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# **Fraud & Abuse:** Recent Trends, Key Developments and What's Next

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## Introduction

According to the United States Department of Justice (DOJ), in FY2025, False Claims Act (FCA) settlements and judgments totaled an astounding and record-breaking $6.8 billion, more than doubling the $3.1 billion recovered the prior year. As in the past, the bulk of these recoveries—$5.7 billion—were in the health care industry. DOJ's press release highlighted that the government "continued and expanded its success" in three key health care enforcement areas: managed care, prescription drugs and medically unnecessary care. In addition to these federal recoveries, DOJ noted that many health care cases also resulted in significant recoveries for state Medicaid programs, reflecting the FCA's joint federal-state impact in the health care arena.

Why the big year-over-year jump? Recoveries in cases filed and prosecuted by relators as well as those filed by the federal government increased – signaling a rise in enforcement activity regardless of who initiated the lawsuit. Non-*qui tam* cases more than tripled, reflecting a major increase in homegrown government-initiated cases. The data also showed a huge jump in recoveries in *qui tam* cases where the U.S. declined to intervene, from $311M in FY24 to more than $2.2B in FY25. This partially reflects a handful of major non-intervened cases that were tried to jury verdict, including the $1.64 billion judgment against Janssen (now Johnson & Johnson Innovative Medicine) relating to promotion of its HIV drugs following a 2024 trial in New Jersey, which Janssen is currently appealing before the Third Circuit.

This year's recoveries present an unusual and telling juxtaposition in FCA enforcement: the record number of *qui tam* filings and historically high recoveries come at a time when courts are giving renewed, non-trivial attention to constitutional challenges to the *qui tam* mechanism itself. In *U.S. ex rel. Zafirov*, the Eleventh Circuit is considering whether relators exercise significant authority under Article II without proper appointment—an argument that, until recently, had been largely academic. The tension is striking: the federal government continues to reap enormous financial and enforcement benefits from private relators, while elements of the judiciary are openly questioning

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the structural legitimacy of that delegation. That dynamic likely cuts against predictions of a wholesale dismantling of *qui tam* enforcement. Even if *Zafirov* were affirmed or similar arguments gain traction, the scale of recoveries and DOJ's reliance on whistleblowers make it far more likely that any constitutional disruption would prompt targeted judicial narrowing or legislative repair, rather than elimination, of the FCA's *qui tam* provisions.

DOJ also underscored DOJ's emphasis on cooperation by enforcement targets, including self-disclosures, cooperating with investigations and other remedial measures such as implementing compliance program enhancements or terminating culpable individuals. Per the press release, those "cooperative measures" resulted in reduced penalties or damage multipliers in those cases and signal to regulated entities that proactive compliance and meaningful cooperation can materially affect outcomes in FCA investigations.

Looking ahead, the number of FCA settlements and judgements likely will continue to rise in the coming years, as there are many investigations and filed cases in the pipeline. In FY2025, whistleblowers filed a record 1,297 new *qui tams* and DOJ opened 401 new investigations, most of which have probably not yet been resolved.

Although some predicted a slowdown in health care fraud enforcement amid the change of administrations and associated shuffling of priorities, the data shows that the government's commitment to health care enforcement is strong, and the industry needs to stay vigilant in its compliance efforts.

# Fraud and Abuse Settlements[1]

As is the case in years past, FCA settlement activity remained robust across the entire health care industry. Although this section groups notable settlements by provider type, many FCA liability theories—such as those based on violations of the Anti-Kickback Statute (AKS)—apply regardless of the types of services rendered.

## Health Systems and Hospitals

- Community Health System and Physician Network Advantage agreed to pay **$31.5 million** to resolve allegations that they provided improper benefits and financial incentives to induce physician referrals, in violation of the FCA and the AKS. The government alleged that the system and network offered lavish entertainment, provided electronic health record subsidies and equipment, and paid bonus compensation disguised as clinical integration payments to physicians in exchange for referring patients covered by Medicare, Medi-Cal, TRICARE and other federal health care programs to Community facilities.

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- SVCMC, Inc., a health care and medical clinics system, paid **$29 million** to resolve allegations that it knowingly retained erroneously inflated payments received from the Department of Defense for health care services provided to retired military personnel. SVCMC allegedly knew and concealed that errors in the capitated rates lead to overpayments over a four-year period. The relators were a former interim CFO in the health system, a former consultant to the CEO and board member of one of the entities in the health care system entities and a member on the board of trustees for that same health care system entity.

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- Dana-Farber Cancer Institute (Dana-Farber), a cancer research and treatment center, agreed to pay **$15 million** to resolve allegations that it made false statements and certifications to the National Institute of Health (NIH) in connection with federal research grants in violation of the FCA. The government alleged that Dana-Farber researchers used NIH grant funds to produce research that included misrepresented data, and that the institution then caused false claims to be submitted by inaccurately certifying compliance with grant requirements, charging unallowable expenses and securing additional funding through misleading statements.

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- Carson Tahoe Health System paid **$8.8 million** to resolve allegations that it and its clinics and hospitals obtained loans through the Paycheck Protection Program and had those loans forgiven, despite being ineligible for the loans because they exceeded the required small business size limitations.

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[1] *All content contained in this e-book is derived from publicly available sources only.*

- New York-Presbyterian Hudson Valley Hospital (NYPHV) paid approximately **$6.8 million** to resolve allegations that it violated the FCA by submitting claims to Medicare and Medicaid that resulted from improper financial arrangements with an oncology practice. The government alleged that NYPHV paid fees under medical directorship and management agreements that were not supported by documented services and were intended to induce referrals, in violation of the AKS and the Stark Law.

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- East El Paso Physician's Medical Center, LLC d/b/a Foundation Surgical Hospital of El Paso agreed to pay over **$2 million** to resolve allegations of improper billing of medical imaging services at the hospital. The government alleged that the hospital retained a percentage of reimbursement for claims billed by third-party Desert imaging Services L.P. using the hospital's NPI for patients that had no connection to the hospital.

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## Physician Practices

- Seoul Medical Group Inc., an independent physician association, and its subsidiary Advanced Medical Management Inc. agreed to pay **$59 million** for allegations that they violated the FCA by submitting false diagnosis codes for two spinal conditions for patients that did not have the conditions to increase payments from the Medicare Advantage Program. The relator was the former Vice President and Chief Financial Officer of Advanced Medical Management.

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- Vohra Wound Physicians Management LLC (Vohra), a bedside wound-care physician group for nursing homes and skilled nursing facilities, and its owner Dr. Ameet Vohra agreed to pay **$45 million** to resolve allegations that they submitted false claims to Medicare by seeking payment for surgical debridement procedures that were not medically necessary, upcoding routine wound care as more complex surgeries and billing evaluation and management services that were not reimbursable. Vohra agreed to enter into a five-year Corporate Integrity Agreement with HHS-OIG requiring enhanced compliance measures, annual certifications, risk assessments and review by an independent review organization.

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- Kamal Kabakibou, M.D., P.C., d/b/a The Center for Pain Management (TCPM), along with Dr. Kabakibou individually, agreed to pay **$3.5 million** to resolve allegations that they violated the FCA and Controlled Substance Act by billing for medically unnecessary testing and pre-signing opioid prescriptions to be dispensed by a nurse practitioner while Dr. Kabakibou was not in the country. TCPM and Dr. Kabakibou entered into a three-year Corporate Integrity Agreement with HHS-OIG, including an annual claims review by an independent review organization.

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- Bloom Care LLC, an urgent care operator, and its owners agreed to pay **$3 million** to resolve allegations that they submitted false claims to Medicare, Medicaid, HRSA's Uninsured Program, TRICARE and VA for medically unnecessary services and inflated evaluation-and-management codes. The government alleged that Bloom used the COVID-19 pandemic as a pretext to bill unnecessary strep and flu tests for asymptomatic patients and routinely billed high-level E/M visits while exaggerating time spent and clinical complexity in order to obtain higher reimbursement.

