post-acute facilities, including the one where the plaintiff worked.[197] The district court dismissed the claims as to the parent company because the plaintiff had not alleged any plausible employer-related connection to the plaintiff personally or any day-to-day working relationship with her location. Similarly, in ***U.S. ex rel. Aharon v. Nuvance Health, Inc.***, the district court dismissed allegations as to three of four named defendants for failure to plead with particularity facts demonstrating how each defendant allegedly violated the FCA, finding the plaintiff's claims as to the three dismissed defendants were vague or overly reliant on their corporate affiliations with the appropriate defendant.[198]

In ***Panowicz v. Charter Health Holdings, Inc.***, a case arising in the private equity (PE) context, the FCA plaintiff, a former CEO of a home health and hospice company acquired by a PE-backed portfolio company, argued that the PE owner qualified as his employer under an integrated-enterprise, joint-employer or alter-ego theory.[199] The district court disagreed and dismissed the PE defendant from the action, finding the plaintiff had not stated a claim that the PE parent qualified as his employer under any legal theory. The plaintiff argued that three PE partners sat on the portfolio company's board of directors and provided "ongoing support and counsel" through "active board participation," but the district court found it was "not clear . . . how this corporate-speak goes beyond what a controlling shareholder and active board member would normally do." Further, although the plaintiff alleged he had "personally experienced" the PE company's control over the portfolio company's operational, financial and human resources decisions, the district court noted that he failed to provide any supporting allegations regarding the same.

194 129 F.4th 93 (1st Cir. 2025).
195 2025 WL 1840727 (N.D. Ga. July 2, 2025).
196 2025 WL 1106998 (E.D.N.C. Apr. 14, 2025).
197 2025 WL 1938666 (W.D.N.Y. July 15, 2025).
198 2025 WL 968583 (S.D.N.Y. Mar. 31, 2025).
199 2025 WL 2928963 (D. Neb. Oct. 15, 2025).

RELATORS' USE OF CONFIDENTIAL INFORMATION

In ***U.S. ex rel. Oak Bull LLC v. Cedars-Sinai Med. Ctr.***, a hospital defendant moved for sanctions based on allegations that the relator, an LLC whose principal was a physician affiliated with the hospital, unlawfully accessed confidential patient medical records and used the records to support its second amended complaint.[200] The district court agreed that the relator's improper access to patient records outside of proper discovery channels warranted sanctions. An audit of the defendant's records showed that the relator accessed at least twelve patient records using login credentials of operating room nurses during surgeries performed at the defendant's hospitals. Additionally, the relator used his own credentials to access a patient's medical records two days after a hearing on the defendant's motion to dismiss the first amended complaint. The district court ruled that the relator's accessing of the records did not fall under any whistleblower exception to privacy laws. As sanctions, the district court excluded the evidence obtained through the misconduct, granted injunctive relief prohibiting future unauthorized access and awarded attorneys' fees and costs to the defendant.

FOLLOWING THE FCA'S FILING REQUIREMENTS

The FCA requires *qui tam* relators to file FCA lawsuits under seal to allow the government an opportunity to investigate the allegations and determine whether to intervene in the lawsuit.[201] Where a relator fails to follow this procedural requirement, such a failure can jeopardize their ability to pursue the claims asserted in their complaint.

In ***U.S. ex rel. STF, LLC v. True Health Diagnostics, LLC***, the district court found that the relator's seal breach did not warrant dismissal of the *qui tam* action.[202] After the government sought and was granted a partial lift of the seal, the government alerted the court that the relator breached the partial seal when one of its members published a book disclosing the existence of the *qui tam* lawsuit prior to the government's intervention. The defendant moved to dismiss the case based on this breach, and the plaintiff and government opposed. The district court analyzed the breach under existing Ninth Circuit case law to determine: (1) the actual harm to the government; (2) the severity of the violation; and (3) any evidence of bad faith. The district court found no harm to the government, a low severity of the violation given the book's small success and no egregious bad faith warranting dismissal, and thus denied the defendant's motion to dismiss.

200 2025 WL 3034708 (C.D. Cal. Sept. 8, 2025).
201 31 U.S.C. § 3730(b)(2).
202 2025 WL 1550098 (E.D. Tex. May 30, 2025).

STARK LAW/ ANTI-KICKBACK STATUTE

The Stark Law and AKS remain essential parts of the government's enforcement efforts. Many FCA cases are premised on allegations that referral source financial arrangements violate the Stark Law or AKS. As described above in our summary of Noteworthy Settlements, many of these cases wind up in settlement, largely a reflection of the dynamics of FCA litigation. In this section, we note several cross-cutting themes from the past year's case law in which courts have considered essential elements of the AKS, with a particular focus on marketing and causation. We also highlight key developments involving the Stark Law and the Eliminating Kickbacks in Recovery Act (EKRA).

PERMISSIBLE ADVERTISING VERSUS UNLAWFUL REFERRALS UNDER THE AKS

Two appellate decisions marked the boundary between permissible marketing and unlawful referrals, holding that payments to advertisers who lack the power to steer healthcare decisions do not violate the AKS, whereas payments to those who make or influence healthcare decisions on behalf of patients can support an AKS violation.

In ***United States v. Sorensen***, the Seventh Circuit reversed the defendant's criminal AKS conviction, holding that payments to advertising and marketing companies—absent influence over healthcare decisions—do not constitute illegal kickbacks.[203] The Seventh Circuit adopted what has been called the "relevant decisionmaker" test, focusing on whether the payee was in a position to influence, control or make healthcare decisions or referrals. It held that the AKS "primarily targets payments to individuals with influence over or access to patients, such as physicians or others who can control or influence healthcare decisions." Because the advertising firms had no authority or informal influence over healthcare decisions, the payments did not support an AKS violation.

Importantly, the Seventh Circuit also clarified that percentage-based compensation structures are not automatically illegal under the AKS; the intent to induce unlawful referrals must also be present. The Seventh Circuit drew on Fifth Circuit precedent in *United States v. Miles*, which similarly held that payments to a public relations firm for advertising services did not violate the AKS because the firm lacked the position or authority to influence healthcare decisions.[204] The Seventh Circuit's opinion in *Sorensen* narrows the reach of the AKS for providers working with marketers and, by persuasive authority, provides ammunition for defendants elsewhere.

In ***United States v. Donofrio***, the Fifth Circuit considered two marketing arrangements, both involving commission-based payments to a distributor for marketing laboratory tests.[205] The second arrangement, however, also involved the distributor taking physicians' orders to one laboratory and redirecting them to a different laboratory. Applying the relevant decisionmaker test, the Fifth Circuit, like the Seventh Circuit in *Sorensen*, held that commission-based payments for marketing services, standing alone, cannot support an AKS conviction. But where, as in the second arrangement, the recipient becomes the relevant decisionmaker—by swapping the forms and redirecting the samples to a different laboratory—the payments can support an AKS conviction.

203 130 F.4th 493 (7th Cir. 2025).
204 360 F.3d 472 (5th Cir. 2004).
205 2025 WL 1443577 (5th Cir. May 20, 2025).

CAUSATION UNDER THE AKS

Courts continued to wrestle with questions of causation in AKS-based FCA claims. As discussed above, pursuant to an amendment made to the AKS by the ACA, a claim for items or services "resulting from" an AKS violation automatically "constitutes a false or fraudulent claim for purposes of [the FCA]."[206] What exactly is required to prove that a claim "resulted from" an AKS violation continues to divide courts, though a growing consensus favors a "but-for" causation standard.

The First Circuit was the most recent circuit court to address this issue in ***United States v. Regeneron Pharmaceuticals, Inc.***[207] Regeneron argued that a false claim "result[s] from" an AKS violation only if it includes items or services that would not have been paid for by the government absent the AKS violation. The First Circuit agreed, holding that "[d]emonstrating falsity under [the 2010 AKS amendment] requires the United States to show that [the] illicit kickback was a but-for cause of the submitted claim." The First Circuit reasoned that claims cannot "result from" a kickback "if that kickback had no causal impact whatsoever."[208]

District courts echoed this reasoning. In ***U.S. ex rel. Folse v. Napper***, the district court granted summary judgment where the plaintiffs' causation theory rested on speculation about contracting decisions without particularized proof that remuneration caused the claims at issue.[209]

Some courts that adopted the "but-for" standard also made clear that the government may still bring FCA claims based on alleged AKS violations through the false certification theory. As the First Circuit explained, the "but-for" versus proximate cause analysis arises from the "resulting from" language in the 2010 amendment, whereas civil enforcement of the AKS through the FCA predates that amendment.[210] FCA theories grounded in express or implied false certification can proceed without demonstrating "but-for" causation, so long as they satisfy *Escobar's* materiality standard.[211]

206 42 U.S.C. § 1320a-7b(g).
207 128 F.4th 324 (1st Cir. 2025).
208 *See also U.S. ex rel. Flanagan v. Fresenius Med. Care Holdings, Inc.*, 142 F.4th 25 (1st Cir. 2025) (affirming dismissal where relator failed to plead but-for causation).
209 2025 WL 2585680 (M.D. Tenn. Sept. 5, 2025).
210 *See also U.S. ex rel. Murphy v. TriHealth, Inc.*, 2025 WL 2104279 (S.D. Ohio July 28, 2025) (recognizing that some FCA theories "depend exclusively" on AKS violations and therefore implicate the § 1320a-7b(g) but-for causation standard); *U.S. ex rel. Solano v. Joint Technology, Inc.*, 2025 WL 978223 (N.D. Okla. Mar. 31, 2025) (recognizing both the § 1320a-7b(g) pathway and false-certification theories).
211 *See U.S. ex rel. Carter v. Emergency Staffing Solutions, Inc.*, 2025 WL 2433526 (N.D. Tex. July 31, 2025).

THE BOUNDARIES OF REMUNERATION UNDER THE AKS

The government and relators have continued to push for a broad understanding of "remuneration," consistent with longstanding OIG guidance that anything of value can qualify. At the same time, some courts emphasized that not every benefit is remuneration and cautioned against criminalizing ordinary commercial interactions absent a transfer of value and evidence of an inducement purpose.

For example, in *Napper*, although the district court ultimately found that the arrangement at issue—one in which free dental services were provided to certain residents of long-term care facilities—constituted remuneration to the defendants, the district court noted the limits placed by the Sixth Circuit in *U.S. ex rel. Martin v. Hathaway*[212] on how expansively the term should be construed, namely that remuneration means "just payments and other transfers of value," not any act of value or benefit.

INDIRECT COMPENSATION ARRANGEMENTS UNDER THE STARK LAW

Few decisions in the past year involved substantive consideration of the Stark Law. One that did is ***U.S. ex rel. Murphy v. TriHealth, Inc.***, in which the relator alleged that a health system, its hospitals and its physician group engaged in a scheme to pay employed physicians compensation in amounts that exceeded fair market value and that took into account their referrals to TriHealth hospitals.[213] According to the complaint, TriHealth leadership compiled proformas to make employment decisions and to set physician compensation based on projected profits from physician referrals. These proformas "regularly included financial losses on the 'physician practice side' offset by projected hospital profits from physician referrals." The resulting losses were then subsidized by TriHealth and its hospitals because, as TriHealth's CFO allegedly stated, the subsidies would "ultimately benefit the hospital side of the business."

> ***The government and relators have continued to push for a broad understanding of "remuneration," consistent with longstanding OIG guidance that anything of value can qualify. At the same time, some courts emphasized that not every benefit is remuneration and cautioned against criminalizing ordinary commercial interactions absent a transfer of value and evidence of an inducement purpose.***

The district court found that these allegations plausibly alleged an indirect compensation arrangement that could not satisfy an exception under the Stark Law. Applying the then-applicable regulatory framework, the court held that Murphy had alleged: (1) an unbroken chain of financial relationships between referring physicians and the entity providing referred services; (2) that an entity in the chain paid the referring physicians aggregate compensation that "varies with, or takes into account, the volume or value of referrals;" and (3) that the entity providing referred services had actual knowledge of (or acted in reckless disregard of) the compensation arrangement. Quoting the Fourth Circuit opinion in *U.S. ex rel. Drakeford v. Tuomey Healthcare Sys.*,[214] the district court emphasized that "[i]t stands to reason that if a hospital provides . . . compensation to a physician that is not based solely on the value of the services the physician is expected to perform, but also takes into account additional revenue the hospital anticipates will result from the physician's referrals, that such compensation by necessity takes into account the volume or value of such referrals."

Because the district court held that the relator plausibly alleged an indirect compensation arrangement that could not satisfy an exception, the district court denied the defendant's motion to dismiss. As discussed in **Issues to Watch**, the case is stayed pending an interlocutory appeal regarding the constitutionality of the FCA's *qui tam* provision.

EKRA: THE NINTH CIRCUIT WEIGHS IN

EKRA prohibits knowingly and willfully paying or receiving any remuneration for referring an individual to laboratories, recovery homes or clinical treatment facilities, unless an exception applies.[215] The statute is similar to the AKS in some respects, but quite different in others. For one, unlike the AKS, EKRA applies to all payers, not just federal healthcare programs like Medicare and Medicaid. For another, EKRA's safe harbor for employee and contractor compensation is narrower than the AKS bona fide employee safe harbor, protecting only payments that do not vary by the number of individuals referred, the number of tests performed or the amount billed to or received from insurance. This limitation has led to many questions about the propriety of incentive compensation paid to marketing staff by laboratories and other covered providers.

212 63 F.4th 1043 (6th Cir. 2023).
213 2025 WL 2104279 (S.D. Ohio July 28, 2025).
214 792 F.3d 364 (4th Cir. 2015).
215 18 U.S.C. § 220.

Although EKRA was enacted in 2018, it has not been interpreted by many courts. In ***United States v. Schena***, the Ninth Circuit issued the first appellate interpretation of EKRA.[216] Schena operated a clinical laboratory that focused on allergy and COVID-19 blood testing. The evidence showed that his marketers misrepresented the laboratory's services to physicians to convince them to order tests. The marketers were compensated on a percentage-of-revenue basis. Schena was convicted on two counts of EKRA violations, one count of conspiracy to violate EKRA and six additional counts.

On appeal, Schena argued that EKRA applies only to payments made directly to referring clinical providers or persons who interact directly with patients, not to marketing intermediaries. The Ninth Circuit rejected this argument, holding that EKRA's prohibition on paying remuneration "directly or indirectly … to induce a referral of an individual" is broad enough to encompass payments to intermediaries who do not themselves refer patients, but who interface with those who do. The Ninth Circuit emphasized that nothing in EKRA's text confines the statute to persons with prescribing or referral authority, and the inclusion of the term "indirectly" counsels a broad reach. In so holding, the Ninth Circuit expressly rejected the district court's reasoning in *S&G Labs Hawaii v. Graves*,[217] which had held that EKRA did not apply to marketing arrangements directed solely at providers.

Importantly, the Ninth Circuit found that percentage-based compensation, without more, does not violate EKRA. Liability attaches when such payments are coupled with undue influence or misrepresentations used to steer referrals—for instance, when marketers are directed to mislead referring providers about the nature of and need for covered medical services. The Ninth Circuit drew on AKS precedent, observing that "induce" implies "wrongful causation" and "an intent to exercise influence over the reason or judgment of another." While declining to define an exhaustive test for undue influence, the Ninth Circuit concluded that Schena's direction to his marketers to deceive physicians was sufficient to sustain liability.

216 142 F.4th 1217 (9th Cir. 2025).
217 2021 WL 4847430 (D. Haw. Oct. 18, 2021); *see also S&G Labs Hawaii, LLC v. Graves*, 2025 WL 1912366 (July 11, 2025).

MANAGED CARE/ MEDICARE ADVANTAGE

Over the past two decades, Medicare Advantage (MA) enrollment has steadily grown and is expected to continue to increase. In 2025, 54% of eligible Medicare beneficiaries (or 34.1 million individuals) elected to enroll in an MA plan, and in 2026, MA enrollment is projected to reach 58% of Medicare-eligible beneficiaries.

Consistent with this growth, regulators have intensified scrutiny of MA marketing and broker/agent compensation, sharpened oversight of risk adjustment practices and pressed procedural transparency in prior authorization and Risk Adjustment Data Validation (RADV) appeals, while courts and litigants continue to test Star Ratings methodologies and agency deference post-*Loper Bright*. Together, these forces point to a durable enforcement agenda keyed to marketing, risk adjustment, utilization management and data governance in MA for the coming years.

