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# Health Care Fraud and Abuse **2024 Year in Review**

## Overview



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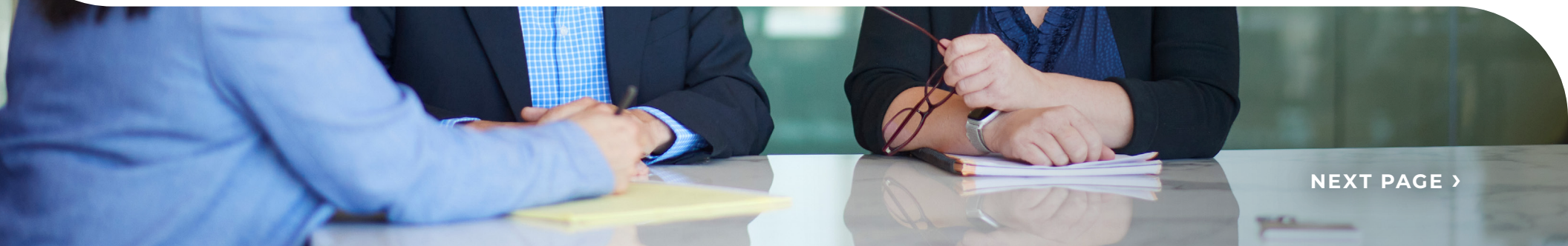
# Introduction

Polsinelli proudly presents the Health Care Fraud and Abuse 2024 Year in Review, offering a comprehensive analysis of False Claims Act (FCA) enforcement and broader fraud and abuse developments over the past year. Now more than three decades since the FCA's revitalization in 1986, the statute remains the government's most powerful and versatile tool for policing health care fraud—and shows no sign of slowing down. In fiscal year 2024, the Department of Justice (DOJ) recovered more than $2.9 billion through FCA settlements and judgments—the highest total since 2021 and a 5% increase over 2023. The government's commitment to FCA enforcement remains vigorous, with Attorney General Pam Bondi emphasizing during her confirmation hearings that she "would defend the constitutionality, of course, of the False Claims Act," and considers it an important piece of legislation particularly given "the money it brings back to our country."

Health care fraud continued to dominate enforcement activity in 2024, with cases spanning the full spectrum of providers and suppliers—including hospitals and health systems, physician practices, laboratories, post-acute providers, pharmaceutical and device manufacturers, pharmacies, and behavioral health facilities. The year also saw a rise in enforcement beyond traditional health care sectors, reflecting the FCA's broad reach. In its annual recap, DOJ emphasized key areas of ongoing focus: the opioid epidemic, fraud involving the Medicare Advantage program, pandemic-related relief fraud, kickback and referral schemes, and medically unnecessary services. At the same time, courts issued decisions that could reshape the FCA's contours—addressing materiality, causation under the Anti-Kickback Statute, the First-to-File bar, and even the constitutionality of *qui tam* provisions.

As always, the pace of enforcement and litigation underscores the need for vigilance and sophistication in navigating compliance obligations. This publication draws upon the insights of Polsinelli's experienced FCA litigators, former government attorneys, and regulatory and compliance counsel to highlight the most significant settlements, court rulings, enforcement trends and advisory guidance shaping the current fraud and abuse landscape. We are pleased to offer this resource to health care stakeholders and compliance professionals seeking to stay ahead of enforcement priorities and legal developments in 2025 and beyond.



# Fraud and Abuse Settlements[1]

In 2024, the FCA continued to serve as the federal government's most potent vehicle for combatting fraud, with settlements and judgments totaling more than **$2.9 billion**—a meaningful increase from 2023's $2.7 billion and the highest annual total since 2021. This year's outcomes reinforce not only the durability of the FCA but also the government's commitment to leveraging it aggressively. The DOJ credited over $2.4 billion of those recoveries to whistleblower-initiated *qui tam* actions and 979 such lawsuits were filed in 2024—a historic high for any single year.

Although no single resolution crossed the billion-dollar threshold, the breadth and depth of enforcement was notable. The volume of settlements and judgments reached 558, coming just behind the record-setting pace of 2023 and continuing a trend of widespread, cross-sector scrutiny. The numbers reflect a deliberate pivot toward data-driven enforcement and expanded focus on Medicare Advantage, kickbacks and referral schemes, medically unnecessary services and pandemic-related fraud.