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- Health First Urgent Care (Health First), a Washington based urgent care clinic, agreed to pay approximately **$2.8 million** to resolve allegations that it violated the FCA by fraudulently billing for polymerase chain reaction respiratory and urinary tract infection panel testing. Health First purportedly did this by billing for each component of a test as one test instead of the entire panel test. The settlement also resolved allegations that Health First improperly billed for more tests that were not medically necessary and more expensive for certain patients.

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## Pharmaceutical Manufacturers and Distributors

- Gilead Sciences, Inc. (Gilead) agreed to pay **$202 million** to resolve allegations that it paid unlawful remuneration to health care providers to induce prescriptions of its HIV medications in violation of the AKS, resulting in the submission of false claims to Medicare, Medicaid and TRICARE. The government alleged that, from 2011 to 2017, Gilead used thousands of speaker programs at luxury restaurants, excessive honoraria, lavish meals, alcohol and paid travel to reward high-prescribing clinicians and encourage further prescribing, while allowing repeat attendance for minimal educational benefit. The government also alleged that Gilead failed to monitor and enforce compliance safeguards through its compliance program. Relator was a physician who treated patients with HIV.

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- Biohaven Pharmaceutical Holding Company Ltd. (Biohaven), a subsidiary of Pfizer Inc., paid nearly **$60 million** to resolve allegations that it knowingly caused the submission of false claims to Medicare and other federal health care programs by paying kickbacks to health care providers to induce prescriptions of Biohaven pharmaceutical drug Nurtec ODT, a migraine medication. Relator was a former sales representative at Biohaven.

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- Assertio Therapeutics Inc., f/k/a Depomed Inc. (Assertio) agreed to pay **$3.6 million** to resolve allegations that it caused the submission of false claims to Medicare and TRICARE by improperly promoting its fentanyl nasal spray, Lazanda. The government alleged Assertio promoted Lazanda to prescribers who treated patients without breakthrough cancer pain (the drug's only approved indication) and targeted high-volume prescribers, including some later charged with drug diversion. Assertio also allegedly used speaker programs and advisory boards to incentivize prescriptions and operated a support program that helped secure federal insurance coverage for inappropriate prescriptions.

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## Pharmacy

- Walgreens Boots Alliance, Walgreen Co., and various subsidiaries (collectively Walgreens) agreed to pay **$300 million** to resolve allegations that it illegally filled millions of controlled substance prescriptions and then submitted claims to Medicare and other federal health care programs for those invalid prescriptions, in violation of the FCA. The government alleged that Walgreens pressured pharmacists to fill prescriptions without proper verification, ignored evidence of unlawful dispensing, withheld internal prescriber data and prevented pharmacists from warning each other about problematic prescribers, enabling continued improper dispensing. Relators were former Walgreens employees.

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- CVS Pharmacy, Inc. (CVS) agreed to pay **$37.76 million** to resolve allegations that it sought reimbursement from government health care programs for insulin pen dispensing and refills that did not comply with program requirements, resulting in the submission of false claims to the government. The government alleged that CVS dispensed insulin in quantities larger than permitted, refilled prescriptions significantly before beneficiaries needed more medication and reported inaccurate daily supplies that obscured these early refills.

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- CVS Pharmacy, Inc. (CVS) agreed to pay **$18.28 million** to resolve allegations that it submitted false claims under both the federal FCA and the California False Claims Act when it falsely certified and submitted reimbursement for unqualifying drugs. The United States alleged that CVS improperly certified certain prescriptions as meeting the requirements for "Code 1" drug reimbursement without the necessary documentation and proper diagnoses to bill for them. Relator was a former CVS pharmacist.

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- VRA Enterprises, LLC d/b/a Precision Rx (VRA), a pharmacy, agreed to pay **$17 million** when it participated in the CMS over-the-counter Covid-19 Test Demonstration Project and billed Medicare for test kits it never provided, shipped test kits months after billing Medicare and failed to issue Medicare a refund. The United States alleged that VRA submitted more than 136,000 claims months before shipping the tests and repeatedly billed Medicare for tests it failed to ship.

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- Excel Pharmacy, Inc. agreed to pay **$3 million** to resolve allegations that it caused the submission of false claims to Medicare Part D and Medicaid for reimbursement for drugs that were never purchased from wholesalers or dispensed to beneficiaries. The government alleged that, from 2015 to 2022, the pharmacy sought reimbursement for medications it did not actually provide, resulting in federal and state health care programs paying for nonexistent prescriptions.

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- Walgreen Co. (Walgreens) has agreed to pay over **$2.8 million** to resolve allegations that it violated the FCA by submitting inflated prices for generic medications to state Medicaid programs. The government alleged that Walgreens pharmacies failed to report the correct usual and customary price for certain generic medications and submitted higher prices, resulting in an improper higher reimbursement. Relators were former employees of Walgreens.

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- Kirtland Corp. aka New Millenium Drugs and Western Wayne Pharmacy, LLC and the two individuals who operated these companies agreed to pay **$1.5 million** to resolve allegations that they submitted false claims to Medicare and Michigan Medicaid for pharmaceuticals that were never dispensed. The government alleged that, from 2017 to 2021, the pharmacies billed for medications that were not actually provided to beneficiaries, and that the scheme also resulted in a related criminal plea. As part of the settlement, the two individual operators agreed to a 10-year exclusion from all federal health care programs.

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- QuickRx LLC agreed to pay **$962,821** to resolve allegations that its affiliated entity, Community Pharmacy, submitted false claims to Medicare Part D and Medicaid for drugs that were never purchased from wholesalers or dispensed to beneficiaries. The government alleged that, from 2015 to 2022, the pharmacy sought reimbursement for medications that were never provided to beneficiaries, resulting in federal and state health programs paying for drugs that were never provided.

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## Laboratories

- Patients Choice Laboratories (PCL) of Indiana, an independent infectious disease laboratory, agreed to pay **$9.62 million** to resolve allegations that it billed Medicare for medically unnecessary respiratory pathogen panels (RPP), billed for services not rendered and paid illegal kickbacks to generate referrals. The government alleged that PCL paid an infection prevention company for referrals, performed RPPs without individualized assessments, added symptoms to order forms and paid commissions to independent contractor sales representatives. PCL entered into a five-year Corporate Integrity Agreement with HHS-OIG.

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- Vault Medical Services, P.A. and Vault Medical Services of New Jersey, P.C. (collectively Vault) agreed to pay **$8 million** to settle allegations that it submitted false claims to HRSA's COVID-19 Uninsured Program for COVID-19 testing, specimen collection and vaccine administration services that were not reimbursable under the program because they were insured. The government alleged that Vault failed to collect complete patient and insurance information, disregarded valid insurance data it possessed and improperly billed uninsured program funds for patients who actually had coverage, resulting in federal funds being used to pay ineligible claims.

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- Clinical laboratory LTD Holding LLC, f/k/a Labtech Diagnostics LLC (Labtech), a clinical laboratory, agreed to pay at least **$6.8 million** to resolve allegations that it violated the FCA by submitting claims to Medicare and Medicaid that were tainted by illegal kickbacks. The government alleged that Labtech paid remuneration disguised as office space rentals, service fees and free supplies to health care providers in exchange for referrals of laboratory testing services, causing false claims to be submitted to federal health care programs.

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- Genexe LLC, Immerge, Inc. and their executives agreed to pay **$6 million** to resolve allegations that they submitted false claims to Medicare for genetic tests procured through illegal kickbacks. The government alleged that, between 2018 and 2019, the companies operated a nationwide scheme in which untrained contractors recruited Medicare beneficiaries for medically unnecessary tests, collected DNA swabs in non-clinical settings and obtained physician orders through kickback-tainted telemedicine arrangements, resulting in Medicare paying thousands of dollars per test for services that were neither medically necessary nor lawfully obtained.