LITIGATION AND ENFORCEMENT: SALES & MARKETING PRACTICES

Enforcement has continued to focus on MA marketing and sales practices, particularly following the Special Fraud Alert (SFA) issued by HHS-OIG in December 2024. The SFA targets MA marketing arrangements, signaling to Medicare Advantage Organizations (MAO), providers, agents and brokers that remuneration for beneficiary steering—in either direction—presents heightened AKS/FCA risk and unfair competition concerns. The SFA also catalogues "suspect characteristics" such as gift cards, compensation keyed to enrollee demographics/health status and volume-based referral payments.

In line with this, in May, the United States intervened in ***U.S. ex rel. Shea v. eHealth, Inc.***[218] In that matter, DOJ's complaint-in-intervention against three large MA insurers and three insurance brokers alleges that the insurers paid hundreds of millions of dollars in commissions to the brokers to induce enrollments into the insurers' MA plans. It alleges that the defendant-insurers violated the FCA by making improper payments to the defendant-brokers, in violation of the AKS. The defendants have moved to dismiss, arguing that the government has failed to plead an AKS violation, as well as the causation requirements for FCA claims predicated on alleged AKS violations. The motion has been briefed, and oral argument was held on January 21, 2026.

Other ongoing litigation involving DOJ scrutinizing marketing arrangements includes ***U.S. ex rel. Gonite v. UnitedHealthcare of Georgia, Inc***.[219] There, the relator alleged that the defendant-insurer engaged in fraudulent schemes to enroll SNF patients in its MA plan through illegal marketing tactics, HIPAA violations and kickbacks to the SNFs. In April, the district court found that the relator had adequately pleaded FCA and AKS violations, allowing discovery to move forward. Dispositive motions are currently scheduled to be filed by mid-2026.

218 No. 1:21-cv-11777-DJC (D. Mass.).
219 785 F. Supp. 3d 1325 (M.D. Ga. 2025).

> ***The government and relators have continued to prioritize retrospective chart reviews, addenda processes and diagnoses lacking sufficient record support—particularly those generated via in-home assessments and downstream chart reviews.***

MA marketing was also at issue in ***U.S. ex rel. Butler v. Shikara***, which involved allegations that in exchange for provider reimbursements, insurance commissions and marketing payments, a doctor who owned a practice and field marketing organization (FMO) steered patients to the two MAO defendants.[220] The parties settled the matter after the district court entered summary judgment in favor of the relator.

Finally, in ***U.S. ex rel. Holt v. Medicare Medicaid Advisors, Inc.***, the relator alleged that an FMO's marketing of MA plans, which involved cold-calling and door-to-door sales, using false lead sheets to justify sales calls and "pushing" beneficiaries to MA plans, violated the FCA.[221] The Eighth Circuit affirmed the district court's dismissal of the case, focusing on the FCA's materiality element and concluding that the allegations failed to meet Rule 9(b)'s particularity requirement.

LITIGATION & ENFORCEMENT: RISK ADJUSTMENT

Risk adjustment enforcement efforts have remained robust. The government and relators have continued to prioritize retrospective chart reviews, addenda processes and diagnoses lacking sufficient record support—particularly those generated via in-home assessments and downstream chart reviews. MA plans and vendors have also continued to see more targeted RADV and investigative activity in these areas.

At the end of 2024, ***Independent Health Association*** and its affiliate, ***Independent Health Corporation*** (Independent Health), agreed to settle for up to $98 million to resolve allegations that unsupported risk-adjusting diagnosis codes were knowingly submitted to CMS through improper use of retrospective chart reviews and medical record addenda.[222] Portions of the settlement amount are contingent payments, subject to Independent Health's ability to pay. Of note, a vendor (DxID) and its CEO (Betsy Gaffney) were included alongside the MAO, Independent Health, in this resolution.

220 2025 WL 2506617 (S.D. Fla. Aug. 11, 2025).
221 115 F.4th 908 (8th Cir. 2024).
222 https://www.justice.gov/usao-wdny/pr/medicare-advantage-provider-independent-health-pay-98m-settle-false-claims-act-suit.

Initially filed in 2011, ***U.S. ex rel. Poehling v. UnitedHealth Group, Inc.***, involves allegations that the defendants improperly retained MA overpayments related to unsupported diagnosis codes submitted to CMS.[223] At issue are codes that were documented by a provider and submitted for payment but were not subsequently identified by coders conducting a retrospective chart review. In March 2025, the Special Master issued a report and recommendation that the defendants' motion for summary judgment should be granted, reasoning that the inconsistency between the provider-submitted codes and the codes identified in the chart review was not sufficient to survive summary judgment absent evidence that the provider codes were actually unsupported. The government moved the district court to decline to accept the Special Master's report and recommendation, which remains pending.

UnitedHealth Group also made headlines this year when it publicly confirmed that it is the subject of criminal and civil investigations by DOJ. On the heels of the announcement of the DOJ-HHS FCA Working Group, UnitedHealth announced that DOJ is investigating certain aspects of its participation in the Medicare program, with a focus on its MA billing and risk adjustment practices. DOJ's interest appears to be centered on whether diagnoses were inflated to increase risk scores, with investigators having interviewed former employees and physicians regarding potential pressure to document certain conditions and the use of in-home assessments.

In March 2025, ***Seoul Medical Group, Inc.*** (SMG), a California-based primary care provider, its former president and majority owner and ***Renaissance Imaging Medical Associates Inc.*** (Renaissance) agreed to pay a combined $62.85 million to resolve allegations of FCA violations related to the submission of unsupported diagnoses codes to MAOs in order to increase reimbursement from the government.[224] According to the complaint, SMG instructed and trained its providers to diagnose patients with certain risk-adjusting conditions that were sometimes unsupported, employed a nurse to add support to medical records for otherwise unsupported risk-adjusting codes, actively concealed potentially unsupported codes by engaging Renaissance to generate false reports and failed to correct unsupported codes identified in an audit. This settlement highlights a sustained enforcement focus on risk adjustment fraud, notably following closely after the Independent Health settlement.

MA CRIMINAL ENFORCEMENT

With respect to criminal enforcement, ***Troy Health, Inc.*** entered into a non-prosecution agreement (NPA) and agreed to pay a criminal penalty of $1.43 million to resolve a criminal investigation into a healthcare fraud and identity theft scheme.[225] Troy employees used proprietary software to unlawfully access pharmacy records and customer lists in order to then make unsolicited sales calls. During those calls, Troy's sales personnel misled beneficiaries, stating that Troy's MA plan was being offered as a supplement to their current health plan. Troy also used beneficiary information it obtained to enroll beneficiaries into its MA plans without the beneficiaries' knowledge or consent. Lastly, Troy marketed an AI platform to pharmacies, claiming that it would lower the cost of care and improve health outcomes. Troy misused the platform, however, by offering participating pharmacies kickbacks for enrollment referrals submitted through the platform. As part of the NPA, Troy admitted and accepted responsibility and has agreed to cooperate with DOJ.

Moreover, in our 2023 Review, we discussed the indictment of ***HealthSun Health Plans, Inc.***'s former director of Medicare risk adjustment analytics. The indictment was based on allegations that the director knowingly submitted unsupported risk-adjusting diagnosis codes that were not diagnosed by the treating provider but were added afterwards into the EHR. After a trial in June 2025, a jury returned a not guilty verdict just four hours after deliberation.[226]

RISK ADJUSTMENT DATA VALIDATION AUDITS AND LITIGATION

In May 2025, CMS announced plans to audit every MA contract annually, dramatically increasing its audit volume and sample sizes, and committed to completing outstanding audits for prior payment years (PY) 2018–2024 by early 2026.[227]

In September 2025, the district court vacated CMS's 2023 RADV Final Rule in ***Humana Inc. v. Becerra***, holding that the rule was procedurally invalid under the Administrative Procedure Act because CMS's rationale for eliminating the fee-for-service (FFS) adjuster was not a "logical outgrowth" of its 2018 proposal.[228] Because the district court concluded that this procedural defect justified vacating the rule, it did not address CMS's authority to extrapolate sample audit results or actuarial equivalence arguments and remanded to the agency. CMS is appealing this outcome to the Fifth Circuit, leaving unresolved near-term questions about audits for PY 2018–2024.

Humana's challenge spotlights CMS's elimination of the FFS adjuster and formalization of extrapolation beginning with PY 2018—changes CMS estimated could recover roughly $4.7 billion over ten years—raising renewed disputes over actuarial equivalence and retrospective application. At the same time, stakeholders should anticipate continued oversight outside the vacated framework, including HHS-OIG's separate audits of diagnosis codes announced in August 2025, with results expected in 2027.

223 2025 WL 682285 (C.D. Cal. Mar. 3, 2025).
224 https://www.justice.gov/opa/pr/medicare-advantage-provider-seoul-medical-group-and-related-parties-pay-over-62m-settle.
225 https://www.justice.gov/opa/pr/troy-health-inc-enters-non-prosecution-agreement-and-admits-fraudulently-enrolling-medicare.
226 *U.S. v. Valle Boza*, No. 1:23-cr-20417-KMW-1 (S.D. Fla.).
227 https://www.cms.gov/newsroom/press-releases/cms-rolls-out-aggressive-strategy-enhance-and-accelerate-medicare-advantage-audits.
228 2025 WL 2734234 (N.D. Tex. Sep. 25, 2025).

LOOKING AHEAD

As an identified priority focus area of the DOJ-HHS FCA Working Group, MA enforcement will continue in the coming years. We expect this to include continued scrutiny of marketing practices and risk adjustment, but also "overlooked" areas, such as barriers to patient access to care, including network adequacy requirements. We also expect scrutiny related to: (1) prior authorization and utilization management (UM), including AI-assisted UM; (2) Stars ratings-related schemes given the 2025 Stars declines and corresponding reductions in quality bonus payments projected for PY 2026; and (3) clinical decision support, generative or assistive tools that prepopulate diagnoses, and automated reviews. Finally, we will continue to monitor AKS-based FCA cases in the MA setting (e.g., vendor fees, sub-capitation incentives, and broker payments), given the evolving causation standards, and whether state attorneys general pursue enforcement actions, in light of developing AI laws and regulations.

PHARMACEUTICAL AND MEDICAL DEVICE DEVELOPMENTS

Government regulators and courts remained active in matters involving pharmaceutical and medical device manufacturers.

PATIENT ASSISTANCE PROGRAMS

Patient assistance programs continued to draw sustained scrutiny, particularly where manufacturers donate to independent charities or sponsor programs that subsidize patient cost-sharing for the manufacturers' own products. As in prior years, the government maintained the view that such arrangements can present AKS risk when structured or administered in a manner that may influence utilization or reimbursement under federal healthcare programs.

In ***United States v. Regeneron Pharmaceuticals, Inc.***, the district court permitted the government—following intervening appellate guidance affecting one theory of AKS-based FCA liability—to proceed on an alternative false-certification theory and to reopen discovery on a limited basis.[229] The district court concluded that the government had plausibly alleged that provider certifications of AKS compliance, combined with manufacturer funding of a disease-specific charity, could support FCA liability under that theory, and that it would be inappropriate to foreclose that approach based on the government's earlier litigation strategy. Although the decision did not resolve whether the alleged patient assistance conduct violated the AKS, it reflects the extent to which litigation over manufacturer-funded assistance programs may proceed on alternative theories and expanded discovery, even where the role of intermediaries remains contested.

Manufacturers also continued to seek prospective clarity through the HHS-OIG advisory opinion process, with limited success. In ***Vertex Pharmaceuticals Inc. v. U.S. Department of Health & Human Services***, the district court rejected Vertex's challenge to an unfavorable advisory opinion addressing a proposed fertility assistance program tied to its gene-therapy product.[230] The district court upheld OIG's conclusion that the proposed subsidies could constitute "remuneration" under both the AKS and the Beneficiary Inducement Statute, and further held that the agency reasonably declined to conclude the program promoted access to care while posing a low risk of harm. The district court also accepted OIG's interpretation that "inducement" and "remuneration" under the AKS do not require proof of corrupt intent. Vertex has appealed the decision to the D.C. Circuit.[231]

As discussed in 2024's Review, a charitable coalition of pharmaceutical manufacturers separately challenged an unfavorable HHS-OIG advisory opinion addressing a proposed oncology cost-sharing program.[232] This year, the Fourth Circuit affirmed the district court's decision upholding that advisory opinion in ***Pharmaceutical Coalition for Patient Access v. United States***.[233] The Fourth Circuit agreed that the proposed subsidies could constitute "remuneration" and "inducement" under the AKS, even in the absence of product-specific steering or proof of corrupt intent, and further held that OIG's refusal to provide assurances against enforcement was an unreviewable exercise of enforcement discretion under the Administrative Procedure Act.

FCA TRIAL DECISIONS

Recent decisions in FCA matters based on inaccurate price reporting and off-label promotion focused on questions of materiality, causation and proof, with outcomes varying based on the nature of the alleged conduct and the evidentiary record developed at trial.

In ***Streck v. Eli Lilly***, the Seventh Circuit affirmed a jury verdict finding FCA liability based on alleged misreporting of pricing under the Medicaid Drug Rebate Program. The Seventh Circuit emphasized that inaccuracies directly affecting rebate calculations go to the "essence of the bargain" with the government and therefore support a finding of materiality.[234] The Seventh Circuit also rejected arguments that continued government payment defeated materiality, reinforcing that price-reporting theories remain viable where the alleged misstatements directly determine payment or rebate amounts.

By contrast, off-label promotion cases continued to present more difficult questions of causation and damages at trial. In ***U.S. ex rel. Penelow v. Janssen Products, LP***, a jury returned a substantial verdict premised on alleged off-label marketing of HIV drugs,[235] but post-trial proceedings and appellate briefing have focused attention on whether promotional conduct can be reliably tied to particular prescriptions and whether the claims paid were not reasonable and necessary for individual patients. In its briefing before the Third Circuit, the government acknowledged that aspects of the jury instructions and damages framework did not fully account for individualized medical necessity determinations. The case remains pending on appeal.[236]

In ***U.S. ex rel. Siegel v. Novo Nordisk***, a federal jury returned a complete defense verdict after a multi-week trial, rejecting claims under the FCA and related state statutes premised on alleged off-label promotion of a hemophilia drug and alleged kickbacks to physicians and patients.[237] The case—pursued by a relator and the state of Washington after the United States declined to intervene—underscored the proof challenges that can arise at trial when plaintiffs must connect promotional conduct and alleged remuneration to medically unsupported prescriptions and specific claims submitted for payment.

229 793 F. Supp. 3d 261 (D. Mass. 2025).
230 774 F. Supp. 3d 211 (D.D.C. 2025).
231 No. 25-5133 (D.C. Cir.).
232 *See Pharm. Coal. for Patient Access v. United States*, 2024 WL 187707 (E.D. Va. Jan. 17, 2024).
233 126 F.4th 947 (4th Cir. 2025).
234 152 F.4th 816 (7th Cir. 2025).
235 2025 WL 937504 (D.N.J. Mar. 28, 2025).
236 No. 25-1818 (3d Cir.).
237 No. 3:23-cv-5459 (W.D. Wash. Nov. 7, 2025).

NOTABLE FCA PRE-T RIAL DISMISSALS

Several courts this year rejected FCA theories advanced against pharmaceutical and medical device manufacturers at the pleading or summary judgment stage, where relators or the government failed to connect alleged promotional, regulatory or quality issues to specific false claims. In ***United States v. Gilead Sciences, Inc.***, the district court granted summary judgment for the manufacturer, concluding that the record did not support an inference that speaker programs or charitable donations induced prescriptions or that subsequent claims resulted from those activities.[238] The district court rejected attempts to establish falsity, scienter or causation based on generalized promotional conduct alone, underscoring the difficulty of sustaining FCA claims premised on off-label promotion without concrete evidence linking conduct to specific reimbursement decisions.