Government-initiated cases held steady, while relators remained instrumental in driving FCA activity nationwide.

The health care industry, once again, dominated FCA enforcement, with enforcement actions spanning the full continuum of care. Several settlements exceeded the $20 million mark and multiple institutions entered into Corporate Integrity Agreements, reflecting DOJ's emphasis on lasting compliance reforms.

The volume and complexity of these cases illustrate the heightened risk environment for providers and suppliers—and the continued imperative for robust internal controls, proactive compliance efforts and a clear-eyed understanding of DOJ's evolving priorities.

## Health Systems and Hospitals

- Cape Cod Hospital agreed to pay **$24.3 million** to resolve allegations that it knowingly submitted claims to Medicare for transcatheter aortic valve replacement (TAVR) procedures that failed to comply with Medicare rules for evaluating patient suitability for the procedure. Specifically, the government alleged that medical record documentation was insufficient and insufficient numbers of physicians examined patient suitability for the procedure. The relator was a physician formerly employed by Cape Cod Hospital. Cape Cod Hospital also entered into a five-year Corporate Integrity Agreement.

  **DOJ's Press Release: https://www.justice.gov/opa/pr/cape-cod-hospital-pay-243-million-resolve-false-claims-act-allegations-concerning-its**

- The University of Colorado Health d/b/a UCHealth, agreed to pay **$23 million** to resolve allegations that it up-coded claims for Evaluation and Management (E&M) services submitted to Medicare and TRICARE. The government alleged that UCHealth used a system for coding E&M services during emergency room visits that automatically used CPT 99285, which is associated with the highest usage of hospital resources, even though services provided did not meet the CPT code's description or facility resource usage requirements.

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

**DOJ's Press Release: https://www.justice.gov/opa/pr/uchealth-agrees-pay-23m-resolve-allegations-fraudulent-billing-emergency-department-visits**

- H. Lee Moffitt Cancer Center & Research Institute Hospital Inc. (Moffitt), a non-profit cancer treatment and research center, agreed to pay **$19.6 million** to resolve allegations that it billed for non-covered items and services provided in connection with clinical trial research. Specifically, the items and services should have been billed to the trial sponsors, not federal healthcare programs. Moffitt voluntarily disclosed the allegations following an internal investigation and compliance review.

  **DOJ's Press Release: https://www.justice.gov/opa/pr/florida-research-hospital-agrees-pay-more-195-million-resolve-liability-relating-self**

- New York-Presbyterian/Brooklyn Methodist Hospital agreed to pay **$17.3 million** to resolve allegations that it paid unlawful kickbacks to physicians at the hospital's chemotherapy infusion center through compensation based on their volume of referrals, in violation of the Stark Law. The Government also alleged that the infusion center physicians inadequately supervised chemotherapy services provided by non-physician practitioners. The Hospital voluntarily disclosed the allegations to the federal government.

  **DOJ's Press Release: https://www.justice.gov/usao-edny/pr/new-york-presbyterianbrooklyn-methodist-hospital-settles-health-care-fraud-claims-173**

- Baylor St. Luke's Medical Center, Baylor College of Medicine (BCM), and Surgical Associates of Texas, P.A., a medical practice group of cardiothoracic surgeons, agreed to pay **$15 million** to resolve allegations that they submitted false claims for concurrent heart surgeries that did not meet applicable Medicare regulations. Specifically, the government alleged that certain surgeons ran two operating rooms at the same time and improperly delegated aspects of the surgeries to unqualified medical residents. The relator was a former professor at BCM.

  **DOJ's Press Release: https://www.justice.gov/usao-sdtx/pr/texas-medical-center-institutions-agree-pay-15m-record-settlement-involving-concurrent**

- Horizon Medical Center of Denton, the operator of an acute long-term care hospital and outpatient surgery centers, agreed to pay **$14.2 million** for allegedly failing to include PN modifiers and location addresses on claims billed to Medicare, which would have indicated that services were provided at not-excepted off-campus outpatient facilities and had improper financial relationships with entities owned by referring physicians. Horizon Medical Center voluntarily disclosed the allegations to the federal government.