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- Physicians Toxicology Laboratory, LLC (PTL), a clinical laboratory, agreed to pay approximately **$4.4 million** to resolve allegations that it violated the FCA by causing physicians to order medically unnecessary urine drug and hormone tests and billing Medicare for those services. The government alleged that PTL encouraged blanket orders for both presumptive and definitive drug testing without individualized medical necessity determinations and billed for duplicative hormone testing. PTL entered into a three-year integrity agreement with HHS-OIG as part of this settlement.

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- Agendia, Inc. (Agendia), a molecular diagnostics company, agreed to pay at least **$3.25 million** to resolve allegations that it violated the FCA by submitting improper reimbursement claims to federal health care programs. The government alleged that Agendia caused providers to order unnecessary breast cancer genomic tests through standing or automatic orders and submitted claims tainted by alleged kickbacks. The settlement resolves two *qui tam* actions filed by a physician and another private individual.

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- Curis Healthcare Inc., other providers and laboratory marketers paid nearly **$2 million** to resolve allegations that the health care providers received kickbacks in the form of commissions, cash payments and inflated lease payments in return for their referrals to a laboratory, in violation of the FCA.

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- Genetic Technological Innovations, LLC (GTI), a diagnostic laboratory, agreed to pay **$1.635 million** to resolve allegations that it billed Medicare for respiratory pathogen panels that were not medically necessary and that it used a purported marketing arrangement to disguise payments to a third-party company for testing referrals. According to the government, the laboratory added large respiratory panels onto COVID-19 specimens regardless of clinical need and paid compensation tied to referral volume.

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- Genco Lab, LLC (Genco), a reference laboratory, paid approximately **$1.2 million** to resolve allegations that it violated the FCA by billing Medicare and Medicaid for medically unnecessary urine drug testing. The government alleged that Genco sought reimbursement for drug tests performed on residents of sober homes for non-covered "residential monitoring" purposes and routinely billed for both screening and more expensive confirmatory tests conducted on the same day without first establishing medical necessity.

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- NEXT Bio-Research Services LLC, d/b/a NEXT Molecular Analytics (NEXT), a Virginia clinical laboratory, agreed to pay **$758,000** to resolve allegations that it violated the FCA by knowingly paying kickbacks to generate laboratory testing referrals and billed the laboratory tests to Medicare, Medicaid and TRICARE. The government alleged that NEXT and outside contractors facilitated monthly payments to physicians in Texas and Arkansas that were labeled as consulting or medical director fees but were intended to incentivize the physicians to order NEXT's laboratory tests. The government also asserted that NEXT paid its contractors commissions based on volume and value of their referrals in violation of the AKS. Relators were co-founders of a third-party marketing contractor.

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## Durable Medical Equipment and Medical Supplies

- Aesculap Implant Systems LLC (Aesculap), a medical device company, paid **$38.5 million** to resolve allegations that it knowingly sold its VEGA System® Knee System despite being aware that the implants failed prematurely at unacceptably high rates, and therefore not reasonable or medically necessary, resulting in false claims being submitted to Medicare and Medicaid. The Government further alleged that Aesculap paid unlawful remuneration, including consulting payments, international travel and entertainment, to a Georgia orthopedic surgeon to induce the use and recommendation of the VEGA System® Knee System. The relators were third-party distributors who filed suit under the *qui tam* provisions of the FCA.

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- Semler Scientific Inc. (Semler), a medical device manufacturer, agreed to pay **$29.75 million**, and its former distributor Bard Peripheral Vascular Inc. (Bard) agreed to pay **$7.2 million**, to resolve allegations that they caused the submission of false Medicare claims for peripheral arterial disease testing devices. The government alleged that the devices did not perform an ankle brachial index and were not eligible for Medicare reimbursement, yet the companies promoted their use as billable under CPT codes that required an ABI. The settlement resolves a *qui tam* action filed by two individuals. Semler also entered into a five-year Corporate Integrity Agreement with HHS-OIG.

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- C.R. Bard, Inc. (Bard) and its affiliates agreed to pay **$17 million** to resolve allegations that it violated the FCA by providing free samples, discounts and other benefits to urology practice groups to induce the use of Bard's prescription form for intermittent catheters. The government alleged that this remuneration violated the AKS and led to the submission of false claims to federal health care programs. The settlement resolves a *qui tam* action filed by a former employee of a competing supplier.

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- Diopsys Inc. (Diopsys), a medical device company, paid up to **$14.25 million** to resolve allegations that the company violated the FCA by causing providers to submit false claims to Medicare and Medicaid in connection with the use of its NOVA electrophysiological device for vision testing services. Specifically, the government alleged that Diopsys caused providers to submit false claims for using the device for tests that its NOVA device had not received FDA clearance for, resulting in claims being submitted for medically unnecessary uses of the device. Relator was a California ophthalmologist.

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- Exactech Inc. (Exactech) agreed to pay **$8 million** to resolve allegations that it knowingly sold defective knee-replacement implant components and caused hospitals and surgeons to submit false claims to Medicare, Medicaid and the VA for procedures using devices the company allegedly knew were prone to premature failure. The government alleged that Exactech failed to disclose material defect information, leading federal health care programs to reimburse procedures involving devices the company allegedly knew were not reasonable or medically necessary.

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- MED-EL Corporation (MED-EL), a cochlear implant company, agreed to pay approximately **$2.1 million** to resolve allegations that it violated the FCA by falsely certifying its eligibility for a second draw Paycheck Protection Program (PPP) loan. The government alleged that, although MED-EL certified that it and its affiliates employed no more than 300 individuals, its combined workforce exceeded that threshold, rendering it ineligible for the loan. The settlement resolves a *qui tam* action filed by an individual.

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## Long Term Care

- Unified Care Services LLC (Unified Care), and its affiliates, a chain of skilled nursing facilities, paid **$18 million** to resolve allegations that they violated the FCA by knowingly providing false information in support of PPP loan applications and loan forgiveness applications submitted by Unified Care. The applications failed to disclose that Unified Care and its affiliates had common ownership with a larger chain of facilities, rendering them ineligible for the program.

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- Providence Park, Inc., d/b/a Ascension Living Providence Village, a Texas based skilled nursing facility and Ascension Providence, f/k/a Providence Health Services of Waco, an acute care hospital, agreed to pay **$6.5 million** to resolve allegations that they submitted medically unnecessary Ultra-High Resource Utilization Group therapy claims, submitted false claims for outpatient group therapy for individual therapy sessions and submitted therapy services without a physician signed plan of care. The entities received cooperation credit per the DOJ's Guidelines for Taking Voluntary Disclosure, Cooperation, and Remediation into Account in False Claims Act Matters. Specifically, they disclosed the results of Ascension Providence's internal investigation that included refunding an overpayment to Medicare, identified overpayments for outpatient therapy services within their OIG Self-Disclosure submission and addressed corrective action taken within their self-disclosure. The settlement resolved a *qui tam* action brought by relators Bland and Ellison, both former employees.

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- Centers Healthcare and 44 affiliated Skilled Nursing Facilities agreed to pay **over $6 million** to resolve allegations that they submitted false Medicare cost reports containing undisclosed related-party transactions and inaccurate allowable cost calculations. The government alleged that Centers Healthcare knowingly failed to disclose business dealings with related organizations and misrepresented whether the transactions involved a home office, resulting in Medicare relying on inaccurate cost data in determining payment rates.

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- Community Options, Inc. and Community Options New York, Inc., Inc. (collectively Community Options), operator of residential and non-residential facilities for adults with developmental disabilities, agreed to pay **$5 million** to resolve allegations that they billed for Day Habilitation services that failed to meet Medicaid requirements and improperly retained overpayments for these services. Community Options entered into a five-year Corporate Integrity Agreement. The government intervened in the *qui tam* action brought by SCOIF LLC, a single-member limited liability company created to bring this lawsuit on behalf of a former employee.