Courts likewise closely scrutinized FCA claims predicated on alleged product or regulatory deficiencies. In ***United States v. Siemens Medical Solutions USA, Inc.***, a relator alleged that Siemens shipped temperature-sensitive diagnostic tests outside FDA-cleared temperature ranges and argued that the products were therefore adulterated or misbranded.[239] The district court dismissed the complaint under Rule 9(b), emphasizing that FCA liability requires particularized allegations linking the alleged shipping issues to device performance and to specific false claims submitted for payment.

In ***United States ex rel. Hearrell v. Allergan, Inc.***, a district court granted summary judgment to Allergan on FCA and AKS theories involving alleged off-label promotion and payments to physicians.[240] The district court found insufficient evidence tying any remuneration to prescribing or referrals, and further concluded that the relator failed to establish falsity or materiality where Medicaid claims disclosed the off-label use at issue and were reimbursed with prior authorization.

OTHER NOTABLE ENFORCEMENT DEVELOPMENTS

Regulators continued to articulate and refine enforcement priorities affecting pharmaceutical and medical device manufacturers, including through the resurrection of the DOJ and HHS-OIG FCA Working Group. HHS-OIG described the Working Group as a mechanism for coordinating civil fraud enforcement across agencies, with stated areas of focus including drug and device pricing practices (including arrangements for discounts, rebates, service fees and formulary placement and price reporting); kickbacks involving drugs, devices and durable medical equipment; and matters involving defective medical devices with potential patient safety implications.[241] The initiative also reflects an effort to integrate data analytics, audit findings and administrative enforcement tools more closely with traditional FCA investigations.

Consistent with prior years, enforcement activity largely reflected familiar areas of scrutiny rather than a shift in substantive theory. DOJ continued to focus on speaker programs and other manufacturer interactions with healthcare providers, with a $202 million settlement involving an HIV drug manufacturer underscoring the government's ongoing concerns, where such programs lack effective controls, monitoring or clear educational value.[242] The resolution also reinforced DOJ's continued emphasis on whether compliance programs are meaningfully implemented and enforced, rather than merely memorialized in policy documents.

Device-related enforcement likewise remained active in cases where alleged violations of FDA regulatory requirements formed the basis of FCA liability. Several resolutions involved allegations that devices were promoted or used outside their cleared or approved indications,[243] that manufacturers made material changes to devices without obtaining the requisite FDA clearance[244] or that quality and durability issues rendered associated claims ineligible for payment.[245] Such resolutions reflect how FCA exposure in device cases often turns on regulatory status, product performance and whether devices functioned as represented at the time claims were submitted.

Enforcement activity also extended into emerging applications of FCA theories. DOJ pursued claims based on cybersecurity representations tied to life sciences products, including a settlement involving genomic sequencing systems.[246] That resolution highlights increasing attention to whether representations regarding software functionality and cybersecurity controls align with applicable FDA requirements, particularly as software-driven technologies and connected devices play a growing role in patient care.

238 2025 WL 2627686 (E.D. Pa. Sept. 11, 2025).
239 2025 WL 240935 (E.D.N.Y. Jan. 17, 2025).
240 2025 WL 675445 (E.D. Tex. Mar. 3, 2025).

241 https://www.hhs.gov/press-room/hhs-doj-false-claims-act-working-group.html.
242 https://www.justice.gov/usao-sdny/pr/us-attorney-announces-202-million-settlement-gilead-sciences-using-speaker-programs.
243 https://www.justice.gov/opa/pr/semler-scientific-inc-and-bard-peripheral-vascular-inc-pay-nearly-37m-resolve-false-claims; https://www.justice.gov/usao-edpa/pr/rst-sanexas-inc-and-its-owners-agree-pay-15-million-resolve-allegations-they-caused.
244 https://www.justice.gov/usao-nj/pr/diopsys-inc-agrees-pay-1425-million-resolve-alleged-federal-false-claims-act-and-state.
245 https://www.justice.gov/usao-edpa/pr/aesculap-implant-systems-agrees-pay-385-million-resolve-false-claims-act-allegations; https://www.justice.gov/usao-md/pr/exactech-agrees-pay-8-million-resolve-false-claims-act-allegations-selling-defective.
246 https://www.justice.gov/opa/pr/illumina-inc-pay-98m-resolve-false-claims-act-allegations-arising-cybersecurity.

> ***DOJ continued to pursue criminal enforcement actions involving telehealth platforms and the prescribing of controlled substances.***

CRIMINAL ENFORCEMENT

DOJ's Criminal Division expanded its Health Care Fraud Strike Force into the District of Massachusetts, extending specialized prosecutorial resources into a major life sciences and healthcare market.[247] The expansion formalized a coordinated, multi-agency approach involving the U.S. Attorney's Office, HHS-OIG, FDA's Office of Criminal Investigations, DEA, FBI and state partners, and paired criminal enforcement with the district's affirmative civil enforcement efforts. DOJ emphasized corporate accountability as a continued priority, signaling sustained attention to complex matters involving pharmaceutical manufacturers, device makers, digital health companies and healthcare providers.

DOJ continued to pursue criminal enforcement actions involving telehealth platforms and the prescribing of controlled substances. Federal authorities secured convictions against the founder and clinical president of a digital health company for conspiring to distribute controlled stimulants, including Adderall, and to commit healthcare fraud.[248] Trial evidence focused on a subscription-based telehealth model that constrained clinical discretion, relied on abbreviated patient encounters and facilitated large-scale prescribing through standardized and automated refill practices. Shortly thereafter, a federal grand jury indicted the company and an affiliated medical practice on related conspiracy and obstruction charges, marking a significant escalation of the government's enforcement posture in this matter.[249]

Product quality and diversion risks also remained a focus of criminal enforcement. A global consumer products company entered into a deferred prosecution agreement and agreed to pay up to $40.4 million to resolve allegations involving the sale of adulterated surgical gowns that did not meet the represented barrier protection standards.[250] The government alleged misbranding, fraudulent testing practices and failures to notify FDA, resulting in the widespread distribution of products that fell short of claimed safety specifications.

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247 https://www.justice.gov/opa/pr/justice-department-expands-health-care-fraud-unit-target-health-care-fraud-massachusetts.
248 https://www.justice.gov/opa/pr/founderceo-and-clinical-president-digital-health-company-convicted-100m-adderall.
249 https://www.justice.gov/opa/pr/digital-health-company-and-medical-practice-indicted-100m-adderall-distribution-scheme.
250 https://www.justice.gov/opa/pr/kimberly-clark-corporation-pay-40m-resolve-criminal-charge-related-sale-adulterated.

APPENDIX
2025 NOTABLE SETTLEMENTS

HOSPITALS AND HEALTH SYSTEMS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
2/14/2025	SVCMC Inc. f/k/a Saint Vincents Catholic Medical Centers of New York	Health system that participated in the Uniformed Services Family Health Plan (USFHP) program agreed to pay $29 million to resolve allegations that it knowingly retained and concealed the existence of mistakenly inflated payments for healthcare services received from the Department of Defense for retired military members and their families.[1]	**$29 million**
3/24/2025	Carson Tahoe Health System	Health system, which owns physician clinics and a continuing care hospital, agreed to pay over $8.8 million to resolve allegations that the health system, clinics and hospital obtained four PPP loans in total for which they were not eligible.[2]	**$8.88 million**
4/2/2025	East El Paso Physician's Medical Center, LLC d/b/a Foundation Surgical Hospital of El Paso	Hospital agreed to entry of a consent judgment of over $2 million to resolve allegations that it engaged in an illegal kickback and pass-through billing scheme in which a medical imaging company used the hospital's National Provider Identifier (NPI) to submit claims for imaging services to obtain a higher rate of reimbursement for hospital outpatient services. In exchange for allowing the imaging company to use its NPI, the hospital retained 17% of payments on the claims.[3]	**$2.08 million**
5/14/2025	Community Health System Physician Network Advantage Inc.	Health system and its affiliate agreed to pay $31.5 million to resolve allegations that they: (1) provided multiple forms of extravagant benefits to induce physicians to refer patients to its facilities; (2) offered financial subsidies for EHR technology and equipment in exchange for referrals; and (3) paid bonuses to physicians for supposed participation in clinical integration activities that were actually intended to reward referrals, in violation of the AKS and Stark Law. As part of the resolution, Community Health System entered into a five-year CIA with HHS-OIG.[4]	**$31.5 million**
5/16/2025	Catholic Health System, Inc.	Health system agreed to pay nearly $3.3 million to resolve allegations that it submitted false claims for services referred by non-employee physicians with whom the hospital had compensation arrangements for administrative services that were not commercially reasonable and/or exceeded fair market value, in violation of the Stark Law.[5]	**$3.29 million**
11/24/2025	Mt. San Rafael Hospital and Rural Health Clinic Dr. Sheryll Castro-Flores Dr. Joseph Jimenez Dr. Douglas McFarland	Hospital, health clinic and three hospital-employed physicians agreed to collectively pay $650,000 to resolve FCA and CSA allegations that they illegally dispensed controlled substances and then sought payment for the prescriptions from Medicare and other federal healthcare programs.[6]	**$650,000**

1 https://www.justice.gov/opa/pr/saint-vincents-catholic-medical-centers-new-york-agrees-pay-29m-resolve-alleged-false-claims.
2 https://www.justice.gov/usao-edca/pr/carson-tahoe-health-system-agrees-pay-over-88-million-settle-allegations-over-pandemic.
3 https://www.justice.gov/usao-wdtx/pr/hospital-medical-imaging-services-company-and-others-pay-31-million-resolve-false.
4 https://www.justice.gov/usao-edca/pr/fresno-based-community-health-system-agree-pay-315-million-resolve-allegations-false.
5 https://www.justice.gov/usao-wdny/pr/catholic-health-agrees-pay-nearly-33-million-resolve-alleged-false-claims-act.
6 https://www.justice.gov/usao-co/pr/southern-colorado-hospital-and-doctors-agree-pay-650000-resolve-allegations-they.

HOSPITALS AND HEALTH SYSTEMS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
12/16/2025	Dana-Farber Cancer Institute Inc.	Cancer hospital and research center agreed to pay $15 million to resolve FCA allegations that it made materially false statements and certifications related to research grants received from the National Institutes of Health (NIH) and spent grant funds on unallowable expenses.[7]	**$15 million**
12/22/2025	New York-Presbyterian Hudson Valley Hospital f/k/a Hudson Valley Hospital Center	Hospital agreed to pay over $6.8 million to resolve allegations that it improperly paid millions of dollars to a contracted oncology practice to induce referrals, in violation of the AKS and Stark Law. The hospital and practice had agreements for work on a proposed melanoma center, breast cancer center and the development and management of an intraoperative radiation therapy service line. The government alleged the hospital made payments despite the oncology practice's frequent failure to perform or document the central services identified in the agreements.[8]	**$6.83 million**

7 https://www.justice.gov/opa/pr/dana-farber-cancer-institute-agrees-pay-15m-settle-fraud-allegations-related-scientific.
8 https://www.justice.gov/usao-sdny/pr/us-attorney-announces-68-million-settlement-new-york-presbyterian-hudson-valley.

HOSPICE, HOME HEALTH AND NURSING FACILITIES

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
2/21/2025	Saad Enterprises Inc. d/b/a Saad Healthcare	Hospice company agreed to pay $3 million to resolve allegations that it knowingly submitted claims for patients who were not eligible for hospice services because they were not terminally ill.[9]	**$3 million**
4/28/2025	Maxim Healthcare Services	Home health agency agreed to pay $100,000 to resolve allegations regarding the adequacy of the agency's documentation of home health aide services. The government alleged that, after a state health department required the agency to make a repayment for insufficient documentation of services following an audit, the agency continued to document in the same manner deemed insufficient by the state health department.[10]	**$100,000**
6/11/2025	Mahlega Abdsharafat a/k/a Mallie Sharafat Creative Hospice Care, Inc.	Hospice care CEO and affiliated companies agreed to pay $9.2 million to resolve allegations that they paid kickbacks to medical directors, including monthly stipends and signing bonuses, in exchange for referrals of hospice patients, in violation of the AKS.[11]	**$9.2 million**
7/11/2025	M&Y Care, LLC	Home healthcare provider agreed to pay nearly $335,000 to resolve allegations that it billed Medicare and Medicaid for services delivered by staff who lacked necessary qualifications.[12]	**$334,807**
11/24/2025	Deer Valley Home Health Services LLC	Home healthcare company agreed to pay over $500,000 to resolve allegations that it submitted claims to Medicaid on behalf of a contractor, who later became an employee, who: (1) falsely overstated his educational credentials; (2) claimed more than 24 hours of service provided in a single day; and (3) performed services he was unqualified to provide.[13]	**$534,475**
12/18/2025	Americare, Inc.	Home care services agency agreed to pay $10 million to resolve allegations that it sought Medicaid reimbursements while failing to comply with wage parity requirements. The company will also pay nearly $45 million to compensate current and former home health aides for their unpaid wages.[14]	**$10 million**

9 https://www.justice.gov/opa/pr/saad-healthcare-agrees-pay-3m-settle-false-claims-act-allegations-it-billed-medicare.
10 https://www.doj.nh.gov/news-and-media/home-health-agency-pay-100000-settlement-over-incomplete-patient-care-records.
11 https://www.justice.gov/usao-ndga/pr/mahlega-abdsharafat-and-creative-hospice-settle-health-care-kickback-claims-92-million.
12 https://www.justice.gov/usao-edmi/pr/home-health-care-provider-pay-334807-settle-false-claims-act-allegations.
13 https://www.justice.gov/usao-edmo/pr/missouri-home-health-care-company-agrees-pay-534475-false-claims-act-settlement.
14 https://ag.ny.gov/press-release/2025/attorney-general-james-secures-45-million-underpaid-home-health-aides.

SKILLED NURSING FACILITIES AND NURSING HOMES

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
1/17/2025	Unified Care Services LLC Emmanual David Various affiliated entities	Skilled nursing facilities chain, its affiliates and its owner agreed to collectively pay $18 million to resolve allegations that they submitted false information on PPP loan applications and loan forgiveness applications.[15]	**$18 million**
2/28/2025	Providence Park, Inc. d/b/a Ascension Living Providence Village Ascension Providence f/k/a Providence Health Services of Waco	Skilled nursing facility and acute care hospital agreed to pay over $6.5 million to resolve allegations that they submitted: (1) medically unnecessary claims for Ultra-High Resource Utilization Group therapy; (2) claims for individual outpatient therapy services when group therapy was actually provided; and (3) claims for therapy services when no plan of care was signed by a physician. The companies received cooperation credit for, among other actions, disclosing the results of an internal investigation, voluntarily identifying overpayments and identifying corrective actions.[16]	**$6.52 million**
4/7/2025	Elkton SNF, LLC Elkton Health Holdco, LLC d/b/a Elkton Nursing and Rehabilitation Center	Nursing and rehabilitation centers agreed to pay more than $1.28 million to resolve allegations that they provided substandard care to residents in violation of the Maryland False Health Claims Act including: (1) understaffing; (2) wound care deficiencies; (3) regulatory violations that compromised patient care; (4) preventable falls; (5) avoidable nutritional and hydration deficits; and (6) failures to respond to residents' changes in condition. As part of the resolution, the companies entered into a three-year quality improvement agreement with the state.[17]	**$1.28 million**
6/3/2025	American Health Foundation AHF Management Corporation Cheltenham Nursing & Rehabilitation Center The Sanctuary at Wilmington Place Samaritan Care Center and Villa	Nonprofit organization and affiliated nursing homes agreed to pay $3.61 million to resolve allegations that they submitted claims to Medicare and Medicaid for substandard care including: (1) failing to follow appropriate infection protocols; (2) not maintaining adequate staffing levels; (3) housing residents in dirty, pest-infested building; (4) giving residents unnecessary medications; (5) verbally abusing patients; (6) providing no activities or stimulation; and (7) failing to safeguard patient possessions. As part of the resolution, the entities entered into a five-year CIA with HHS-OIG.[18]	**$3.61 million**
7/1/2025	Riverpark Operations, LLC Avamere Group, LLC	Skilled nursing home provider and its parent company agreed to pay $2 million to resolve allegations that they submitted claims to Medicare and Oregon Medicaid for substandard care, including not meeting minimum staffing requirements. As part of the resolution, the companies entered into a five-year CIA with HHS-OIG.[19]	**$2 million**

15 https://www.justice.gov/usao-cdca/pr/south-bay-based-nursing-facilities-chain-and-owner-agree-pay-18-million-resolve-0.
16 https://www.justice.gov/usao-wdtx/pr/skilled-nursing-facility-and-acute-care-hospital-pay-65-million-settle-civil-false.
17 https://oag.maryland.gov/News/Pages/Attorney-General%e2%80%99s-Medicaid-Fraud-and-Vulnerable-Victims-Unit-Secures-a-$1%2c289%2c679-Settlement-and-Corporate-Oversight.aspx.
18 https://www.justice.gov/opa/pr/ohio-based-nonprofit-and-affiliated-nursing-homes-agree-pay-361m-resolve-false-claims-act.
19 https://www.justice.gov/usao-or/pr/us-attorneys-office-participates-national-health-care-fraud-takedown-resulting-2-million.