  **DOJ's Press Release: https://www.justice.gov/usao-ndtx/pr/north-texas-medical-center-pays-142-million-resolve-potential-false-claims-act**

- Siouxland Surgery Center LLP, d/b/a Dunes Surgical Hospital, United Surgical Partners International Inc. and USP Siouxland Inc. agreed to pay over **$14.1 million** to settle allegations that Dunes Surgical Hospital made significant financial contributions to a non-profit affiliated with referring physicians and provided free or discounted clinic space, staff and supplies to physician groups, in violation of the AKS and Stark Law. The settlement was reached after the settling parties voluntarily disclosed these allegations to the government following an internal compliance review and independent investigation.

**DOJ's Press Release: https://www.justice.gov/opa/pr/south-dakota-surgical-hospital-agrees-pay-more-127m-resolve-alleged-false-claims-act**

- Penn State Health (PSH), a multi-hospital health system, agreed to pay **$11.7 million** to resolve allegations of improperly submitting claims to Medicare for Annual Wellness Visit (AWV) services that violated Medicare rules and regulations. PSH voluntarily disclosed the allegations to the United States Attorney's Office following its discovery that the services were not supported by medical records.

  **DOJ's Press Release: https://www.justice.gov/usao-mdpa/pr/penn-state-health-agrees-pay-more-eleven-million-dollars-following-its-voluntary**

- St. Peter's Health (St. Peter's) agreed to pay **$10.84 million** to settle allegations that it submitted claims for E&M services that were up-coded or did not meet requirements of a significant, separately identifiable service. Specifically, the government alleged that St. Peter's relied on an employed oncologist's documentation and certifications in submitting the claims and should have known they were false. The government also alleged that St. Peter's compensated the oncologist based on such false claims, in violation of the Stark Law. The settlement agreement was reached after St. Peter's voluntarily self-disclosed the misconduct after an internal investigation.

  **DOJ's Press Release: https://www.justice.gov/usao-mt/pr/us-attorney-jesse-laslovich-announces-108-million-civil-settlement-st-peters-health-over**

- Oroville Hospital agreed to pay **$10.3 million** to resolve allegations that it paid kickbacks to physicians for patients they admitted to the hospital in the form of bonuses and submitted false claims for inpatient stays that were not medically necessary and/or included false diagnosis codes. Oroville hospital also entered into a five-year Corporate Integrity Agreement.

  **DOJ's Press Release: https://www.justice.gov/usao-edca/pr/oroville-hospital-pay-1025-million-resolve-allegations-kickbacks-and-false-billing**

- The CEO of Rockdale Hospital d/b/a Little River Healthcare (Little River), a critical access hospital system, agreed to pay **$5.34 million** to settle allegations that he caused the submission of false claims for laboratory testing by agreeing to kickback schemes to pay physicians for their referrals in violation of the AKS. Specifically, the government alleged that the CEO (1) agreed to pay commissions to recruiters who used management service organizations payments to induce doctors to send referrals for laboratory testing to Little River, (2) agreed to pay compensation to referring physicians for medical director services never provided and (3) signed Medicare cost reports falsely certifying Little River's compliance with the AKS. The CEO was also excluded from participating in federal healthcare programs for 25 years and agreed to cooperate with DOJ's investigations of other participants in the alleged schemes. The relators were a physician and another individual with ties to the health care industry.

  **DOJ's Press Release: https://www.justice.gov/opa/pr/texas-hospital-ceo-pay-over-53m-settle-kickback-allegations-involving-laboratory-testing**

- Inova Health System Foundation and related entities, a hospital and emergent care network, agreed to pay **$2.4 million** to resolve allegations of submitting claims to Medicaid with falsified information. Inova voluntarily disclosed to the government that it improperly received over $1.5 million from Medicaid claims for sterilization and hysterectomy procedures that had improperly modified documentation.

**DOJ's Press Release: https://www.justice.gov/usao-edva/pr/virginia-hospital-system-agrees-237m-false-claims-settlement**

- Pomona Valley Hospital Medical Center (Pomona Valley), a general acute care hospital, agreed to pay **$2.1 million** to resolve allegations that it overbilled Medi-Cal for prescription medication purchased and reimbursed under the federal 340B Drug Pricing Program. Specifically, Pomona Valley allegedly failed to charge Medi-Cal the "actual acquisition cost rates," of the medications following a court ruling that lifted a temporary ban on using such rates. Pomona Valley voluntarily disclosed the allegations to the government.