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- Villa Financial Services LLC, Villa Olympia Investment LLC and six affiliated Villa nursing homes (the Villa Entities) agreed to pay **$4.5 million** to resolve allegations that they submitted false claims to Medicare and Michigan Medicaid for grossly substandard and / or worthless nursing services. The government alleged that the facilities systematically failed to provide adequate staffing, infection control, fall prevention, activities-of-daily-living support and proper treatment of pressure ulcers. These failures allegedly resulted in reimbursement for services that did not meet regulatory standards and were not reasonable, necessary, or properly provided. The Villa Entities entered into a five-year Corporate Integrity Agreement.

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- American Health Foundation (AHF), its management company and three affiliated nursing homes agreed to pay **$3.61 million** to resolve allegations that they submitted false claims to Medicare and Medicaid for grossly substandard services. The government alleged widespread failures in infection control, staffing, sanitation, medication management and resident care. AHF also entered into a five-year Corporate Integrity Agreement.

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- Sola, Inc., a former operator of adult residential group homes, paid **$2 million** to resolve allegations it billed for nursing services that were not performed because the amount of time billed exceeded the number of hours worked as reported by Sola nurses.

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- Riverpark Operations, LLC (Riverpark), a skilled nursing facility and Avamere Group, LLC (Avamere), the operator and parent company of Riverpark, agreed to pay **$2 million** to resolve allegations that Riverpark billed for substandard nursing home services including failing to meet minimum staffing requirements. Riverpark and Avamere agreed to enter a five-year Quality-of-Care Corporate Integrity Agreement.

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## Hospice, Home Health and Home Care

- Mahlega Abdsharafat, a/k/a Mallie Sharafat, Creative Hospice Care, Inc. and affiliated companies (collectively, Creative Hospice entities), agreed to pay **$9.2 million** to resolve allegations that they engaged in illegal kickback arrangements with medical directors in exchange for referring hospice patients, in violation of the AKS and the FCA. The government alleged that Creative Hospice paid monthly stipends and signing bonuses to medical directors increased referral volume and decreased with lower volume, causing false claims to be submitted to federal health care programs. The government's investigation arose from three separate whistleblower complaints.

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- Saad Enterprises Inc. d/b/a Saad Healthcare paid **$3 million** to resolve allegations that it violated the FCA by knowingly submitting false claims for the care of hospice patients by certifying Medicare beneficiaries that were not terminally ill as eligible for hospice care. Relators were former employees of Saad Healthcare.

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## Behavioral Health

- Summit BHC New Jersey, LLC, d/b/a Seabrook (Seabrook), a drug and rehabilitation facility in New Jersey, agreed to pay **$19.75 million** to resolve allegations that it submitted false claims to Medicaid and the Veterans Health Administration's Community Care Program for substance-abuse treatment services it was not licensed or authorized to provide. The government alleged that, from 2022 to 2024, Seabrook illegally billed for unlicensed residential partial-hospitalization services and concealed unapproved veteran residents during state inspections. It further alleged that Seabrook relied heavily on uncredentialed interns to provide care, falsely represented that it offered specialized veteran-focused treatment and billed full rates for counseling services that were not actually delivered. Relator was a former Seabrook employee.

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- NUWAY Alliance, Inc. (NUWAY), a provider for intensive outpatient treatment for substance use disorder, agreed to pay **$18.5 million** to resolve allegations that they provided incentives to Medicaid recipients to induce them to receive intensive outpatient treatment in violation of the AKS and submitted false claims for either services not provided or double billed for overlapping treatment time periods. NUWAY agreed to enter a five-year Corporate Integrity Agreement. The settlement agreement resolves multiple *qui tam* complaints brought against NUWAY.

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- Community Health Care Solutions, LLC, a counseling service, and its deceased operator through the estate of Yolanda Burnom agreed to pay **$4.6 million** to resolve allegations of improperly offering Medicaid recipients financial incentives to share their patient information and falsely submitting claims for crisis intervention services that never occurred.

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- American Psychiatric Centers, Inc., d/b/a Comprehensive Psychiatric Services, a behavioral medicine provider, agreed to pay **$2.75 million** to resolve allegations that they submitted false claims for services of psychotherapy services through add-on CPT codes 90833 and 90836. The government alleged that from January 1, 2015, through December 31, 2022, the provider used these add-on codes that are billed with an evaluation and management visit and either submitted improper documentation or failed to altogether provide the care.

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## Imaging and Monitoring

- Fairfax Radiological Consultants, PLLC f/k/a Fairfax Radiological Consultants, P.C. (FRC) paid **$2.8 million** to settle FCA allegations that it falsely reported its eligible payroll costs to receive full forgiveness of a $6.7 million PPP loan. At the time FRC applied for full forgiveness, it employed more employees than the maximum allowable to qualify for full forgiveness.

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- LiveCare Inc., a provider of remote patient monitoring services for Type 2 diabetes patients, agreed to pay **$4.9 million** to resolve allegations that they violated the AKS and FCA for paying on a referral-based arrangement for marketing services. The two relators were former employees including a "health coach."

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## Biotech

- Illumina Inc. (Ilumina) agreed to pay **$9.8 million** to resolve FCA allegations that Illumina knowingly provided federal agencies with genomic sequencing software that lacked required security and quality processes and misrepresented cybersecurity compliance. The government alleged that from February 2016 to September 2023 Illumina failed to identify and address cybersecurity vulnerabilities including implementing cybersecurity protections into the product, implementing on-market monitoring for security issues and rectifying any features that demonstrated vulnerabilities. The government alleged that Illumina falsely represented that their product complied with cybersecurity standards including standards of the International Organization for Standardization and National Institute of Standards and Technology. Relator was a former Illumina employee.

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## Court Decisions

This section delves into notable cases involving the FCA, spanning opinions rendered in federal appellate courts. These cases offer valuable insights into evolving legal standards and judicial interpretations surrounding FCA claims.

### First Circuit Cases

- *United States v. Regeneron Pharmaceuticals, Inc.*, 128 F.4th 324 (1st Cir. 2025)

  The First Circuit held as a matter of first impression for this court that demonstrating falsity under AKS requires the government to show that an illicit kickback was the but-for cause of a submitted claim. This appeal stemmed from allegations that Regeneron Pharmaceuticals induced prescriptions of Eylea, an ophthalmological drug, by covering copayments for certain recipients of the drug. The government contended that the funding of copayments constituted kickbacks and therefore resulted in false claims made to Medicare in violation of the FCA. At issue for the First Circuit was the interpretation of "resulting from" in the 2010 amendment to the AKS, which provides that a "claim that includes items or services *resulting from* a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA]." (emphasis added). The Court decided that "statutory history provides no reason to deviate from the ordinary course, in which we treat 'resulting from' as requiring but-for causation[.]" While this decision aligns the First Circuit with the Sixth and Eighth Circuits, the decision contrasts with the Third Circuit, which requires only a demonstration of a link "between the alleged kickbacks and the medical care received . . ."

- *United States ex rel. Flanagan v. Fresenius Medical Care Holdings, Inc.*, 142 F.4th 25 (1st Cir. 2025)

  The First Circuit affirmed dismissal of an FCA complaint because it failed to adequately plead that alleged kickbacks were the "but-for" cause of claims submitted to the government. The relator, a former employee of the defendant Fresenius, a large dialysis clinic, alleged that Fresenius paid kickbacks by signing below-cost hospital contracts to induce referrals to its dialysis clinics and compensating medical directors based on their volume of referrals. The First Circuit affirmed the district court's dismissal of the complaint for failing to meet Rule 9(b)'s requirement to plead causation with particularity, citing its recent decision in *Regeneron Pharmaceutical*s, which held that but-for causation is required for AKS-based claims under the FCA.