SKILLED NURSING FACILITIES AND NURSING HOMES

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
7/1/2025	Centers Healthcare	Skilled nursing facility provider agreed to pay over $6 million to resolve allegations that 44 of its facilities submitted cost reports to Medicare that included false statements or failed to disclose required allowable cost information about their transactions with related entities.[20]	**$6.06 million**
7/2/2025	Villa Financial Services LLC Villa Olympia Investment LLC Six Related Nursing Facilities	Nursing home companies and six related nursing homes agreed to pay $4.5 million to resolve allegations that they provided substandard care, including failing to: (1) sufficiently staff facilities; (2) prevent, control and treat infections; (3) prevent resident falls; (4) provide for residents' toileting needs; and (5) prevent and treat pressure ulcers. As part of the resolution, the companies entered into a five-year CIA with HHS-OIG.[21]	**$4.5 million**
11/4/2025	Granite Md Opco d/b/a Patapsco Healthcare	Skilled nursing facility agreed to pay $200,000 to resolve allegations that it provided insufficient care to residents including: (1) wound care failures leading to hospitalizations; (2) failure to provide adequate nutrition and hydration to residents; (3) regulatory abuses compromising patient care; (4) preventable falls; and (5) failure to avoid opiate overdoses. As part of the resolution, the companies entered into a four-year quality improvement agreement with the state.[22]	**$200,000**
12/9/2025	Orchard Hill Operator, LLC d/b/a Orchard Hill Rehabilitation and Healthcare Center	Nursing home agreed to pay $400,000 to resolve allegations that it provided substandard care to Medicaid beneficiaries, including: (1) serious wound care inadequacies leading to hospitalizations; (2) failure to provide residents with adequate nutrition and hydration; (3) regulatory violations which compromised patient care; (4) numerous preventable falls; and (5) insufficient staffing. As part of the resolution, the nursing home entered into a three-year quality improvement agreement with the state of Maryland. [23]	**$400,000**

20 https://www.justice.gov/usao-ndny/pr/centers-healthcare-pays-over-6-million-false-statements-medicare-cost-reports.
21 https://www.michigan.gov/ag/news/press-releases/2025/07/02/attorney-general-nessel-announces.
22 https://oag.maryland.gov/News/Pages/Attorney-General%E2%80%99s-Medicaid-Fraud-and-Vulnerable-Victims-Unit-Secures-a-$200,000-Settlement-and-Corporate-Oversight-of-Pata.aspx.
23 https://oag.maryland.gov/News/Pages/Attorney-General%E2%80%99s-Medicaid-Fraud-and-Vulnerable-Victims-Unit-Secures-a-$400,000-Settlement-and-Corporate-Oversight-of-Orch.aspx.

PHARMACEUTICAL AND DEVICE

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
1/6/2025	Athira Pharma Inc.	Biopharmaceutical company agreed to pay over $4.06 million to resolve allegations that it failed to disclose and report allegations of research misconduct to the National Institutes of Health and HHS's Office of Research Integrity in grant applications and grant award progress reports and guarantees.[24]	**$4.06 million**
1/23/2025	C.R. Bard, Inc. Liberator Medical Supply, Inc. Liberator Holdings Rochester Medical Corporation	Medical device and supply company and its affiliates agreed to pay $17 million to resolve allegations that they provided free samples and discounts to induce urology practices to use its prescription form for prescribing intermittent catheters, in violation of the AKS.[25]	**$17 million**
1/24/2025	Pfizer Inc. o/b/o Biohaven Pharmaceutical Holding Company Ltd.	Pharmaceutical company agreed to pay nearly $60 million to resolve allegations that its subsidiary improperly paid healthcare providers through honoraria, meals and other benefits through its speaker programs to induce prescriptions of a specific drug, in violation of the AKS.[26]	**$59.74 million**
3/26/2025	The Prometheus Group Richard Poore	Medical device manufacturer and its president and sole owner agreed to collectively pay $550,000 to resolve allegations that they caused healthcare providers to bill for services where the providers improperly re-used single-use rectal sensors and catheters on multiple patients, which rendered the services ineligible for coverage.[27]	**$550,000**
3/27/2025	Diopsys, Inc.	Medical device company agreed to make guaranteed payments of $1.22 million and additional contingent payments of up to $13.02 million to resolve allegations that it caused providers to submit false claims for vision tests using its electrophysiological device. In particular, the government alleged that the device was utilized for medically unnecessary uses, including for a different test for which the device lacked FDA clearance, and that the company made substantial changes to the device without the required submission for FDA clearance.[28]	**Up to $14.25 million**
4/29/2025	Gilead Sciences, Inc	Pharmaceutical manufacturer agreed to pay $202 million to resolve allegations that it paid for travel, expensive meals and honoraria to healthcare practitioners who repeatedly participated in its speaker programs to induce prescriptions of the company's HIV drugs, in violation of the AKS. As part of the settlement, the company accepted responsibility for certain conduct and for the failure of its compliance policies and procedures to prevent the conduct.[29]	**$202 million**

24 https://www.justice.gov/opa/pr/athira-pharma-inc-agrees-pay-4m-settle-false-claims-act-allegations-related-scientific.
25 https://www.justice.gov/usao-ndga/pr/cr-bard-inc-and-affiliates-pay-17-million-resolve-allegations-healthcare-kickbacks.
26 https://www.justice.gov/opa/pr/pfizer-agrees-pay-nearly-60m-resolve-false-claims-allegations-relating-improper-physician.
27 https://www.justice.gov/usao-wdmi/pr/2025_0326_Prometheus_Settlement.
28 https://www.justice.gov/usao-nj/pr/diopsys-inc-agrees-pay-1425-million-resolve-alleged-federal-false-claims-act-and-state.
29 https://www.justice.gov/usao-sdny/pr/us-attorney-announces-202-million-settlement-gilead-sciences-using-speaker-programs.

PHARMACEUTICAL AND DEVICE

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
5/9/2025	Assertio Therapeutics, Inc. f/k/a Depomed, Inc.	Pharmaceutical company agreed to pay $3.6 million to resolve allegations that it caused false claims to be submitted for its drug Lazanda, a transmucosal immediate-release fentanyl, for individuals who did not have breakthrough cancer pain.[30]	**$3.6 million**
7/31/2025	Illumina Inc.	Biotechnology and medical device company agreed to pay $9.8 million to resolve allegations that it sold government agencies genomic sequencing systems with software that had cybersecurity exposures and falsely represented that the software followed national and international cybersecurity standards.[31]	**$9.8 million**
9/5/2025	MED-EL Corporation	Hearing implant and device technology company agreed to pay approximately $2.1 million to resolve allegations that it falsely certified its eligibility for a second draw Paycheck Protection Program loan. The company received cooperation credit for, among other actions, producing materials without a subpoena, cooperating with the government's investigation, seeking to resolve the matter expeditiously and providing cooperation in an ongoing government investigation.[32]	**$2.1 million**
9/16/2025	Exactech Inc.	Medical device company agreed to pay $8 million to resolve allegations that it submitted or caused the submission of claims for two defective components of its knee-replacement systems. The company is currently in bankruptcy, and the U.S. Bankruptcy Court for the District of Delaware approved the settlement as part of the pending proceedings.[33]	**$8 million**
9/26/2025	Semler Scientific Inc. Bard Peripheral Vascular Inc.	Medical device company agreed to pay $29.75 million, and its former distributor and related companies agreed to pay $7.2 million to resolve allegations that they caused the submission of claims to Medicare for photoplethysmography tests using devices that were not approved for diagnosis of peripheral arterial disease, contrary to the company's representations. As part of the resolution, Semler Scientific entered into a five-year CIA with HHS-OIG. Bard Peripheral Vascular received cooperation credit for admitting certain allegations.[34]	**$36.95 million**
11/17/2025	Aesculap Implant Systems, LLC	Medical device company agreed to pay $38.5 million to resolve allegations that it: (1) sold knee replacement devices that it knew would fail prematurely at a higher-than-acceptable rate and require revision surgery; and (2) unlawfully paid remuneration, including consulting payments, international travel and entertainment, to an orthopedic surgeon to induce him to recommend the devices, in violation of the AKS. The company also entered into a non-prosecution agreement related to its distribution of two non-approved medical devices in violation of the Food, Drug and Cosmetic Act.[35]	**$38.5 million**

30 https://www.justice.gov/usao-dc/pr/pharmaceutical-manufacturer-assertio-therapeutics-inc-pay-36-million-resolve-allegations.
31 https://www.justice.gov/opa/pr/illumina-inc-pay-98m-resolve-false-claims-act-allegations-arising-cybersecurity.
32 https://www.justice.gov/usao-ma/pr/med-el-corporation-agrees-pay-21-million-resolve-allegations-ppp-loan-fraud.
33 https://www.justice.gov/usao-md/pr/exactech-agrees-pay-8-million-resolve-false-claims-act-allegations-selling-defective.
34 https://www.justice.gov/opa/pr/semler-scientific-inc-and-bard-peripheral-vascular-inc-pay-nearly-37m-resolve-false-claims.
35 https://www.justice.gov/usao-edpa/pr/aesculap-implant-systems-agrees-pay-385-million-resolve-false-claims-act-allegations.

PHARMACEUTICAL AND DEVICE

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
12/16/2025	RST-Sanexas, Inc. Richard Sorgnard Lisa Sorgnard Morhea Sorgnard	Manufacturer and marketer of electric stimulation devices and its principal owners agreed to collectively pay $1.5 million to resolve allegations that they caused false claims to be submitted to Medicare by: (1) improperly marketing a medical device for indications that were outside its FDA clearance and not reasonable and necessary; (2) encouraging providers to conduct epidermal nerve fiber density (ENFD) testing that was not medically reasonable following treatment with the medical device; (3) offering volume-based discounts and paying value-based commissions to distributorships owned and operated by providers who performed procedures using the medical device; and (4) receiving commissions from a laboratory for referring providers to perform ENFD testing in conjunction with the medical device treatment, in violation of the AKS.[36]	**$1.5 million**

36 https://www.justice.gov/usao-edpa/pr/rst-sanexas-inc-and-its-owners-agree-pay-15-million-resolve-allegations-they-caused.

PHARMACY SERVICES

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
1/14/2025	Medsinbox Pharmacy LTC LLC d/b/a Farmacia San Antonio	Pharmacy agreed to pay $625,000 to resolve allegations that it billed for medications that were not dispensed.[37]	**$625,000**
2/4/2025	A Plus Pharmacy LLC	Pharmacy agreed to pay $350,000 to resolve allegations that it billed for certain medications that were not dispensed.[38]	**$350,000**
3/27/2025	Walgreen Co.	Pharmacy agreed to pay over $2.8 million to resolve allegations that it submitted an inflated usual and customary price to Medicaid programs for certain generic medications.[39]	**$2.85 million**
4/11/2025	People's Rx, Inc. d/b/a The People's Pharmacy Shoppe	Pharmacy agreed to pay nearly $1 million to resolve allegations that it billed for medications that were not dispensed.[40]	**$995,420**
4/21/2025	Walgreens Boots Alliance Walgreen Co.	National pharmacy chain and various subsidiaries agreed to pay $300 million to resolve FCA and CSA allegations that they: (1) illegally filled invalid prescriptions for opioids and other controlled substances, including the drug combination known as the "holy trinity;" (2) pursued payment for many of those illegal prescriptions from federal healthcare programs; and (3) pressured pharmacists to quickly fill prescriptions without confirming prescriptions were lawful and for a legitimate medical purpose. The companies agreed to pay an additional $50 million if certain corporate transactions are undertaken. As part of the resolution, the company entered into a seven-year Memorandum of Agreement (MOA) with DEA and a five-year CIA with HHS-OIG.[41]	**$300 million (guaranteed)** **$50 million (contingent)**
5/16/2025	OHM Pharmacy Services a/k/a Benzer a/k/a Auburndale	Pharmacy agreed to pay over $1 million to resolve allegations related to Evzio, a naloxone product that often requires prior authorization, including that the pharmacy completed prior authorization forms rather than the prescribing physician, and in some instances, that personnel signed prior authorization forms without physician authorization and submitted information to insurers that made it appear as though a physician was submitting the information. As part of the resolution, Benzer previously entered into an IA with HHS-OIG. The company also pleaded guilty to one count of healthcare fraud and was sentenced to one year of probation and ordered to pay restitution of $82,000.[42]	**$1.01 million (civil)** **$82,000 (criminal)**

37 https://www.justice.gov/usao-nj/pr/pharmacy-agrees-resolve-false-claims-act-allegations-billing-drugs-not-dispensed.
38 https://www.justice.gov/usao-nj/pr/pharmacy-llc-agrees-resolve-false-claims-act-allegations-billing-drugs-not-dispensed.
39 https://www.justice.gov/usao-ma/pr/walgreen-co-agrees-pay-over-28-million-settle-allegations-overbilling-medicaid-programs.
40 https://www.justice.gov/usao-nj/pr/union-city-pharmacy-agrees-resolve-false-claims-act-allegations-billing-drugs-not.
41 https://www.justice.gov/usao-mdfl/pr/walgreens-agrees-pay-350m-illegally-filling-unlawful-opioid-prescriptions-and.
42 https://www.justice.gov/usao-ma/pr/florida-pharmacy-pleads-guilty-health-care-fraud-and-agrees-pay-more-1-million-settement.

PHARMACY SERVICES

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
5/28/2025	2818 JFK Pharmacy LLC 518 Summit Care Pharmacy LLC 1850 Greenville Pharmacy LLC 327 Alexandria Pharmacy LLC 516 Broadway Care Pharmacy LLC	Five pharmacies agreed to collectively pay $1.93 million to resolve allegations that they billed federal healthcare programs for medications that were not dispensed.[43]	**$1.93 million**
8/8/2025	West End Services, Inc. Christopher Leon	Pharmacy and its owner agreed to pay $825,000 to resolve allegations that they billed Medicare for prescriptions that were not dispensed.[44]	**$825,000**
8/27/2025	CVS Pharmacy, Inc.	National pharmacy chain agreed to pay $12.25 million to resolve allegations that it charged the government higher prices than it offered to the general public through a discount program for the same drugs. As part of the resolution, the pharmacy will implement a yearly reconciliation process to review its prescription drug pricing.[45]	**$12.25 million**
9/26/2025	Andrew Do	Owner and operator of three mail-order pharmacies agreed to pay $600,000 to resolve allegations that he paid kickbacks in exchange for the referral of prescriptions for compounded topical creams, in violation of the AKS.[46]	**$600,000**
10/29/2025	Various retail pharmacies	Nine retail pharmacies agreed to pay $157,000 in total to resolve allegations that they billed the Oklahoma Medicaid Program for unauthorized over-the-counter COVID-19 tests.[47]	**$157,000**
11/14/2025	VRA Enterprises, LLC d/b/a Precision Rx	Pharmacy agreed to pay over $17 million to resolve allegations that it billed Medicare for over-the-counter COVID-19 tests that were not provided to beneficiaries or that were sent to beneficiaries months after claims were submitted. The government alleged that the pharmacy received thousands of complaints from beneficiaries about missing OTC COVID-19 tests, and also repeatedly acknowledged internally that it had billed Medicare for tests it failed to ship and should issue a refund to Medicare immediately for such tests, but did not do so.[48]	**$17.06 million**
11/17/2025	CVS Pharmacy, Inc.	National pharmacy chain agreed to pay over $18.28 million to resolve allegations that it failed to confirm and document diagnoses on prescriptions for certain drugs, as required by California's Medi-Cal program, and in some instances billed the government after dispensing drugs for non-approved diagnoses without submitting a request with a justification for the non-approved use.[49]	**$18.28 million**

43 https://www.justice.gov/usao-nj/pr/five-new-jersey-pharmacies-agree-pay-1935-million-resolve-false-claims-act-allegations.
44 https://www.justice.gov/usao-edpa/pr/allentown-area-pharmacy-and-its-owner-agree-pay-825000-resolve-allegations-false.
45 https://www.mass.gov/news/ag-campbell-secures-1225-million-settlement-with-cvs-for-failure-to-comply-with-masshealth-prescription-drug-pricing-regulations.
46 https://www.justice.gov/usao-nj/pr/owner-mail-order-pharmacies-settles-false-claims-act-investigation-involving-allegations.
47 https://oklahoma.gov/oag/news/newsroom/2025/october/affiliated-pharmacies-to-pay-more-than-150000-for-false-claims-act-allegations.html.
48 https://www.justice.gov/usao-mdfl/pr/vra-enterprises-agrees-pay-over-17-million-allegedly-billing-medicare-over-counter.
49 https://www.justice.gov/usao-edca/pr/cvs-pharmacy-inc-pays-182-million-resolve-alleged-false-claims-act-violations.