  **DOJ's Press Release: https://www.justice.gov/usao-cdca/pr/pomona-hospital-agrees-pay-more-2-million-after-self-reporting-overbilling-medi-cal**

- Baptist Health System Inc. (Baptist Health) agreed to pay **$1.5 million** to resolve allegations that it knowingly caused its subsidiaries to offer discounts on patient cost sharing obligations in violation of the AKS. The government alleged such discounts targeted certain categories of Medicare beneficiaries regardless of financial need and were provided to induce the purchase or referral of services. Baptist Health voluntarily disclosed their conduct to the federal government.

  **DOJ's Press Release: https://www.justice.gov/opa/pr/florida-hospital-system-agrees-pay-15-million-resolve-liability-relating-self-disclosure**

## Physicians and Physician Practices

- Oak Street Health (Oak Street), primary care clinics, agreed to pay **$60 million** to resolve allegations that it compensated third-party insurance agents for referring Medicare Advantage beneficiaries to the clinics, in violation of the AKS. The government alleged that Oak Street Health enter into arrangements with insurance agents and brokers to market Oak Street Health clinics to seniors and paid them around $200 for each beneficiary referred to the clinics. The relator was the president of an insurance services company that was allegedly solicited by Oak Street to enter into such an agreement.

  **DOJ's Press Release: https://www.justice.gov/opa/pr/oak-street-health-agrees-pay-60m-resolve-alleged-false-claims-act-liability-paying-kickbacks**

- Bluestone Physician Services of Florida LLC, Bluestone Physician Services, P.A. and Bluestone National LLC (collectively, Bluestone), health care providers that provided primary and geriatric health care services to residents of long term care facilities, agreed to pay nearly **$15 million** to resolve allegations that they knowingly submitted up-coded claims for certain evaluation and management (E&M) services. The relator was the former General Manager for Bluestone's Florida market. Bluestone also entered into a five-year Corporate Integrity Agreement.

  **DOJ's Press Release: https://www.justice.gov/opa/pr/chronic-disease-management-provider-pay-149m-resolve-alleged-false-claims**

- National Radiology Partners PLLC, an entity made up of holding companies and surgical centers that manage physician-owned surgical centers and its founder and CEO agreed to pay nearly **$9 million** to resolve allegations that they paid kickbacks to physicians for referrals to surgery centers designed to treat specific cardiology conditions, in violation of the AKS. The government alleged that the CEO/founder raised investments from physicians who would be strong referral sources for the surgery centers and told physician investors that monthly dividends would increase with the more referrals they made for revascularization surgeries.

The relator was a board-certified interventional radiologist who never worked for National Radiology Partners.

**DOJ's Press Release: https://www.justice.gov/usao-sdtx/pr/nirp-and-founder-pay-nearly-9m-resolve-alleged-kickback-referral-violations**

- KareFirst Management, an independent nurse practitioner group and its former owners agreed to pay nearly **$2 million** for allegedly using self-developed patient charting and billing software that up-coded claims submitted to Medicare and Medicaid. The relator was a former employee of KareFirst.

  **DOJ's Press Release: https://www.justice.gov/usao-ndil/pr/chicago-health-care-company-and-its-former-owners-pay-nearly-2-million-settle-false**

- Active Integrated Medical Centers, PC, a medical practice and two chiropractors and co-owners of the practice agreed to pay **$1.9 million** to resolve allegations that they improperly billed Medicare Part B for services that national and local coverage determinations excluded from reimbursement. Specifically, Active Integrated Medical Centers billed for the application of electric stimulation devices in combination with vitamin injections using improper CPT codes for the administered services and that were medically unnecessary as administered.

  **DOJ's Press Release: https://www.justice.gov/usao-edpa/pr/us-attorney-announces-two-additional-civil-settlements-part-national-effort-combat**

## Laboratories

- Fountain Health Services, LLC, Verify Health, Landmark Diagnostics LLC, First Choice Laboratory LLC and Sonoran Desert Pathology Associates LLC and their owner agreed to pay over **$27 million** to resolve allegations they paid kickbacks to marketers, marketing companies, reference laboratories and telemedicine providers to induce referrals of cancer genomic (CGx) tests that were not medically necessary, in violation of the AKS. The relator was a minority owner of Sonora Desert Pathology and the civil settlement is based on an ability to pay. The owner also plead guilty to conspiracy to commit healthcare fraud.