- *United States ex rel. OMNI Healthcare Inc. v. MD Spine Solutions LLC*, 160 F.4th 248 (1st Cir. 2025)

  The First Circuit affirmed the district court's summary judgment dismissal of relator's *qui tam* action under the FCA. Relator alleged that defendant MD Spine Solutions LLC (MD Labs), an independent clinical laboratory, submitted false claims to Medicare by utilizing, and seeking reimbursement for, a more expensive testing method with polymerase chain reaction (PCR) technology to diagnose urinary tract infections (UTIs), instead of the traditional bacterial urine culture (BUC) test, which the relator alleged was medically unnecessary. The First Circuit affirmed

the dismissal on the basis that the relator had failed to present sufficient evidence demonstrating that MD Labs had knowingly submitted false claims. In particular, the relator failed to show that MD Labs believed or otherwise should have known that the PCR tests were medically unnecessary, as MD Labs offered evidence that it was merely fulfilling orders for UTI testing as prescribed by the ordering provider and / or upon the belief that PCR testing was superior to BUC testing for diagnosing UTIs.

## Second Circuit Cases

- *United States ex rel. Sisselman v. Zocdoc, Inc.*, 2025 WL 1100601 (2d Cir. Apr. 14, 2025)

  The Second Circuit affirmed dismissal of relator's *qui tam* action under the AKS and FCA for failure to state a claim. Physician relator alleged that defendant Zocdoc, Inc.'s (Zocdoc) pricing model, which charges providers a "booking fee" was actually a referral fee and that Zocdoc improperly pushed federal health care program beneficiaries to medical providers willing to pay the fee by making them more visible on their platform than those providers who paid only the annual subscription fee. The Second Circuit affirmed the dismissal, emphasizing that OIG had already issued an opinion that expressly addressed these concerns and found that these practices did not violate the AKS, and the relator did not plausibly allege that Zocdoc had acted with the requisite fraudulent intent because the complaint pointed only to isolated phrases in what were essentially sales and marketing communications that the relator had received as a Zocdoc customer, which did not demonstrate a "strong inference" of fraudulent intent.

## Third Circuit Cases

- *Bennett v. Bayer Corp.*, 2025 WL 1435591 (3d Cir. Apr. 10, 2025)

  The Third Circuit affirmed the dismissal of relator's *qui tam* action under the FCA for failure to state a claim. Relator alleged that the defendants, several pharmaceutical manufacturers, fraudulently induced the FDA to approve two antibiotic drugs without appropriate warning labels by omitting or misrepresenting the drugs' serious side effects, which, in turn, caused the submission of claims that would have never been reimbursed by the government had the defendants been truthful. The Third Circuit affirmed the district court's dismissal on the basis that the relator had failed to plead sufficient facts showing that the FCA's elements of falsity and materiality had been met. In particular, the relator failed to allege facts showing what, if anything, the defendants intentionally withheld from the FDA, or that the data presented by defendants to the FDA amounted to a false or fraudulent statement. Additionally, even if the data was misleading, the relator failed to demonstrate that such data was material to the FDA's approval decisions.

- *United States v. Bracco USA, Inc.*, 2025 WL 1261779 (3d Cir. May 1, 2025)

  The Third Circuit affirmed the dismissal of relator's *qui tam* action for failure to state a claim. Relator alleged that defendant Bracco USA, Inc. (Bracco), a manufacturer and seller of imaging agents, had entered into agreements with medical providers in which Bracco would provide them with free power injector machines and other discounts in exchange for their agreement to buy 90% of their imaging agents from Bracco for a three-to-five-year period. Allegedly, the providers would, in turn, submit claims for imaging services to the government for payment. The Third Circuit affirmed the district court's dismissal on the basis that the relator had only alleged facts showing how these agreements *could* have been used to defraud the government, rather than particular facts showing that the defendants had indeed failed to disclose the value of these agreements resulting in submission of false claims to the government.

- *United States v. Fillmore Cap. Partners, LLC*, 2025 WL 971668 (3d Cir. Apr. 1, 2025)

  The Third Circuit affirmed the dismissal of relator's *qui tam* action under the FCA and related state laws for failure to meet the heightened pleading standard for fraud under Rule 9(b). The relator, a registered nurse formerly employed by the defendants, alleged that the defendants had intentionally admitted high-acuity residents who required more intensive care, despite knowing that their facilities were understaffed and did not provide adequate care to these residents, and had billed the government for care provided to these residents. The Third Circuit affirmed the district court's dismissal on the basis that the relator had failed to allege facts demonstrating a "reliable indicia" of fraud that led to a strong interference that false claims were actually submitted. In particular, the factual details alleged by the relator, including reports from experts opining that the staffing was wholly inadequate, merely demonstrated that there was an opportunity for fraud, which was discounted by the fact that there was a "legitimate business explanation" for the defendants' low staffing decisions.

## Fourth Circuit Cases

- *United States ex rel. Rosales v. Amedisys North Carolina, L.L.C.*, 128 F.4th 548 (4th Cir. 2025)

  The Fourth Circuit affirmed the district court's dismissal of the relator's *qui tam* complaint against a hospice care provider, Amedisys North Carolina, L.L.C. (Amedisys) based on the first-to-file rule. The relator alleged that Amedisys fraudulently admitted and recertified patients for hospice care that were ineligible. Amedisys moved to dismiss Rosales's complaint under the first-to-file rule, citing an earlier *qui tam* complaint filed in 2014. Rosales amended her complaint on October 15, 2021, adding new defendants, reasserting her original four claims and incorporating a fifth claim under the AKS, but the district court dismissed Rosales's complaint under the first-to-file rule. The Fourth Circuit affirmed the dismissal, ruling that Rosales's claims, though amended, were based on the same core fraudulent conduct as the earlier suit, thus upholding the FCA's first-to-file bar to prevent duplicative litigation. In doing so, the Court emphasized that that the first-to-file rule applies to individual claims rather than entire complaint, and (2) must be analyzed on a defendant-by-defendant basis. The Fourth Circuit's ruling clarifies that the first-to-file rule is not an automatic bar to all later FCA claims, thus ensuring that whistleblowers can still bring new and distinct allegations of fraud even if similar cases were filed previously.

- *United States ex rel. Wheeler v. Acadia Healthcare Company, Inc.*, 127 F.4th 472 (4th Cir. 2025)

  The Fourth Circuit reversed a district court's dismissal of a *qui tam* case brought against Acadia Healthcare Company, Inc. (Acadia), one of the largest addiction treatment and behavioral health care service providers in the United States. The relator, a former assistant medical director at a clinic providing substance abuse disorder treatment in North Carolina, alleged that Acadia was falsifying patient records by fabricating notes from therapy sessions that purportedly never occurred, and relying on those notes to submit claims to the government for reimbursement. The district case found the relator failed to show the claims were material or actually submitted to the government and thus dismissed the case. The Fourth Circuit reversed, holding that the requirements of Acadia's Corporate Integrity Agreement created an "obligation" to the government sufficient to trigger a reverse false claim. The Fourth Circuit also held that the relator adequately alleged the presentment of a false claim under Rule 9(b), thus siding with more relator-friendly circuits which do not require a relator to plead the details of an actual false claim presented to the government for payment to satisfy Rule 9(b)'s particularity requirement.

## Fifth Circuit Cases

- *United States ex rel. Gentry v. Encompass Health Rehabilitation Hospital of Pearland,* L.L.C., 2025 WL 3063921 (Nov. 3, 2025)

  The Fifth Circuit affirmed the dismissal of a whistleblower's *qui tam* complaint. The relator, a former sales representative at an inpatient-rehabilitation facility (IRF), alleged that the IRF submitted false Medicare claims by allowing nonclinical employees to influence patient admission decisions. The Fifth Circuit held that the complaint failed to allege sufficient facts showing that false claims were submitted or that any alleged misconduct was material to government payments. Most importantly, in a concurring opinion, Judge James C. Ho agreed with the outcome, but urged the court to revisit "serious constitutional problems" with the *qui tam* provisions. Judge Ho called on the Fifth Circuit to reconsider its recent decision in *Riley v. St. Luke's Episcopal Hosp.*, 252 F.3d 749 (5th Cir. 2001), which affirmed the constitutionality of the FCA's *qui tam* structure. Judge Ho emphasized that relators exercise executive authority on behalf of the U.S. without appointment or accountability to the President, raising separation-of-powers concerns under Article II. Judge Ho's concurring opinion echoed Justice Thomas's dissent and Justice Kavanaugh's concurrence (joined by Justice Barrett) in *United States ex rel. Polansky v. Executive Health Res., Inc.*, which questioned whether allowing private relators to litigate on behalf of the country is consistent with the Constitution's separation of powers.