PHARMACY SERVICES

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
12/2/2025	CVS Pharmacy, Inc.	National pharmacy chain agreed to pay $37.76 million to resolve allegations that it improperly billed for insulin pens by: (1) requesting and receiving reimbursement for premature refills; (2) dispensing in a higher quantity than patients needed according to their prescriptions; and (3) falsely under-reporting the days-of-supply of insulin that its pharmacies dispensed.[50]	**$37.76 million**

50 https://www.justice.gov/usao-sdny/pr/us-attorney-announces-3776-million-settlement-cvs-over-dispensing-insulin-pens.

LABORATORY, PATHOLOGY, RADIOLOGY AND DIAGNOSTICS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
1/2/2025	Laboratory Corporation of America Holdings Laboratory Corporation of America Labcorp Tennessee, LLC University Health System, Inc.	Laboratory group and a health system agreed to pay over $388,000 to resolve allegations that they delayed the submission of physician orders for specific laboratory tests to circumvent a Medicare Date of Service Rule, resulting in improper claims being made to Medicare.[51]	**$388,667**
1/3/2025	Physicians Toxicology Laboratory, LLC Lund Capital Group, LLC Matthew Ryan Lund Thomas C. Lund	Laboratory and its owners agreed to collectively pay $4.42 million to resolve allegations that they submitted false claims for presumptive and definitive urine drug testing and hormone tests that were medically unnecessary. Additionally, the government alleged the laboratory billed for hormone level tests with almost every urine drug test despite knowing the practice was ordering tests as a form of specimen validity testing that is already reimbursed in the cost of the urine drug test. As part of the resolution, the companies entered into a three-year IA with HHS-OIG.[52]	**$4.42 million**
1/17/2025	BioReference Health LLC f/k/a BioReference Laboratories Inc. OPKO Health Inc.	Laboratory company and its parent company agreed to pay over $700,000 to resolve allegations that it submitted claims for laboratory tests that: (1) had not been ordered by a patient's provider or were processed at a more expensive rate; and (2) were not medically necessary.[53]	**$704,349**
1/31/2025	LiveCare Inc.	Remote patient monitoring company agreed to pay up to $4.9 million to resolve allegations that it paid a marketing service for Medicare beneficiary referrals, in violation of the AKS.[54]	**Up to $4.9 million**
3/26/2025	Renaissance Imaging Medical Associates Inc.	Radiology group agreed to pay $2.35 million to resolve allegations that it conspired with an affiliated physician provider group to cause the submission of false diagnosis codes for two spinal conditions to increase payments from the Medicare Advantage program.[55]	**$2.35 million**
4/2/2025	Fairfax Radiological Consultants, PLLC f/k/a Fairfax Radiological Consultants, P.C.	Radiology group agreed to pay over $2.8 million to resolve allegations that it wrongly reported payroll costs to receive full forgiveness of a $6.7 million PPP loan.[56]	**$2.88 million**

51 https://www.justice.gov/usao-edtn/pr/labcorp-and-university-health-system-agree-pay-388667-resolve-alleged-false-claims-act.
52 https://www.justice.gov/usao-wdmi/pr/2025_0103_physicians_toxicology_laboratory_settlement.
53 https://www.justice.gov/opa/pr/bioreference-health-and-opko-health-agree-pay-704349-settle-allegations-they-billed.
54 https://www.justice.gov/usao-mdfl/pr/livecare-inc-agrees-pay-49-million-resolve-false-claims-act-allegations.
55 https://www.justice.gov/opa/pr/medicare-advantage-provider-seoul-medical-group-and-related-parties-pay-over-62m-settle.
56 https://www.justice.gov/usao-edva/pr/medical-group-agrees-pay-28m-settle-false-claims-act-allegations.

LABORATORY, PATHOLOGY, RADIOLOGY AND DIAGNOSTICS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
4/2/2025	Desert Imaging Services, L.P. In Tandem Solutions Group, LLC Leroy Candelaria Vox Intus, LLC Donald Burris	Medical imaging company and other entities and individuals agreed to pay or forfeit over $1 million to resolve allegations engaged in an illegal kickback and pass-through billing scheme in which the imaging company used a hospital's NPI to submit claims for imaging services. The government alleged that the patients who received these services had no connection to the hospital and billing the claims as hospital outpatient services allowed the imaging company to obtain a higher rate of reimbursement.[57]	**$1.01 million**
4/23/2025	Genexe, LLC Immerge, Inc. Jason Green Jason Gross	CGx and PGx testing companies and their CEO and COO agreed to pay $6 million to resolve allegations that they participated in kickback schemes meant to cause fraudulent claims to Medicare for medically unnecessary testing. The government alleged that they: (1) paid remuneration to independent contractors for referrals of Medicare beneficiaries and to physicians for prescriptions of CGx and PGx testing; (2) obtained Medicare patient information and swabs by having Medicare beneficiaries complete genetic test kits; (3) obtained prescriptions for CGx and PGx testing for those beneficiaries by paying kickbacks to physicians or telemedicine providers; and (4) received kickbacks for sending completed CGx and PGx testing swabs and prescriptions to laboratories for processing and billing. Both companies are no longer operating.[58]	**$6 million**
4/23/2025	Vault Medical Services, P.A. Vault Medical Services of New Jersey, P.C.	Healthcare screening companies agreed to pay $8 million to resolve allegations that they knowingly submitted or caused the submission of false claims for services to the COVID-19 Uninsured Program for patients who had active health insurance.[59]	**$8 million**
5/21/2025	Agendia, Inc.	Global molecular diagnostics company agreed to pay at least $3.25 million to resolve allegations that it submitted false claims for MammaPrint genomic tests that were: (1) medically unnecessary; and/or (2) tainted by illegal remuneration, in violation of the AKS.[60]	**$3.25 million (minimum)**
5/21/2025	Knoxville Dermatopathology Laboratory	Dermatopathology laboratory agreed to pay $207,500 to resolve allegations that it participated in a diagnostic company's scheme to obtain referrals for MammaPrint genomic tests that were: (1) medically unnecessary; and/or (2) induced by illegal remuneration, in violation of the AKS.[61]	**$207,500**
6/26/2025	Health Wealth Safe, Inc. Dr. Subodh Agrawal	Remote patient monitoring company and its physician owner agreed to pay $1.29 million to resolve allegations that they knowingly caused false claims to be submitted for remote physiologic monitoring services, which are not reimbursable.[62]	**$1.29 million**

57 https://www.justice.gov/usao-wdtx/pr/hospital-medical-imaging-services-company-and-others-pay-31-million-resolve-false.
58 https://www.justice.gov/usao-edpa/pr/genetic-testing-marketing-companies-genexe-llc-and-immerge-inc-and-two-executives.
59 https://www.justice.gov/usao-nj/pr/vault-agrees-pay-8-million-settle-allegations-billing-false-claims-covid-19-uninsured.
60 https://www.justice.gov/usao-edtn/pr/agendia-inc-knoxville-comprehensive-breast-center-pllc-and-knoxville-0.
61 https://www.justice.gov/usao-edtn/pr/agendia-inc-knoxville-comprehensive-breast-center-pllc-and-knoxville-0.
62 https://www.justice.gov/usao-ndga/pr/remote-patient-monitoring-company-settles-false-claims-act-lawsuit-129-million.

LABORATORY, PATHOLOGY, RADIOLOGY AND DIAGNOSTICS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
8/13/2025	Genco Lab, LLC Paul Conroy Tricia Conroy Charles Orefice	Reference laboratory and its owners and officers agreed to pay over $1.2 million to resolve allegations that they submitted claims for: (1) medically unnecessary urine drug tests for residents of sober homes solely for the prohibited purpose of residential monitoring; and (2) medically unnecessary duplicative presumptive and definitive urine drug testing.[63]	**$1.25 million**
9/8/2025	Christopher Grottenthaler	Laboratory CEO agreed to pay $4.25 million to resolve an FCA lawsuit alleging that he engaged in a kickback scheme in which marketers, including some of the lab's own employees, offered and paid physicians kickbacks disguised as MSO distributions to induce the physicians' referrals of lab testing. The settlement also resolves allegations that the CEO arranged for the lab company to pay kickbacks disguised as consulting fees, processing and handling fees and waivers of co-payments and deductibles, to induce laboratory testing referrals.[64]	**$4.25 million**
11/13/2025	Patients Choice Laboratories	Diagnostic laboratory agreed to pay $9.62 million to resolve allegations that it knowingly submitted claims for respiratory pathogen panels that were obtained through kickbacks in the form of commissions paid to independent sales representatives and marketing firms based on the volume or value of referrals. The government also alleged that the laboratory submitted claims for medically unnecessary respiratory pathogen panels. As part of the resolution, the company agreed to enter a five-year CIA with HHS-OIG.[65]	**$9.62 million**
11/20/2025	Genetic Technological Innovations, LLC	Diagnostic laboratory agreed to pay over $1.63 million to resolve allegations that it submitted claims for respiratory pathogen panels that were: (1) medically unnecessary; or (2) obtained through kickbacks paid under a Marketing Services Agreement, in violation of the AKS.[66]	**$1.63 million**
12/4/2025	NEXT Bio-Research Services LLC d/b/a NEXT Molecular Analytics	Clinical laboratory agreed to pay a minimum of $758,000, plus additional amounts if certain financial contingencies occur, to resolve allegations that it paid doctors kickbacks, disguised as consulting and medical director fees, to induce the ordering of lab tests and that it paid volume- and value-based commissions to independent contractor marketers to arrange for and recommend that doctors order lab tests, in violation of the AKS.[67]	**$758,000 (minimum)**

63 https://www.justice.gov/usao-ct/pr/connecticut-lab-its-owners-and-officers-pay-more-12-million-settle-false-claims-act.
64 https://www.justice.gov/opa/pr/laboratory-ceo-marketers-and-physicians-pay-over-6m-settle-allegations-management-service.
65 https://www.justice.gov/usao-md/pr/diagnostic-laboratory-agrees-pay-more-9-million-settle-alleged-false-claims-act.
66 https://www.justice.gov/usao-md/pr/diagnostic-laboratory-agrees-pay-more-1-million-settle-alleged-false-claims-act.
67 https://www.justice.gov/opa/pr/virginia-laboratory-pay-758000-settle-allegations-kickbacks-doctors-and-marketers.

BEHAVIORAL HEALTH AND SUBSTANCE ABUSE TREATMENT

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
1/27/2025	Dr. Ghodrat Pirooz Sholevar Nueva Vida Multicultural/Multilingual Behavioral Health, Inc.	Behavioral health company and physician agreed to pay $900,000 to resolve allegations that they submitted claims to Medicaid for medication management appointments that did not meet the minimum time requirements and often resulted in more appointments than could actually be completed in a workday. The company ceased operations in 2018.[68]	**$900,000**
1/28/2025	Substance Abuse Treatment Labs Paul Fribush	Substance abuse company and its owner agreed to pay $850,000 to resolve allegations that they billed NC Medicaid for medically unnecessary urine drug screening tests.[69]	**$850,000**
2/27/2025	Community Health Care Solutions, LLC Estate of Yolanda Burnom	Counseling provider and the estate of its deceased owner/operator agreed to pay $4.6 million to resolve allegations that they submitted claims to Medicaid for services that were not actually rendered. The government alleged that the company financially incentivized Medicaid recipients to share their patient information and then directed employees to create generic notes that could be cut and pasted into patient files to bill for crisis intervention, which offered the highest reimbursement. Before her death, the company operator was indicted for related criminal charges.[70]	**$4.6 million**
3/26/2025	Community Options, Inc. Community Options New York, Inc.	Nonprofit operator of residential and nonresidential facilities and programs for adults with developmental or intellectual disabilities and its affiliate company agreed to pay over $5 million to resolve allegations that it submitted claims for day habilitation services that did not meet state program requirements. As part of the resolution, the companies entered into a five-year CIA with HHS-OIG.[71]	**$5.01 million**
4/30/2025	Seabrook	Drug and alcohol rehabilitation facility agreed to pay $19.75 million to resolve allegations that it improperly billed the Community Care Program of Veterans Health Administration (VHA) as a result of: (1) providing services for which it was not properly licensed or contracted; (2) failing to employ a sufficient number of properly-credentialed caregivers; (3) failing to employ a sufficient number of caregivers credentialed in treating patients with both mental health and addiction issues; (4) providing the same care to veterans it provided to other patients, while claiming to be providing specialized care; and (5) maintaining inconsistent and inadequate medical record documentation of the care provided to patients.[72]	**$19.75 million**
5/5/2025	Steven Osbey	Co-owner of behavioral health clinic agreed to entry of a consent judgment of over $4.7 million to resolve allegations that his clinic billed NC Medicaid for in-home physician visits with patients that never occurred. The clinic's other co-owner previously pled guilty to related and other criminal charges and was sentenced to 52 months in prison.[73]	**$4.71 million**

68 https://www.justice.gov/usao-edpa/pr/philadelphia-mental-health-clinic-and-its-psychiatrist-owner-agree-pay-900000-resolve.
69 https://www.justice.gov/usao-mdnc/pr/greensboro-laboratory-and-owner-agree-pay-850000-resolve-allegations-false-claims.
70 https://www.justice.gov/usao-wdla/pr/community-health-care-solutions-llc-and-estate-yolanda-burnom-agree-pay-46-million.
71 https://www.justice.gov/usao-sdny/pr/acting-us-attorney-announces-5-million-false-claims-act-settlement-providers-programs.
72 https://www.justice.gov/usao-nj/pr/cumberland-county-drug-and-alcohol-rehabilitation-center-agrees-pay-1975-million-resolve.
73 https://www.justice.gov/usao-wdnc/pr/charlotte-clinic-owner-agrees-settle-allegations-medicaid-fraud.