## Sixth Circuit Cases

- *United States v. Tenet Healthcare Corp.*, 2025 WL 1166894 (6th Cir. Apr. 22, 2025)

  The Sixth Circuit affirmed the dismissal of the relators' *qui tam* action under the federal FCA and the Michigan Medicaid False Claims Act for failure to state a claim. The relators, three physicians who either currently or formerly worked at the defendants' hospitals, alleged that the defendants fraudulently billed the government for inpatient care while patients were waiting for a bed in the emergency department, a practice known as "boarding." The Sixth Circuit affirmed the district court's dismissal on the basis that the relators failed to plead with particularity that these boarding practices had resulted in the submission of fraudulent claims for payment. The Court reasoned that while the relators had provided specific examples of patient boarding suggesting "egregious lapses in patient care" or "troubling mismanagement," the prolonged boarding practices did "not create an automatic inference of fraud on part of defendants." Because the relators failed to plead specific examples of false quotes and invoices submitted by defendants, or facts which supported a strong inference that defendants had submitted false claims, they did not satisfy Rule 9(b)'s minimum pleading requirements. The relators have since petitioned the United States Supreme Court for a writ of certiorari, which, as of this report, is pending.

- *United States ex rel. Laughlin v. Radiation Therapy Services*, P.S.C., 148 F.4th 791 (6th Cir. 2025)

  The Sixth Circuit affirmed dismissal of a relator's FCA action. The relator, a former employee of radiation and chemotherapy providers, brought a *qui tam* action against the providers, alleging that they falsely represented that their services were either supervised or performed by qualified physicians when they billed Medicare and other federal programs, when in fact, either unqualified physicians were used, or no physicians were present in the offices. The district court granted the providers' motion to dismiss in part and subsequently granted the providers' motion for summary judgment as to the relators' remaining claims. The Sixth Circuit upheld the decisions, finding the relator failed to provide specific evidence of fraudulent Medicare claims for radiation / chemotherapy services, instead relying on general schedules and statistical arguments, which the Sixth Circuit found to be insufficient.

## Seventh Circuit Cases

- *United States ex. rel. Streck v. Eli Lilly and Co.*, 152 F.4th 816 (7th Cir. 2025)

  The Seventh Circuit upheld a jury verdict that resulted in a $183 million award against pharmaceutical company Eli Lilly (Lilly) for violations of the FCA. Relator Ronald Streck filed a complaint alleging that Lilly falsely under-reported its Average Manufacturer Price (AMP) for Medicaid by excluding "price increase values" (referred to as clawbacks) that wholesalers were required to remit back to Lilly when Lilly raised drug prices after initial wholesale sales but before those wholesalers sold to pharmacies. This had the effect of lowering Lilly's AMP and thereby reducing its Medicaid rebate obligations. A jury found Lilly liable, awarding over $61 million, which was trebled to $183.7 million under the FCA. The Seventh Circuit affirmed the ruling, holding that Lilly's exclusion of the price increase values from its AMP was not permissible, finding that adjustments to prices "actually realized" must be included in AMP, even if those adjustments occur after initial sale to wholesalers.

- *United States v. Sorensen*, Case No. 24-1557 (7th Cir. Apr. 14, 2025)

  The Seventh Circuit reversed the district court's denial of the defendant's motion for judgment of acquittal after a jury found him guilty of violating the AKS. The defendant, the owner and the operator of a Medicare-registered distributor of durable medical equipment (DME), entered into an agreement whereby marketing firms published advertisements for orthopedic braces, contacted interested patients who responded to the advertisements and with the patients' permission, faxed a prefilled but unsigned prescription form to the patients' physicians. The marketing firms were paid based on the number of leads that were generated—while another DME manufacturer who assisted in fulfilling orders, and a medical billing agency who assisted in billing orders on behalf of the defendant's company received a percentage of funds collected from Medicare or other payors as a result of this agreement. The Seventh Circuit reversed the defendant's conviction, finding that the payments to advertisers did not reflect an intent to induce referrals under the AKS because the advertisers had no influence over health care providers' decisions. As such, the Seventh Circuit described the scheme as amounting to a proposal for care, rather than a referral for care violative of the AKS.

## Ninth Circuit Cases

- *United States v. PST Servs.* LLC, 2025 WL 1564345 (9th Cir. June 3, 2025)

  The Ninth Circuit affirmed dismissal of the relator's *qui tam* action under the FCA and the California False Claims Act for failure to state a claim. The relator alleged that the defendants had falsely submitted claims by using a modifier meant to describe care provided by a Certified Registered Nurse Anesthetist (CRNA), alone and without any supervision by an anesthesiologist, even though such care had actually been provided by a CRNA under the medical supervision of an anesthesiologist, and omitting the anesthesiologist from the claim for payment. The Ninth Circuit affirmed the district court's dismissal on the basis that the relator had failed to provide any authority establishing it was legally false to omit an anesthesiologist from a claim for payment where the anesthesiologist was merely supervising the care, rather than directing the care, provided by a CRNA.

- *United States ex rel. 3729, LLC v. Evernorth Health, Inc.*, 2025 WL 383801 (9th Cir. Feb. 4, 2025)

  The Ninth Circuit reversed dismissal of the relator's *qui tam* action under the FCA, overturning the district court's finding that the relator's claim was precluded under the public-disclosure bar. The relator alleged that the defendant Express Scripts, Inc. (ESI) systematically dispensed more pills than medically necessary to TRICARE beneficiaries through its auto-refill program. The Ninth Circuit reversed the district court's dismissal on the basis that the two public sources at issue did not disclose facts from which one could "reasonably infer a substantially similar theory that, in the sort of 'transactions' addressed in the complaint, ESI secretly engaged in 'flagrant and persistent overutilization of services' without regard to need." Specifically, while these sources provided vague and general descriptions of wasteful practices, they lacked sufficient detail "to supply any basis for inferring that ESI was engaged in a fraudulent practice that is substantially similar to" the fraud alleged in the relator's *qui tam* action.

- *United States ex rel. Silbersher v. Allergan, Inc.*, 2025 WL 325761 (9th Cir. Jan. 29, 2025)

  The Ninth Circuit affirmed dismissal of the relator's *qui tam* complaint holding that the action was precluded by the public-disclosure bar. The relator alleged that defendants violated the FCA by fraudulently obtaining patents for two drugs used to treat Alzheimer's disease, thus preventing generic manufacturers from entering the market, and allowing defendants to submit artificially high prices for reimbursement by the government. The Ninth Circuit affirmed the district court's dismissal on the basis that the relator had conceded that the drugs' patent prosecution history provided relevant information from which the inference of fraud could be drawn, and by doing so, was precluded from arguing against application of the public-disclosure bar.

- *United States ex rel. Sam Jones Company, LLC v. Biotronik, Inc.*, 152 F.4th 946 (9th Cir. Sept. 10, 2025)

  The Ninth Circuit reversed a district court's decision dismissing FCA, AKS and the Stark Law claims against Biotronik. The relator filed a *qui tam* complaint alleging that under a three-way compensation arrangement; Biotronik, the manufacturer of cardiac rhythm devices, hired a sales representative who recommended the devices to his brother, a doctor, who implanted the devices at a medical center. Biotronik allegedly paid the sales representative a commission for these sales. The district court found that the allegations in the complaint were barred because *The New York Times* previously published an article that reported Biotronik's

use of various financial incentives to encourage physicians to use the devices over their competitors. The Ninth Circuit reversed, finding that the scheme alleged in the complaint was not "substantially the same" fraud that had already been reported, but instead provided new and material information, including allegations related to the Stark Law, AKS and Biotronik's alleged practice of hiring doctors' relatives in violation of federal law.

## Eleventh Circuit Cases

- *United States v. Quest Diagnostics Inc.*, 2025 WL 1951196 (11th Cir. July 16, 2025)

  The Eleventh Circuit affirmed the dismissal of the relator's *qui tam* action under the FCA, the Georgia False Medicaid Claims Act and the Georgia Medical Assistance Act for failure to state a claim. The relator, a compliance officer at defendant Quest Diagnostics Inc. (Quest), alleged that Quest implemented custom lab panels in doctors' offices that were purposely confusing, causing providers to unknowingly order medically unnecessary tests for their patients. The Eleventh Circuit affirmed the dismissal on the basis that the relator did not allege any facts specifically demonstrating that a doctor's use of a custom panel had actually resulted in the ordering of medically unnecessary tests for a particular patient, and / or that the relator had actual knowledge of false claims being submitted as a result of this practice by either observing "the submission of an actual false claim" or "personally participat[ing] in submitting false claims." The Court emphasized that even though the relator alleged that she had direct knowledge of Quest's improper practices by virtue of her position as a compliance officer, she still had 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."

- *Milner v. Baptist Health Montgomery*, 132 F.4th 1354 (11th Cir. 2025)

  The Eleventh Circuit affirmed dismissal of the relator's *qui tam* action under the FCA as barred by the doctrine of res judicata. The relator alleged that the defendants had caused false claims to be submitted to Medicare and Medicaid by forcing their physicians to overprescribe opioids—allegations that had been brought by the relator in a prior wrongful termination / retaliation lawsuit, which had been dismissed with prejudice. The Eleventh Circuit upheld the district court's dismissal because both the employment action and the FCA action: 1) involved the same parties, even though the relator was technically bringing the FCA action on behalf of the government; and 2) arose from the same nucleus of operative fact, even if the claims themselves differed, because both actions involved the same time period, the same hospital and the same allegation that the defendants had overprescribed opioids and overbilled for medically unnecessary prescriptions.

- *Vargas v. Lincare, Inc.*, 134 F.4th 1150 (11th Cir Apr. 16, 2025)

  The Eleventh Circuit affirmed in part and reversed in part the district court's dismissal of the relators' complaint. The relators, former employees of medical supplier Lincare, Inc. and its subsidiary Optigen, Inc., alleged that the defendants violated the FCA by participating in four fraudulent schemes including systematic upcoding of durable medical equipment to defraud TRICARE health insurance programs for military personnel and their families, routine waiver of co-pays required by TRICARE, automatic shipment of unordered supplies billed to TRICARE, and improper kickback arrangements with health care providers. The district court previously dismissed the relators' complaint under all four theories, holding that it failed to meet Rule 9(b)'s requirement that claims be plead with particularity. The Eleventh Circuit reversed the district court as to only the upcoding theory, finding that relators' examples

of specific patients whose supplies were allegedly upcoded, their claim numbers and the amount TRICARE reimbursed for the supplies satisfied Rule 9(b). However, the Eleventh Circuit affirmed the district court's holding for the remaining three theories, finding that, while the relators had generally alleged fraudulent schemes, there were without enough detail or particular examples—specifically, examples of how the alleged fraud resulted in false claims being submitted to the government.

## D.C. Circuit Cases

- *United States ex rel. Winnon v. Lozano*, 146 F.4th 1197 (D.C. Cir. 2025)

  The D.C. Circuit affirmed the district court's dismissal of the relator's complaint. The relator, a former assistant and controller for skilled nursing facility (SNF) operators, brought this *qui tam* action against operators, SNFs, a contracted therapy provider and physicians, alleging FCA violations based on improper referrals and inflated therapy services. The district court dismissed the relator's allegations against the therapy provider under FCA's public disclosure bar and dismissed allegations against SNF defendants for failing to plead allegations with particularly as required by Rule 9(b). The D.C. Circuit affirmed dismissal, holding that relator's FCA claims were based on publicly available information—specifically a prior Corporate Integrity Agreement with the OIG and government press release—that already exposed the alleged fraud, thus triggering the FCA's public-disclosure bar.

## Summaries of Advisory Opinion 25-01 through 25-11

- **Advisory Opinion 25-01** (01/15/25) is a favorable opinion regarding a program to provide qualified patients free access to a pharmaceutical drug that has limited federal health care coverage. OIG advised that the risk for fraud and abuse was low for several reasons, including the fact that the product itself had never been billed to federal payors under the free program, the agreement was not tied to purchase requirements and physicians and infusion sites were financially incentivized to prescribe the product. The arrangement also did not steer patients to a particular provider or insurance plan as eligibility determinations did not take into consideration the provider or plan selected by the patient.

  OIG ADVISORY OPINION IS HERE.

- **Advisory Opinion 21-13** (02/12/25) is a favorable opinion regarding subsidizing the Medicare cost-sharing obligations for a clinical trial using positron emission tomography (PET) scans to detect the presence of beta amyloid plaque, which is a feature in patient's diagnosed with Alzheimer's disease. This opinion was previously posted on October 4, 2021 and was re-issued with modifications in February of 2025. The modification was due to a CMS memorandum ending previous Medicare coverage through Coverage with Evidence Development (CED), which allowed one PET A scan per patient for clinical studies. The OIG advised the arrangement would generate prohibited remuneration under the AKS, if intent was present, and generate prohibited remuneration under the Beneficiary Inducement CMP. However, the OIG confirmed their favorable opinion citing to the reasons previously detailed including that the clinical study was developed in consultation with CMS, the low risk of overutilization and the one-time billable scan avoids problematic seeding arrangements that ensure future reimbursable services.

  OIG ADVISORY OPINION IS HERE.
  OIG ADVISORY OPINION (MOD) IS HERE.

- **Advisory Opinion 25-02** (04/09/25) is a favorable opinion regarding a community health center's (health center), as designated by 42 U.S.C. § 254b, proposed arrangement to integrate access facilitation into its delivery of social services by identifying individuals in need of primary care services, providing that individual with a non-promotional list of local primary care providers and then offering to schedule an appointment with the patient's chosen provider. OIG advised that the proposed arrangement was low risk under the AKS because it included safeguards to reduce the risk of steering patients to the health center and could increase access to health care services in alignment with the health center's federal designation under the Public Health Service Act.

  OIG ADVISORY OPINION IS HERE.

- **Advisory Opinion 25-03** (06/11/25) is a favorable opinion regarding a management support organization and physician practice's request to enter into an agreement with telehealth providers to lease health care clinicians to provide telehealth services to patients covered by insurance plans in which the physician practice maintains a contract. The agreement would also involve the use of a platform that provided certain administrative services to the professional corporation. OIG advised that the service fee, which would be renumeration, would be protected by the regulatory safe harbor for personal services and management contracts since the service fee would be set in writing, signed by the parties, be for a term of at least one year and specify the services provided. Additionally, the service fee would be fair market value and the lease fee for services would be paid regardless of reimbursement by third-party payors.

  OIG ADVISORY OPINION IS HERE.

- **Advisory Opinion 25-04** (06/20/25) is an unfavorable opinion regarding a medical device company's request to pay customers' costs for third-party screening and monitoring of the company's exclusion from federal health care programs and compliance with other legal requirements. OIG advised that the proposed agreement could induce customers to purchase items or services from the company that could be reimbursable by federal health care programs. The proposed arrangement also presented an anti-competitive risk and risk of inappropriately steering customers to the company over its competitors that may not be able or willing to pay the fees for their customers.

  OIG ADVISORY OPINION IS HERE.