BEHAVIORAL HEALTH AND SUBSTANCE ABUSE TREATMENT

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
6/2/2025	The Opportunity Alliance	Residential treatment provider agreed to pay $346,369 to resolve allegations that it caused the submission of false claims to Medicare and MaineCare for medically unnecessary presumptive and definitive urine drug tests ordered through standing orders without regard to individualized treatment needs, in violation of Maine's residential monitoring rules.[74]	**$346,369**
6/26/2025	NUWAY Alliance, Inc.	Addiction treatment provider agreed to pay $18.5 million to resolve allegations that it: (1) submitted false claims to Medicaid for intensive outpatient treatment services that were not actually provided or were double billed; and (2) compensated Medicaid patients for seeking specialized treatment, in violation of the AKS. As part of the resolution, the company entered into a five-year CIA with HHS-OIG.[75]	**$18.5 million**
8/19/2025	American Psychiatric Centers, Inc. d/b/a Comprehensive Psychiatric Services	Behavioral health provider agreed to pay $2.75 million to resolve allegations that it submitted claims using "add-on" CPT codes for psychotherapy without providing or sufficiently documenting the provision of the additional services.[76]	**$2.75 million**
12/2/2025	Mindpath Care Centers, North Carolina, PLLC Jeff Williams Abigail Sheriff Sarah Williams	Behavioral health provider and three of its former officers agreed to pay $1.9 million to resolve allegations that they billed Medicare without providing documentation of separate and distinct psychotherapy treatments and failed to adequately correct billing problems repeatedly raised by its employees.[77]	**$1.9 million**
12/10/2025	LifeWorks Counseling Associates, PLLC Dr. David Ferruolo	Telehealth mental health provider and its owner agreed to pay $300,000 to resolve allegations that they submitted claims to Medicaid for services provided by an excluded individual.[78]	**$300,000**
12/10/2025	Recovery Centers of America	Addiction and mental healthcare company agreed to pay $1 million to resolve allegations that, at certain of its facilities, it billed the Federal Employees Health Benefits Program and Medicaid for the care of beneficiaries to whom it failed to provide and document the requisite treatment services.[79]	**$1 million**

74 https://www.justice.gov/usao-me/pr/residential-treatment-provider-agrees-pay-346369-settle-false-claims-act-allegations.
75 https://www.justice.gov/usao-mn/pr/nuway-alliance-agrees-pay-18500000-settlement-medicaid-kickbacks-scheme-false-claims-act.
76 https://www.justice.gov/usao-ndca/pr/california-behavioral-medicine-provider-agrees-pay-275-million-resolve-alleged-false.
77 https://www.justice.gov/usao-ednc/pr/largest-north-carolina-behavioral-health-practice-agrees-pay-19-million-resolve.
78 https://www.justice.gov/usao-nh/pr/telehealth-company-agrees-pay-300000-resolve-false-claims-act-allegations.
79 https://www.justice.gov/usao-edpa/pr/recovery-centers-america-agrees-pay-2-million-resolve-allegations-it-violated.

MANAGED CARE AND HEALTH PLANS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
1/17/2025	Commonwealth Care Alliance, Inc.	MA plan agreed to pay over $520,000 to resolve self-disclosed allegations that a company it acquired in 2022 provided cash payments to induce the referral of Medicare beneficiaries to enroll in the company's MA Plan, in violation of the AKS. The company received cooperation credit for voluntarily self-disclosing the conduct, taking remedial measures and providing the government with a detailed written statement describing its investigation.[80]	**$520,355**

80 https://www.justice.gov/usao-edmi/pr/health-care-plan-agrees-pay-over-500000-part-self-disclosure-potential-false-claims.

SPECIALTY CARE AND OTHER PROVIDER ENTITIES

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
1/3/2025	CompreCare Health LLC d/b/a Meditelecare LLC	Telehealth company agreed to pay $358,514 to resolve allegations that it billed Medicare for psychotherapy sessions that did not satisfy minimum time requirements and that it relied on false time records to support these telehealth services.[81]	**$358,514**
1/7/2025	Dr. Lakshmi Bethi New Haven Dental LLC New Haven Family Dental LLC New Haven Family Dental Group LLC	Dentist and her former dental practices agreed to pay over $600,000 to resolve allegations that they submitted false claims to the Connecticut Medical Assistance Program (CTMAP) for patients referred by a third-party patient recruiting company who they paid for each referral whenever the patient received services over and above routine preventative care, in violation of the AKS and CTMAP provider agreement. The dentist also pled guilty to conspiracy to violate the AKS and was sentenced to two years of probation and ordered to forfeit $500,000 in December 2024.[82]	**$608,296**
1/23/2025	Northwest Anesthesiology and Pain Services	Anesthesiology service provider agreed to pay nearly $1 million to resolve self-disclosed allegations that its practice manager incorrectly calculated bonus payments to its independently contracted pain management practices, resulting in an improper financial relationship between the provider and the pain management practices and in kickbacks for referrals, in violation of the Stark Law. The provider received cooperation credit for its self-disclosure and cooperation with the investigation.[83]	**$999,999**
2/19/2025	Western New York Medical P.C.	Medical practice agreed to pay over $250,000 to resolve allegations that it submitted claims for chronic care management services that took less than the 20 minutes of clinical staff time per month required by the CPT code used for billing.[84]	**$251,477**
3/18/2025	Aqua Vision Care, LLC	Vision care center agreed to pay $143,336 to resolve allegations that they billed Maryland Medicaid for eye exams that were not actually provided.[85]	**$143,336**
3/20/2025	Pain Specialists, P.A.	Pain clinic agreed to pay $240,000 to resolve civil allegations that it wrongly listed a physician as the provider rendering services when a non-physician practitioner provided the services with no physician present in the office, in violation of Medicare billing requirements. The clinic also pled guilty to a related criminal charge and agreed to pay over $140,000 in criminal restitution and fines.[86]	**$240,000 (civil)** **$140,076 (criminal)**

81 https://www.justice.gov/usao-wdky/pr/telehealth-company-pays-386000-resolve-allegations-overbilling-medicare-telehealth.
82 https://www.justice.gov/usao-ct/pr/connecticut-dentist-pays-more-600k-settle-false-claims-allegations.
83 https://www.justice.gov/usao-sdtx/pr/anesthesiology-service-provider-pays-almost-1m-settle-false-claims-act-liability.
84 https://www.justice.gov/usao-wdny/pr/wny-medical-agrees-pay-250000-resolve-allegations-improper-medicare-billing-chronic.
85 https://fcfreepresspa.com/aqua-vision-care-settles-for-over-143000-in-medicaid-fraud-case.
86 https://www.justice.gov/usao-nj/pr/new-jersey-pain-clinic-admits-health-care-fraud-and-agrees-criminal-and-civil-penalties.

SPECIALTY CARE AND OTHER PROVIDER ENTITIES

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
3/26/2025	Seoul Medical Group, Inc. Advanced Medical Management Inc. Dr. Min Young Cha	Primary care and specialist physician provider group and its subsidiary agreed to pay $58.74 million, and its former president and majority owner agreed to pay $1.76 million, to resolve allegations that it caused the submission of false diagnoses codes for two spinal conditions to increase payments from the Medicare Advantage program. The government alleged that when the provider group was questioned by an MA plan about its use of a diagnosis code, it enlisted the assistance of a radiology group to create radiology reports that appeared to support the diagnosis.[87]	**$60.5 million**
4/2/2025	Med-Surg Physician Group Inc. Dr. Oluyemisi Sangodeyi	Physician group and its owner agreed to pay over $150,000 to resolve allegations that they improperly billed for telehealth visits that originated in the patients' homes by charging a facility fee intended only for in-person visits at approved medical sites and that they falsely certified that they were meeting required program standards.[88]	**$152,382**
5/9/2025	Advanced Dental Center PC Dr. Tal Yossefi Dr. Elad Yossefi	Dental practice and its owners agreed to pay $495,721 to resolve allegations that they submitted false claims to CTMAP for patients referred by a third-party patient recruiting company who they paid for each referral, in violation of the AKS and CTMAP provider agreement.[89]	**$495,721**
5/9/2025	Dr. Nazneen Jaffri	Dental provider agreed to pay $150,000 to resolve allegations that she submitted or caused the submission of false claims to CTMAP for services provided to Medicaid beneficiaries referred by a third-party patient recruiting company, in violation of the AKS.[90]	**$150,000**
5/16/2025	Pain Management LLC Dr. Halina Snowball	Pain management practice and its owner agreed to pay $427,129 to resolve allegations that they improperly submitted E&M claims to Medicare with Modifier 25 when providing pain injections, when no significant, separately identifiable E&M services were actually provided. The government further alleged that, even though they were notified of the improper Modifier 25 use and assessed an overpayment, the practice and its owner continued to submit improper claims.[91]	**$427,129**
5/16/2025	Pinellas Eye Care, P.A. d/b/a Gulfcoast Eye Care	Ophthalmology practice agreed to pay $615,000 to resolve allegations that it submitted false claims for transcranial Doppler ultrasounds (TCDs) that were premised on false diagnoses and were medically unnecessary. In addition, the government alleged that claims were tainted by an arrangement with a third-party TCD provider that was based on the value or volume of tests ordered, in violation of the AKS and Stark Law.[92]	**$615,000**

87 https://www.justice.gov/opa/pr/medicare-advantage-provider-seoul-medical-group-and-related-parties-pay-over-62m-settle.
88 https://www.justice.gov/usao-sdwv/pr/beckley-medical-clinic-and-physician-agree-pay-15238270-resolve-false-claims-act.
89 https://www.justice.gov/usao-ct/pr/norwalk-dentists-pay-more-600k-settle-false-claims-allegations.
90 https://www.justice.gov/usao-ct/pr/norwalk-dentists-pay-more-600k-settle-false-claims-allegations.
91 https://www.justice.gov/usao-ct/pr/connecticut-physiatrist-and-practice-pay-427k-settle-false-claims-improper-billing.
92 https://www.justice.gov/usao-mdfl/pr/florida-ophthalmology-practice-agrees-pay-615000-resolve-allegations-fraudulent-claims.

SPECIALTY CARE AND OTHER PROVIDER ENTITIES

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
5/21/2025	Knoxville Comprehensive Breast Center	Breast care center agreed to pay $322,500 to resolve allegations that it participated in a diagnostic company's scheme to obtain referrals for MammaPrint genomic tests that were: (1) medically unnecessary; and/or (2) induced by illegal remuneration, in violation of the AKS.[93]	**$322,500**
5/30/2025	Dr. William Philip Werschler Spokane Dermatology Clinic Premier Clinical Research L.L.C. 3rd and Sherman Plaza L.L.C.	Dermatologist and his three businesses agreed to pay $1.4 million to resolve allegations that they applied for Economic Injury Disaster Loans during the COVID-19 pandemic and misused the funds for personal purchases.[94]	**$1.4 million**
6/20/2025	Vascular and Interventional Specialists, LLC Vascular and Spine Institute, Inc. Dr. Oscar Sosa Dr. Osmany DeAngelo	Endovascular surgery center, an affiliated practice group and two physicians agreed to pay $810,301 to resolve allegations that they billed for medically unnecessary percutaneous transluminal angioplasties (PTA).[95]	**$810,301**
6/30/2025	Various medical transportation companies	Sixteen medical transport companies agreed to collectively pay over $13 million to resolve allegations that they defrauded the New York Medicaid Program in taking patients to and from healthcare appointments. The allegations included billing for fake trips and adding fake tolls to inflate expenses; falsely extending the mileage of trips; overbilling for false addresses; using unlicensed drivers; and paying patients kickbacks in exchange for requesting transportation services. Some of the settling companies include American Base No. 1 ($4.77 million), Agape Luxury Corp. ($2.45 million), NBT Transportation ($1.51 million) and Angel Medical Transportation ($1.1 million).[96]	**$13 million**
7/1/2025	Courtesy Transport Services, LLC Melanie Burger Dr. John Milanick	Ambulance company and its two owners agreed to pay $900,000 to resolve allegations that they submitted claims for non-emergency medical transport services that were not medically necessary or were not actually provided.[97]	**$900,000**
7/15/2025	Bloom Care LLC	Urgent care operator and its owners agreed to pay $3 million to resolve allegations that they billed for unnecessary streptococcus and influenza tests during the COVID-19 pandemic and submitted claims for higher-level E&M services for COVID-19 patients than appropriate, justifying those claims by exaggerating the time spent with patients or the services performed.[98]	**$3 million**

93 https://www.justice.gov/usao-edtn/pr/agendia-inc-knoxville-comprehensive-breast-center-pllc-and-knoxville-0.
94 https://www.justice.gov/usao-edwa/pr/spokane-dermatologist-agrees-pay-14-million-resolve-claims-fraudulently-obtaining.
95 https://www.justice.gov/usao-sdfl/pr/south-florida-medical-providers-agree-pay-810301-resolve-allegations-fraudulently.
96 https://ag.ny.gov/press-release/2025/attorney-general-james-secures-more-13-million-sweeping-takedown-transportation.
97 https://www.justice.gov/usao-mdfl/pr/ambulance-company-and-its-owners-agree-pay-900000-settle-false-claims-act-allegations.
98 https://www.justice.gov/usao-id/pr/urgent-care-operator-pays-3-million-dollars-resolve-alleged-violations-false-claims-act.

SPECIALTY CARE AND OTHER PROVIDER ENTITIES

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
7/16/2025	Traveler's Transit, Inc.	Non-emergency transportation provider agreed to pay $1.04 million to resolve allegations that it submitted false claims to the Massachusetts Department of Developmental Services and MassHealth for contracted routes not driven and that it failed to require staff monitors onboard for certain routes. As part of the resolution, the company will implement a three-year independent compliance monitoring program.[99]	**$1.04 million**
7/21/2025	Eye Consultants of Pennsylvania, PC	Eye care practice agreed to pay $790,000 to resolve allegations that it submitted claims to Medicare Part B for E&M services on the same date of service for beneficiaries receiving bilateral eye injections, in violation of the applicable Medicare rules and regulations.[100]	**$790,000**
7/30/2025	Forefront Dermatology S.C. d/b/a Henghold Dermatology Henghold Surgery Center LLC	Dermatology practice and now-closed ambulatory surgery center agreed to pay nearly $850,000 to resolve allegations that they caused the submission of false claims by upcoding billing codes for wound repair procedures.[101]	**$847,394**
8/4/2025	Brewster Ambulance Service, Inc. EasCare, LLC Mark Brewster George Brewster, Jr.	Two ambulance companies and their owners agreed to pay $6 million to resolve allegations that they: (1) billed MassHealth for emergency services when only non-emergency services were provided or required; (2) billed MassHealth for medically unnecessary services and/or for non-emergency services without maintaining relevant medical necessity documentation; and (3) failed to disclose to MassHealth relevant information concerning owners, managers and employees of the companies when submitting MassHealth provider applications. As part of the resolution, the companies and owners will implement a three-year independent compliance monitoring program at their own expense.[102]	**$6 million**
9/9/2025	Family Choice Urgent Care, LLC	Urgent care company agreed to pay nearly $490,000 to resolve allegations that it improperly billed Medicaid for medically unnecessary office visits. The settlement also resolved allegations that it billed higher levels of visits than were actually provided for asymptomatic patients.[103]	**$489,280**
9/24/2025	Health First Urgent Care	Urgent care clinic agreed to pay over $2.8 million to resolve allegations that it overbilled respiratory and urinary tract infection diagnostic testing by unbundling the panel tests and individually billing for each test comprising the panel.[104]	**$2.8 million**

99 https://www.mass.gov/news/ag-campbell-announces-over-1-million-settlement-with-worcester-county-transportation-provider-for-defrauding-masshealth-and-department-of-developmental-services.
100 https://www.justice.gov/usao-mdpa/pr/eye-consultants-pennsylvania-pc-agrees-pay-79000000-settle-false-claims-act.
101 https://www.justice.gov/opa/pr/dermatology-providers-agree-pay-nearly-850000-resolve-allegations-false-wound-repair-claims.
102 https://www.mass.gov/news/ag-campbell-secures-6-million-settlement-with-weymouth-based-ambulance-companies-for-masshealth-false-claims.
103 https://www.doj.state.or.us/media-home/news-media-releases/doctor-and-urgent-care-clinic-settle-allegations-over-medicaid-fraud/.
104 https://www.justice.gov/usao-edwa/pr/tri-cities-urgent-care-clinic-agrees-pay-28-million-resolve-claims-overbilling.

SPECIALTY CARE AND OTHER PROVIDER ENTITIES

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
11/19/2025	Dent Plus Family Dentistry, PLLC L&M Family Dentistry, LLC Dr. Ivan Makar Dr. Oleg Losin	Two dentists and their now-dissolved dental practices agreed to pay nearly $715,000 to resolve allegations that they submitted false claims to CTMAP for patients referred by a third-party patient recruiting company who they paid for each referral, in violation of the AKS and CTMAP provider agreement.[105]	**$714,446**
11/21/2025	Vohra Wound Physicians Management LLC Dr. Ameet Vohra	Provider of specialty wound care and its physician owner agreed to pay $45 million to resolve an FCA lawsuit alleging that they submitted false claims to Medicare for medically unnecessary surgical procedures, procedures that were not performed, more profitable surgical procedures when only routine wound management had been done and E&M services that were not billable under Medicare rules. The government further alleged that the provider programmed EHR and billing software to ensure that Medicare was always billed for the higher-reimbursed surgical excisional procedure and to create false medical record documentation to support the improper billing. As part of the resolution, the provider entered into a five-year CIA with HHS-OIG.[106]	**$45 million**
12/12/2025	Alexandra Gehrke Jeffrey King	Owners of several wound graft companies agreed to collectively pay over $309 million to resolve civil FCA allegations that they submitted medically unnecessary claims for wound grafts, received illegal kickbacks from a wholesale wound allograft distributor in exchange for orders, purchases and referrals, and paid illegal kickbacks to other parties. The owners also pled guilty to related criminal charges for causing over $1.2 billion of false claims to be submitted to federal healthcare programs. They were sentenced to 14 and 15.5 years of prison and ordered to pay restitution for their actions.[107]	**$309.9 million**
12/18/2025	Advanced Pain Care Dr. Mark Malone Various affiliated entities	Interventional pain management practice, its founder-doctor and related entities agreed to pay $13.62 million to resolve allegations that they submitted false claims for concurrent presumptive and definitive urine drug testing for the same patient on the same date of service, without reviewing the results of the presumptive test to determine whether a definitive test was medically necessary, and for definitive drug testing using separate CPT codes for individual analytes. As part of the resolution, the parties entered into a five-year CIA with HHS-OIG.[108]	**$13.62 million**

105 https://www.justice.gov/usao-ct/pr/connecticut-dentists-pay-more-714k-settle-false-claims-allegations.
106 https://www.justice.gov/opa/pr/vohra-wound-physicians-and-its-owner-agree-pay-45m-settle-fraud-allegations-overbilling.
107 https://www.justice.gov/opa/pr/wound-graft-company-owners-sentenced-12b-health-care-fraud-and-agree-pay-309m-resolve-civil.
108 https://www.justice.gov/usao-wdtx/pr/austin-pain-management-doctor-and-pain-medicine-practice-pay-13625000-settle-civil.

INDIVIDUAL PROVIDERS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
1/2/2025	Dr. Scott Saffold Chesapeake Bay, ENT, P.C.	Doctor and his practice agreed to pay $625,000 to resolve allegations that they billed for services that were not medically necessary, performed related procedures at separate times to increase reimbursement and billed for endoscopies with sphenoid sinusoscopy under a certain CPT code when they were not actually performing that code.[109]	**$625,000**
1/2/2025	Dr. Naimetulla Ahmed Syed	Psychiatrist agreed to pay over $455,000 to resolve FCA and CSA allegations that he: (1) issued medically unnecessary prescriptions, including for controlled substances; (2) billed for medically unnecessary office visits related to those prescriptions; (3) issued prescriptions for controlled substances without a legitimate medical purpose and not in the usual course of professional practice; (4) issued prescriptions for excessive and unsafe amounts and combinations; and (5) failed to maintain proper patient files and treatment records. As a part of the resolution, the doctor agreed to a 20-year exclusion from federal health programs and a 20-year suspension from CTMAP. The doctor voluntarily surrendered his DEA licenses in 2021 and agreed in 2024 to cease the practice of medicine and not renew his physician license. A pharmacy and its owner resolved related CSA allegations in 2024.[110]	**$455,439**
1/7/2025	Dr. Abbesalom Ghermay Dr. James Cook Family Medical Centers, P.C. Dr. Daniel Theesfeld H8 Pain Management Center of Texas PLLC Troy Belton Advantage Medical Group	Four physicians and their respective medical practices agreed to collectively pay nearly $600,000 to resolve allegations that they received kickbacks, disguised as investment distributions from MSOs and arranged through third-party marketers, for ordering testing from certain laboratories, in violation of the AKS.[111]	**$597,914**
1/16/2025	Dr. Paul Baumert Cori Lempiainen	Doctor and nurse practitioner agreed to collectively pay over $164,000 to resolve allegations that they participated in a telemedicine scheme involving visits and discussions not actually provided, resulting in false claims being submitted to Medicare for medically unnecessary services and DME.[112]	**$164,326**
1/23/2025	Dr. Kamal Kabakibou Kamal Kabakibou, M.D., P.C. d/b/a The Center for Pain Management	Doctor and his medical practice agreed to pay $3.5 million to resolve FCA and CSA allegations that they billed for medically unnecessary and duplicative laboratory testing and that he pre-signed opioid prescriptions that were dispensed by nurse practitioners while the doctor was out of the country. As part of the resolution, the parties agreed to submit regular monitoring reports to the DEA for five years and entered into a three-year IA with HHS-OIG.[113]	**$3.5 million**

109 https://www.justice.gov/usao-edva/pr/virginia-beach-doctor-agrees-625000-false-claims-act-settlement.
110 https://www.justice.gov/usao-ct/pr/new-haven-psychiatrist-pay-more-450k-settle-false-claims-act-and-controlled-substances.
111 https://www.justice.gov/usao-nj/pr/marketers-and-healthcare-providers-texas-virginia-and-south-carolina-agree-pay-over-11.
112 https://www.justice.gov/usao-sdia/pr/two-iowa-healthcare-practitioners-settle-allegations-false-submission-claims-federal.
113 https://www.justice.gov/usao-ndga/pr/pain-management-doctor-and-medical-practice-pay-35-million-resolve-false-claims-act.

INDIVIDUAL PROVIDERS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
2/3/2025	Mihir Taneja	Pharmaceutical company executive agreed to pay $2 million to resolve allegations that he conspired with the owner of a pharmacy to negotiate an arrangement with a marketing company under which the marketing company was paid a percentage of the profits from TRICARE claims that it referred to the pharmacy, in violation of the AKS. The pharmacy had previously returned over $19 million it had received from TriCare.[114]	**$2 million**
2/21/2025	Ronald F. Ambrosia	Physician agreed to pay $600,000, plus contingent payments, to resolve allegations that he performed the application of P-Stim devices in patients' ears in an office setting and improperly billed Medicare for surgically implanted neurostimulators.[115]	**$600,000 (minimum)**
3/6/2025	Dr. Henry Goolsby Patricia Lenae Goolsby Infinite Health Integrative Medical Center	Doctor, his wife and clinic co-founder and their medical clinic agreed to pay $450,000 to resolve allegations that they improperly billed Medicare for surgically implanted neurostimulators but actually only placed P-Stim devices in patients' ears.[116]	**$450,000**
3/6/2025	Dr. Gerald Congdon Coastal Urgent Care, LLC Coastal Wellness Center, LLC	Physician and his medical practice agreed to pay $400,000 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.[117]	**$400,000**
3/6/2025	Dr. Gbenga Aluko Eagle Medical Center, PC.	Physician and his medical practice agreed to pay $250,000 to resolve allegations that they received kickbacks, disguised as purported office space rental, phlebotomy and toxicology payments, from a laboratory in return for ordering testing, in violation of the AKS.[118]	**$250,000**
3/6/2025	Dr. Anup Banerjee Gastonia Medical Specialty Clinic P.A.	Physician and his medical practice agreed to pay $206,000 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.[119]	**$206,000**
3/10/2025	Dr. John Patterson	Physician agreed to pay $468,626 to resolve allegations that he received kickbacks from a hospice care center to falsely verify patients as eligible for hospice services when the patients were not actually eligible. The doctor received cooperation credit by, among other actions, agreeing to cooperate with an ongoing criminal investigation and to testify truthfully in any resulting criminal prosecutions.[120]	**$468,626**

114 https://www.justice.gov/usao-mdfl/pr/tampa-man-agrees-pay-us-government-2-million-his-role-medical-kickback-scheme.
115 https://www.justice.gov/usao-sdoh/pr/ohio-doctor-agrees-pay-600000-settle-false-claims-act-allegations.
116 https://www.justice.gov/usao-wdla/pr/lake-charles-physician-wife-and-clinic-agree-pay-medicare-improper-billing-related.
117 https://www.justice.gov/usao-sc/pr/healthcare-providers-and-laboratory-marketers-agree-pay-over-19m-settle-kickback.
118 https://www.justice.gov/usao-sc/pr/healthcare-providers-and-laboratory-marketers-agree-pay-over-19m-settle-kickback.
119 https://www.justice.gov/usao-sc/pr/healthcare-providers-and-laboratory-marketers-agree-pay-over-19m-settle-kickback.
120 https://www.justice.gov/usao-wdtx/pr/doctor-agrees-pay-468000-settle-civil-false-claims-act-allegations.

INDIVIDUAL PROVIDERS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
3/14/2025	Dr. Robert Burkich Preventive Medicine Anti-Aging & Chelation, Inc.	Doctor and his practice agreed to pay $700,000 to resolve allegations that they submitted false claims for medically unnecessary chelation therapy to patients who were not suffering from lead poisoning and lead encephalopathy.[121]	**$700,000**
3/20/2025	Dr. Zachary J. Lipman Dr. Michael Woo-Ming	Two physicians agreed to collectively pay $375,000 to resolve allegations that they both solicited and accepted kickbacks in exchange for referring patients to a chiropractor for the furnishment of a disposable electroacupunture device, in violation of the AKS. The chiropractor previously admitted to billing the government for surgically implanted neurostimulators when he actually used the disposable device that did not require surgery or implantation. The chiropractor settled these allegations in 2024.[122]	**$375,000**
4/16/2025	Jordona Ndon	Former nurse practitioner agreed to pay $50,000 to resolve allegations that she ordered medically unnecessary orthotic braces for Medicare beneficiaries without examining the patients and often based on telemedicine visits of 2 minutes or less.[123]	**$50,000**
5/30/2025	Dr. Samad Khan	Physician agreed to pay $3.5 million to resolve allegations that he submitted false claims for higher level E&M services that were not performed by appropriate healthcare professionals at COVID-19 testing sites and for billing E&M codes for informing patients of their test results, resulting in improper reimbursement from the COVID-19 Uninsured Program.[124]	**$3.5 million**
6/3/2025	Dr. Benjamin Tiongson	Pain management doctor agreed to pay $390,082 to resolve allegations that he submitted claims to Medicare for the surgical implantation of neurostimulator electrodes when he actually used an electro-acupuncture device secured behind patients' ears with adhesive.[125]	**$390,082**
7/22/2025	Dr. Mohd Azfar Malik	Psychiatrist agreed to pay over $501,000 to resolve allegations that he submitted claims to Medicare and MO Medicaid stating that he provided face-to-face psychotherapy services when he was out of town and for services that other practitioners provided. The doctor also pleaded guilty to related criminal charges and was sentenced to five years of probation, fined $20,000 and ordered to pay restitution of $19,442. He also agreed to surrender his DEA registrations.[126]	**$501,556**
7/31/2025	Dr. Rocky Cullens	Dentist agreed to pay more than $532,000 to resolve allegations that he submitted claims to SoonerCare for double-billed and upcoded patient encounters, including for general anesthesia and tobacco cessation counseling.[127]	**$532,055**

121 https://www.justice.gov/usao-ndga/pr/robert-burkich-md-settles-case-alleging-he-submitted-false-claims-chelation-therapy.
122 https://www.justice.gov/usao-edca/pr/two-california-doctors-agree-settlements-totaling-375000-resolve-allegations-fraud.
123 https://www.justice.gov/usao-de/pr/former-nurse-practitioner-agrees-50000-settlement-alleged-false-claims-act-violations.
124 https://www.justice.gov/usao-edtx/pr/collin-county-physician-agrees-pay-35-million-resolve-false-claims-act-allegations.
125 https://www.justice.gov/usao-sdtx/pr/houston-doctor-pays-six-figures-settle-false-claims-act-liability-involving.
126 https://www.justice.gov/usao-edmo/pr/united-states-reaches-501556-civil-settlement-resolving-allegations-false-claims; https://www.justice.gov/usao-edmo/pr/st-louis-area-doctor-sentenced-70-months-prison.
127 https://oklahoma.gov/oag/news/newsroom/2025/july/broken-arrow-dentist-to-pay-more-than-500-000-after-false-claims-act-allegations.html.

INDIVIDUAL PROVIDERS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
8/6/2025	Armand Ntchana Integrated Procare Services, LLC Brookside Residential Care Home, LLC 134 Franklin Street Extension, LLC Riverview Residential Care Home, LLC 92 Lexington Avenue, LLC	Advanced Practice Registered Nurse and his medical practice agreed to pay over $614,000 to resolve allegations that they improperly billed Medicare and Connecticut Medicaid for services not rendered, claims that included an impossible number of hours in a day, services of an unlicensed provider and upcoded or duplicative claims. As part of the resolution, the parties entered into a Suspension Agreement and Consent Order with the Connecticut Department of Social Services (DSS) to be suspended from participating in all programs administered by DSS for two years. They will also not apply for reinstatement in Connecticut Medicaid or any state-funded program thereafter.[128]	**$614,427**
8/11/2025	Dr. Ajay Aggarwal	Anesthesiologist and pain medicine doctor agreed to pay over $2 million to resolve allegations that he submitted false claims for the surgical implantation of neurostimulator electrodes, when patients actually received electro-acupuncture devices that were not surgically implanted.[129]	**$2.05 million**
8/11/2025	Daniel Jacobsen	Licensed clinical social worker agreed to pay $449,014 to resolve allegations that he submitted claims to Virginia Medicaid and Medicare for services not rendered, including claims that billed for more than 16 hours of services in one day, and that he used billing codes for more complex services than were provided, using false psychotherapy progress notes to support the claims. He pleaded guilty to related criminal charges in 2024, for which he paid $316,338 in restitution and was ordered to pay $335,821.31 in forfeiture and a $100,000 fine.[130]	**$449,014**
8/12/2025	Dr. Richard Zielinski	Psychiatrist agreed to pay over $173,000 to resolve allegations that he knowingly submitted upcoded claims for E&M services to SoonerCare and used fabricated records to support his claims.[131]	**$173,143**
8/27/2025	Dr. James Charasika Louisville Patient Centered Medical Home	Physician and his practice agreed to pay $250,000 to resolve allegations that they submitted false claims to Medicare, Medicaid and TRICARE for services provided by the physician when, in fact, the services were provided by nurse practitioners.[132]	**$250,000**
9/8/2025	Dr. Hong Davis Dr. Elizabeth Seymour	Two physicians agreed to collectively pay $358,842 to resolve allegations that they received kickbacks from two purported MSOs in return for ordering tests from certain laboratories, in violation of the AKS. Both physicians were previously ordered to pay additional monetary amounts in a related criminal proceeding.[133]	**$358,842**

128 https://www.justice.gov/usao-ct/pr/aprn-and-medical-practice-pay-over-600k-and-cease-connecticut-medicaid-participation.
129 https://www.justice.gov/usao-sdtx/pr/houston-doctor-agrees-pay-over-2-million-settle-allegations-fraudulent-billing-federal.
130 https://www.justice.gov/usao-edva/pr/richmond-psychotherapist-convicted-healthcare-fraud-pay-over-1m.
131 https://oklahoma.gov/oag/news/newsroom/2025/august/watonga-psychiatrist-to-pay-more-than-170k-for-false-claims-act-allegations.html.
132 https://www.justice.gov/usao-wdky/pr/louisville-physician-agrees-pay-250000-settle-false-claims-act-allegations.
133 https://www.justice.gov/opa/pr/laboratory-ceo-marketers-and-physicians-pay-over-6m-settle-allegations-management-service.

INDIVIDUAL PROVIDERS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
9/12/2025	Irene Oluwatoyin Oshiyoye	Home healthcare operator agreed to pay $250,000 to resolve allegations that she submitted claims to Medicare and Medicaid for home health visits performed by unlicensed and unsupervised foreign doctors.[134]	**$250,000**
11/4/2025	Dr. Ali Tural Tural Pediatrics, Inc.	Doctor and his pediatric group agreed to pay $175,000 to resolve allegations that they submitted false claims for services provided to MassHealth members that were actually provided by physician assistants and certified nurse practitioners. As part of the resolution, the parties agreed to a three-year independent compliance monitoring program.[135]	**$175,000**
11/18/2025	Dr. Mark Shermer	Nephrologist agreed to pay over $375,000 to resolve allegations that he billed Medicare for end-stage renal disease treatment services for dialysis patients that he never performed.[136]	**$375,296**
12/17/2025	Dayna L. Giordano, APRN	Nurse and her medical office agreed to pay over $455,000 to resolve allegations that she caused pharmacies to bill Medicaid for specialty injectable drugs used in Medicated Assisted Treatment that she failed to administer to patients, due to improper medication inventory tracking and substandard record keeping.[137]	**$455,598**

134 https://www.justice.gov/usao-edmi/pr/former-home-health-care-operator-settles-fraud-allegations-billing-federal-health-care.
135 https://www.mass.gov/news/ags-office-secures-175000-from-fall-river-pediatrician-for-submitting-false-claims-to-masshealth.
136 https://www.justice.gov/usao-wdtn/pr/memphis-doctor-pay-37529690-settle-fraudulent-billing-allegations-0.
137 https://portal.ct.gov/ag/press-releases/2025-press-releases/attorney-general-tong-announces-false-claims-settlement-with-branford-nurse.