- **Advisory Opinion 25-05** (06/30/25) is a favorable opinion regarding a medical device manufacturer's request to reimburse purchasers up to $2,500 for costs incurred from needle stick injuries caused by the failure of the manufacturer's device. The costs include, but are not limited to, retraining staff, staff absence and replacement, counseling for injured workers and certain legal consequences. OIG advised that the proposed arrangement would be protected by the warranties safe harbor under the AKS because the warranty provides that the device would not cause a needle stick injury if used as instructed and there is a set term for the warranty. Additionally, the proposed arrangement did not include any price reductions, the manufacturer would not pay remuneration for any expenses incurred by an enrollee and the manufacturer did not condition the warranty on the exclusive use or minimum purchase of the device.

  OIG ADVISORY OPINION IS HERE.

- **Advisory Opinion 25-06** (07/02/25) is a favorable opinion regarding a pharmaceutical manufacturer's request to provide assistance for certain travel, lodging and other associated expenses for certain patients receiving the manufacturer's autologous hematopoietic stem-cell based gene therapy. OIG advised the arrangement is low risk under the AKS for several reasons, including the fact that the proposed arrangement removes barriers to accessing medically necessary care, facilitates compliance with the instructions of health care providers for a patient to remain at the treatment center and the manufacturer's product is a one-time treatment, distinguishing it from remuneration related to problematic seeding arrangements. Additionally, OIG found that the arrangement included additional safe harbors, such as not assisting with expenses covered by insurance, the treatment center, or a charitable third-party organization and the arrangements are not used as a promotion tool to encourage prescriptions.

  OIG ADVISORY OPINION IS HERE.

- **Advisory Opinion 25-07** (07/02/25) is a favorable opinion regarding a drug manufacturer's request to offer a companion laboratory test, for free, to eligible patients prior to a provider prescribing a particular drug produced by the manufacturer. OIG advised the arrangement is low risk under the AKS because the proposed arrangement is unlikely to result in inappropriate utilization, skew clinical decision-making, or result in unfair competition. Additionally, the arrangement includes various safeguards to prevent it from being used as a marketing or sales tool to steer providers to order from the manufacturer, including the fact that a provider's use of the arrangement is not tracked, the manufacturer is not provided with any information that would allow it to identify providers and data received from the lab is not used for sales and marketing activities.

  OIG ADVISORY OPINION IS HERE.

- **Advisory Opinion 25-08** (07/07/25) is an unfavorable opinion regarding a medical device company's request to pay a third-party vendor to access an electronic billing system operated by the vendor. The billing system is also used by some of the device company's customers for certain billing operations. OIG advised that the device company's payments to the vendor could constitute remuneration to customers and induce the purchase of medical devices that may be reimbursable by federal health care payors. The arrangement also presents anti-competitive and inappropriate steering risks because the device company's payments to the vendor could inappropriately steer customers to the device company over competitors that are not willing or able to pay similar fees.

  OIG ADVISORY OPINION IS HERE.

- **Advisory Opinion 25-09** (08/12/25) is a favorable opinion regarding a medical device manufacturer's request to offer investment interests to passive physician owner-investors that are in the position to make or influence referrals to the manufacturer. OIG advised that the proposed arrangement is protected by the small entity investment safe harbor. Specifically, because no more than 40% of the value of the investment interests are held by investors in a position to influence referrals, the terms offered to the passive physician owner-investors do not differ from those offered to other passive investors, the terms offered are not related to the volume of referrals made, there is not requirements to make referrals, no more than 40% of the gross revenue comes from referrals or business generated from investors, no loans have been furnished by the manufacturer or investors and the manufacturer had not made any profit distributions to physician owners.

  OIG ADVISORY OPINION IS HERE.

- **Advisory Opinion 25-10** (09/11/25) is a favorable opinion regarding a therapy company's request to operationalize and make financial contributions to a foundation that provides grants to families of children receiving a type of therapy that the company provides. OIG advised that the arrangement is low risk under the AKS because the arrangement is unlikely to lead to overutilization or inappropriate increase in cost to federal health care programs and is unlikely to lead to inappropriate steering or unfair competition. Specifically, the donations from the therapy company are unrestricted and not contingent on further action by the foundation, including referrals, the foundation is a non-profit charitable organization that awards grants in an objective manner not associated with any remuneration and a family's eligibility for funding is not dependent on the use of a specific therapy provider.

  OIG ADVISORY OPINION IS HERE.

- **Advisory Opinion 25-11** (12/18/25) is a favorable opinion regarding a biopharmaceutical manufacturer's request to provide certain upfront discounts and rebates on a vaccine it manufactures. The discounts and rebates are categorized as upfront discounts, upfront discounts with a purchase requirement, bundled upfront discounts with a purchase requirement and bundled rebates. OIG advised that the proposed discounts and rebates would either qualify for the discounts safe harbor under the AKS or were low risk for fraud and abuse. The upfront discounts are protected under the safe harbor because the discounts are known to the customer and applied at the time of sale. The upfront discounts with purchase requirements are protected because they have no services or promotional activity requirements and are based solely on purchasing metrics. The upfront bundled discounts and bundled rebates do not qualify as discounts under the safe harbor but nevertheless are low risk for fraud and abuse because each vaccine in the bundle is discounted, the discounts are clearly attributable to each product, each reimbursement system benefits proportionally and competing vaccines with similar pricing exist in the market.

  OIG ADVISORY OPINION IS HERE.

# Other Fraud and Abuse Developments

## DOJ-HHS False Claims Act Working Group

On July 2, 2025, the DOJ announced that it and HHS were reestablishing the DOJ-HHS False Claims Act Working Group. The group was initially established during the first Trump administration, aimed at strengthening collaboration between HHS and the DOJ's Civil Division to combat health care fraud in "priority enforcement areas."

The DOJ-HHS False Claims Act Working Group will be jointly led by HHS General Counsel, Chief Counsel to HHS-OIG and the Deputy Assistant Attorney General of the Commercial Litigation Branch. The group will also be comprised of leaders of HHS, the DOJ's civil division and the Centers for Medicare and Medicaid Services Center for Program Integrity.

In its announcement, DOJ identified six priority enforcement areas:

- Medicare Advantage
- Drug, device and biologics pricing, including arrangements involving discounts, rebates, service fees, formulary placement and price reporting
- Barriers to patient access to care, including violations of network adequacy requirements
- Kickbacks
- Materially defective medical devices
- Manipulation of electronic health records to drive inappropriate utilization of Medicare covered products and services

OIG ANNOUNCEMENT IS HERE.

## OIG Report on Remote Patient Monitoring

On August 25, 2025, OIG issued a report analyzing Medicare billing for remote patient monitoring (RPM). OIG conducted this review because it found that the use of these services continued to increase in 2024, accounting for $536 million in payments, a 31% increase from 2023. OIG also found that RPM would likely "greatly" expand in the future, and additional oversight was needed to safeguard Medicare from fraud, waste and abuse.

The report identified specific practices that signal a need for further scrutiny:

- Significant spikes of enrollees at a medical practice. OIG found instances of practices that submitted a large increase in RPM services, as high as 150% in a single month. OIG conceded that this practice may be legitimate, but warranted scrutiny.
- Medical practices billing Medicare for RPM services for patients whom the practices have no prior medical relationship. Having a prior relationship with an RPM enrollee is required by CMS, but OIG found instances of medical practices that did not have a prior relationship with over 80% of their patients.
- Patient enrollees receiving RPM services without receiving treatment management. A provider must spend at least 20 minutes per month reviewing an enrollees' health data to make decisions regarding their treatment. However, OIG found that some medical practices failed to conduct treatment management for more than 75% of their enrollees.
- Multiple medical practices billing for the same enrollee. This was a relatively uncommon occurrence, but OIG found instances of medical practices billing Medicare for the same enrollee—raising concerns that the monitoring is either not necessary or not provided.
- Medical practices billing for multiple devices for the same enrollee. Despite Medicare generally only allowing practices to bill for one RPM device per enrollee, OIG found some instances of practices engaging in this practice. This raises concerns that the practices were double billing or providing devices that were not medically necessary.

OIG REPORT IS HERE.

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