OTHER

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
1/7/2025	Shahram Naghshbandi	Marketer agreed to pay $400,000 to resolve allegations that he entered into illegal schemes with three laboratories to pay kickbacks, disguised as investment distributions from MSOs, to physicians for laboratory referrals. The marketer and his marketing company received commissions from the laboratories based on reimbursements from the physicians' lab testing referrals. As part of the resolution, the marketer has been excluded from federal healthcare programs for ten years.[138]	**$400,000**
1/7/2025	John Bello RiteRx4U LLC	Marketer and his marketing company agreed to pay $140,000 to resolve allegations that they paid kickbacks, disguised as investment distributions from MSOs, to a physician for laboratory referrals.[139]	**$140,000**
2/18/2025	Health Net Federal Services Inc. Centene Corporation	Healthcare administration company and its corporate parent agreed to pay over $11.25 million to resolve allegations that the company falsely certified compliance with cybersecurity requirements when it failed to scan for known vulnerabilities and remedy security flaws as part of a contract with the Department of Defense to administer the TRICARE program. The corporate parent acquired the healthcare administration company in 2016 and assumed its liabilities.[140]	**$11.25 million**
3/6/2025	Omar Hussain Curis Healthcare Inc. Saeed Medical Group Ltd. d/b/a Alliance Immediate and Primary Care	Marketer, his marketing company and a medical group agreed to collectively pay more than $1 million to resolve allegations that: (1) the marketer and marketing company received commissions from a laboratory as independent contractors based on the volume and/or value of referrals for lab testing that they arranged for and/or recommended; and (2) the medical group received cash payments from the marketer and marketing company in return for ordering testing from the laboratory, in violation of the AKS.[141]	**$1.05 million**
4/17/2025	MJH Healthcare Holdings, LLC MJH Life Sciences, LLC Several affiliates	Medical communication and education publishing company, its subsidiary and several affiliates agreed to pay over $2 million to resolve allegations that they knowingly misrepresented their eligibility to use a lower postage rate offered by the United States Postal Service for their shipping needs by falsely certifying the number of individuals who had requested their publications.[142]	**$2 million**
7/31/2025	Georgina Exposito	Medical billing company owner agreed to pay $400,000 to resolve allegations that she and her company altered patients' medical diagnoses to acquire prior authorizations on behalf of pharmacies, resulting in the submission of false claims to Medicare and TRICARE.[143]	**$400,000**

138 https://www.justice.gov/usao-nj/pr/marketers-and-healthcare-providers-texas-virginia-and-south-carolina-agree-pay-over-11.
139 https://www.justice.gov/usao-nj/pr/marketers-and-healthcare-providers-texas-virginia-and-south-carolina-agree-pay-over-11.
140 https://www.justice.gov/opa/pr/health-net-federal-services-llc-and-centene-corporation-agree-pay-over-11-million-resolve.
141 https://www.justice.gov/usao-sc/pr/healthcare-providers-and-laboratory-marketers-agree-pay-over-19m-settle-kickback.
142 https://www.justice.gov/usao-nj/pr/mjh-healthcare-holdings-llc-agrees-pay-2-million-settle-false-claims-act-allegations.
143 https://www.justice.gov/usao-nh/pr/florida-woman-pay-400000-settle-allegations-falsifying-diagnoses-connection-amherst.

OTHER

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
9/8/2025	Courtney Love Stephen Kash Laura Howard Jeffrey Parnell Stanley Jones LGRB Management Services LLC Jordan Perkins Ruben Marioni Next Level Healthcare Consultants LLC	Seven marketers and certain associated entities agreed to pay more than $1.45 million in total to resolve allegations that they paid kickbacks, disguised as investment distributions from MSOs, to physicians for laboratory referrals.[144]	**$1.45 million**
12/15/2025	PenRad Technologies, Inc.	Software company agreed to pay nearly $530,000 to resolve allegations that it caused providers to bill for breast cancer screenings that were considered medically unnecessary, as a result of the company sometimes configuring its breast cancer risk software with "competing mortality" disabled, contrary to recommended use. The companies received cooperation credit for, among other actions, disclosing the facts of its internal investigation, summarizing materials relevant to the government's investigation, voluntarily producing materials without a subpoena, seeking to resolve the matter expeditiously and implementing remedial measures.[145]	**$529,069**

144 https://www.justice.gov/opa/pr/laboratory-ceo-marketers-and-physicians-pay-over-6m-settle-allegations-management-service.
145 https://www.justice.gov/usao-ma/pr/medical-software-company-agrees-pay-500000-resolve-allegations-causing-medically.

CONTROLLED SUBSTANCES ACT SETTLEMENTS CHART

DATE	ENTITY	CSA ALLEGATIONS	AMOUNT
1/2/2025	Dr. Naimetulla Ahmed Syed	Psychiatrist agreed to pay over $455,000 in part to settle allegations that he issued controlled substance prescriptions without a legitimate medical purpose or within the usual course of professional practice, including prescribing excessive and unsafe quantities and high-risk drug combinations to patients exhibiting clear red flags of abuse, addiction or diversion. He also allegedly failed to establish or document proper doctor-patient relationships, examinations or medical justification, maintaining patient records that lacked basic treatment information. The settlement also resolved related FCA allegations (see above). The doctor voluntarily surrendered his DEA licenses in 2021 and agreed in 2024 to cease the practice of medicine and not renew his physician license. A pharmacy and its owner resolved related CSA allegations in 2024.[146]	**$455,439**
1/22/2025	Tilton Veterinarian Hospital Dr. Sara Laroux	Veterinarian hospital and its owner agreed to pay $53,500 to resolve allegations that they failed to keep accurate records of controlled substances, including those of the opioids received and dispensed, and that they failed to provide effective controls and procedures to guard against theft and diversion of controlled substances.[147]	**$53,500**
1/23/2025	Dr. Kamal Kabakibou Kamal Kabakibou, M.D., P.C. d/b/a The Center for Pain Management	Doctor and his medical practice agreed to pay $3.5 million in part to resolve allegations that the doctor pre-signed prescriptions for opioids that were later illegally dispensed by nurse practitioners while the doctor was out of the country. As part of the resolution, the parties agreed to submit regular monitoring reports to the DEA for five years. The settlement also resolved related FCA allegations (see above).[148]	**$3.5 million**
2/27/2025	Prescriptions Plus	Pharmacy agreed to pay $204,000 to resolve allegations that it failed to keep accurate records of the receipt and distribution of controlled substances in connection with diversion of controlled substances by a staff pharmacist. As part of the resolution, the company entered into a MOA with DEA.[149]	**$204,000**

146 https://www.justice.gov/usao-ct/pr/new-haven-psychiatrist-pay-more-450k-settle-false-claims-act-and-controlled-substances.
147 https://www.justice.gov/usao-nh/pr/tilton-veterinarian-agrees-pay-53500-settle-allegations-controlled-substances-act.
148 https://www.justice.gov/usao-ndga/pr/pain-management-doctor-and-medical-practice-pay-35-million-resolve-false-claims-act.
149 https://www.justice.gov/usao-wdnc/pr/gastonia-pharmacy-pay-204000-resolve-alleged-controlled-substances-act-violations.

CONTROLLED SUBSTANCES ACT SETTLEMENTS CHART

DATE	ENTITY	CSA ALLEGATIONS	AMOUNT
4/21/2025	Walgreens Boots Alliance Walgreen Co.	National pharmacy chain and various subsidiaries agreed to pay $300 million to resolve FCA and CSA allegations that they: (1) illegally filled invalid prescriptions for opioids and other controlled substances, including the drug combination known as the "holy trinity;" (2) pursued payment for many of those illegal prescriptions from federal healthcare programs; and (3) pressured pharmacists to quickly fill prescriptions without confirming prescriptions were lawful and for a legitimate medical purpose. The companies agreed to pay an additional $50 million if certain corporate transactions are undertaken. As part of the resolution, the company entered into a seven-year MOA with DEA and a five-year CIA with HHS-OIG.[150]	**$300 million (guaranteed)** **$50 million (contingent)**
4/24/2025	Community Health Pharmacy, LLC	Retail pharmacy agreed to pay $192,000 to resolve allegations that it failed to keep and maintain complete and accurate records related to the receipt and dispensing of controlled substances including: (1) failure to perform a biennial inventory; (2) failure to execute a valid power of attorney; and (3) failure to accurately complete DEA Form 222s as required by the CSA. As part of the resolution, the company agreed to enter into a three-year MOA with DEA.[151]	**$192,000**
6/4/2025	Dr. Philip Yen	Radiologist, who was serving as DEA registrant for a location of Sutter Health hospital system that included an outpatient surgery center and other services, agreed to pay $125,000 to resolve allegations that he failed to comply with CSA recordkeeping requirements.[152]	**$125,000**
7/2/2025	Lehigh Valley Hospital Network, Inc.	Hospital system agreed to pay more than $2.7 million to resolve allegations that it failed to prevent diversion of controlled substances by a pharmacy tech in one of its hospitals and failed to maintain complete and accurate records of its stocks of controlled substances.[153]	**$2.75 million**
8/8/2025	Dr. Juan Kurdi	Cardiologist agreed to pay $1.2 million to resolve allegations that he issued prescriptions for opioids and other controlled substances outside the usual course of professional practice and not for a valid medical purpose, including prescribing drugs to relatives that were for his personal use. As part of the resolution, the doctor previously agreed to voluntarily surrender his DEA registration.[154]	**$1.2 million**

150 https://www.justice.gov/usao-mdfl/pr/walgreens-agrees-pay-350m-illegally-filling-unlawful-opioid-prescriptions-and.
151 https://www.justice.gov/usao-ct/pr/new-haven-pharmacy-pays-192k-resolve-controlled-substances-act-allegations.
152 https://www.justice.gov/usao-edca/pr/sacramento-doctor-agrees-pay-125000-controlled-substances-act-violations-sutter.
153 https://www.justice.gov/usao-edpa/pr/lehigh-valley-hospital-network-agrees-pay-275-million-resolve-allegations-drug-theft.
154 https://www.justice.gov/usao-ndtx/pr/lubbock-cardiologist-agrees-pay-12-million-resolve-alleged-controlled-substance-act.

CONTROLLED SUBSTANCES ACT SETTLEMENTS CHART

DATE	ENTITY	CSA ALLEGATIONS	AMOUNT
8/28/2025	Shekhar Thakur	Doctor agreed to pay over $700,000 to resolve allegations that he prescribed opioids and other controlled substances outside the usual course of practice, without a legitimate medical purpose and at times in dangerous combinations, despite numerous indications that the patients were abusing or diverting substances. The doctor previously voluntarily surrendered his DEA registration and lost his license to practice medicine. As part of the settlement, the doctor agreed never to apply for reinstatement of his DEA registration.[155]	**$705,075**
9/8/2025	Janelle Harris	Owner-pharmacist paid $100,000 to resolve allegations that the pharmacy she operated repeatedly filled prescriptions for controlled substances that contained red flags that should have created a reasonable suspicion that the prescriptions were not legitimate. The amount of the settlement was based on the pharmacist's ability to pay, and she also executed a consent judgment of $16.7 million.[156]	**$100,000**
9/15/2025	Allcare Discount Pharmacy	Pharmacy agreed to pay $250,000 to resolve allegations that it failed to keep adequate records pertaining to the receipt and disposition of controlled substances and failed to provide effective controls and procedures to prevent theft and diversion, in connection with significant diversion by two pharmacy techs who stole hydrocodone for illicit sale. As part of the settlement, the pharmacy agreed to enter into a MOA with DEA.[157]	**$250,000**
9/22/2025	Daniel Reif, Inc. d/b/a The Medicine Shoppe	Retail pharmacy agreed to pay $200,000 to resolve allegations that it failed to maintain complete and accurate records and inventories of controlled substances and failed to maintain certification records for retail sales as required by the Combat Methamphetamine Epidemic Act.[158]	**$200,000**
11/24/2025	Mt. San Rafael Hospital and Rural Health Clinic Dr. Sheryll Castro-Flores Dr. Joseph Jimenez Dr. Douglas McFarland	Hospital, health clinic and three hospital-employed physicians agreed to collectively pay $650,000 to resolve FCA and CSA allegations that they repeatedly issued opioid and other controlled substance prescriptions without a legitimate medical purpose or outside the usual course of professional practice. The alleged misconduct includes disregarding numerous red flags of improper or unsafe prescribing, such as high opioid dosages, dangerous drug combinations, signs of substance abuse or diversion and suspicious prescribing and payment patterns.[159]	**$650,000**
12/3/2025	Luis Carlos Cordova	Medical spa operator paid $70,000 to resolve alleged recordkeeping violations including incorrect execution of the biennial inventory and failure to record the actual dates of receipt for controlled substance shipments on four occasions.[160]	**$70,000**

155 https://www.justice.gov/usao-wdmi/pr/Thakur%20Settlement%20PR.
156 https://www.justice.gov/usao-sdny/pr/government-announces-settlement-manhattan-pharmacist-unlawful-distribution-controlled.
157 https://www.justice.gov/usao-ndil/pr/us-attorneys-office-announces-settlement-chicago-pharmacy-alleged-violations.
158 https://www.justice.gov/usao-ks/pr/owner-kansas-city-kansas-pharmacy-agrees-pay-200000-resolve-allegations-violating.
159 https://www.justice.gov/usao-co/pr/southern-colorado-hospital-and-doctors-agree-pay-650000-resolve-allegations-they.
160 https://www.justice.gov/usao-nm/pr/southern-new-mexico-medical-spa-operator-settles-allegations-controlled-substance.

CONTROLLED SUBSTANCES ACT SETTLEMENTS CHART

DATE	ENTITY	CSA ALLEGATIONS	AMOUNT
12/10/2025	Recovery Centers of America	Addiction and mental healthcare company agreed to pay $1 million to resolve allegations that it dispensed controlled substances in an unlawful manner, that certain controlled substances were missing from the company's records and that the company failed to comply with additional recordkeeping requirements of the CSA.[161]	**$1 million**
12/10/2025	Dr. Duncan Lahtinen	Physician agreed to pay $120,000 to resolve allegations that he wrote prescriptions for controlled substances that lacked a reasonable medical purpose or were outside the usual course of his practice.[162]	**$120,000**

161 https://www.justice.gov/usao-edpa/pr/recovery-centers-america-agrees-pay-2-million-resolve-allegations-it-violated.
162 https://www.justice.gov/usao-edwa/pr/spokane-physician-pays-120000-resolve-allegations-he-prescribed-controlled-substances.

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 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 over 2,200 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.

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Modern Healthcare

Ranked 4th Largest Healthcare Law Firm in the U.S. (2025)

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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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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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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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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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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, 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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Ben Schrader is a former federal prosecutor, an accomplished litigator and an experienced trial attorney. He counsels clients in responding to government investigations, conducting internal investigations, and navigating other complex civil and criminal defense matters. Before joining Bass, Berry, & Sims, Ben served as Chief of the Criminal Division at the U.S. Attorney's Office for the Middle District of Tennessee. In that role, Ben supervised all of the Office's criminal prosecutions, including matters involving financial and healthcare fraud, money laundering and asset forfeiture, and public corruption. Prior to serving as Criminal Chief, Ben served as Deputy Chief of the Organized Crime Section, where he supervised racketeering and other complex conspiracy cases. Over his nearly 15-year career with DOJ, which included more than four years as an Assistant United States Attorney in the U.S. Attorney's Office for the District of Columbia, Ben served as lead government counsel in dozens of federal jury trials and in approximately 40 bench trials.

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