  **DOJ's Press Release: https://www.justice.gov/opa/pr/florida-businessman-daniel-hurt-pay-over-27-million-medicare-fraud-connection-cancer-genomic**

- Precision Toxicology, LLC d/b/a Precision Diagnostics, Inc., (Precision), an operator of drug testing laboratories, agreed to pay **$27 million** to resolve allegations of billing for medically unnecessary urine drug tests and providing free items to physicians who referred laboratory testing to Precision in violation of the AKS. The government alleged Precision caused physicians to order excessive urine drug tests through standing orders without individual assessment of patient need. The government also alleged that Precision provided free testing cups to physicians who agreed to return collected specimens to Precision for testing. Precision also entered into a five-year Corporate Integrity Agreement. The relators included the director of a treatment center and the operator of a rehabilitation center that had referred patients to Precision for testing.

  **DOJ's Press Release: https://www.justice.gov/opa/pr/precision-toxicology-agrees-pay-27m-resolve-allegations-unnecessary-drug-testing-and-illegal**

- Capstone Healthcare, LLC, Capstone Diagnostics, a clinical laboratory and its owner agreed to pay **$14.3 million** for allegedly paying volume-based commissions to independent contractor sales

representatives for recommending medically unnecessary urine drug tests and respiratory pathogen panels (RPPs), in violation of the AKS. The government also alleged that, in submitting orders for the RPPs, the independent sales representatives forged physician signatures and added sham diagnosis codes. The relator was Capstone's former lab manager. Certain individuals involved in the scheme also plead guilty to conspiracy to commit health care fraud.

**DOJ's Press Release: https://www.justice.gov/opa/pr/georgia-laboratory-owner-pleads-guilty-felony-charge-and-pays-143-million-resolve-liability**

- Gamma Healthcare Inc., a laboratory and three owners, agreed to pay **$13.6 million** to resolve allegations that they submitted Medicare claims for testing that were not ordered by a treating provider and not medically necessary. The government alleged that Gamma performed and submitted claims for higher-reimbursed UTI PCR tests whenever physicians ordered a lower-reimbursed urinalysis with a culture and sensitivity test, regardless of medical necessity. The relator was a physician who ordered tests from Gamma.

  **DOJ's Press Release: https://www.justice.gov/opa/pr/gamma-healthcare-and-three-its-owners-agree-pay-136-million-allegedly-billing-medicare-lab**

- RDx Bioscience, a clinical laboratory and its owner and CEO agreed to pay **$13.25 million** to resolve allegations that they provided kickbacks and submitted claims for unnecessary laboratory testing. The government alleged multiple forms of remuneration through paying: (1) commissions to independent contractor marketers, (2) "specimen collection fees" to the staff members of referring providers and (2) kickbacks disguised as management services organization payments, consulting fees or medical director compensation. The United States also alleged that the settling parties submitted claims for medically unnecessary, duplicative and uncovered testing.

  **DOJ's Press Release: https://www.justice.gov/usao-nj/pr/new-jersey-laboratory-and-ownerceo-agree-pay-13-million-settle-allegations-kickbacks-and**

- LabTox, LLC (LabTox), a toxicology lab, its owner and its operations director/compliance officer agreed to pay **$10.4 million** to resolve allegations that they submitted false claims for medically unnecessary urine drug testing services to Medicare and Kentucky Medicaid. The tests at issue were court-ordered and thus not medical tests covered by these programs. The owner and compliance officer were also convicted of criminal health care fraud, sentenced to prison and excluded from participating in federal health care programs.

  **DOJ's Press Release: https://www.justice.gov/usao-edky/pr/lexington-lab-agrees-104-million-civil-judgments-resolve-false-claims-act-allegations**

- R&B Medical Group Inc. d/b/a UDL Diagnostic Laboratories, a diagnostic testing laboratory, Southern California Medical Center (SCMC) and two co-owners of the lab agreed to pay **$10 million** to resolve allegations that they paid various forms of kickbacks to referral sources of SCMC and the lab, in violation of the AKS. The alleged kickbacks included compensation paid to third-party marketers, above fair market value rent paid to third-party clinics, discounts on or free laboratory services for clinic staff and writing offs balances owed by patients and clinic staff. The government also alleged a Stark Law violation for referring SCMC patients to the lab for testing.

  **DOJ's Press Release: https://www.justice.gov/opa/pr/southern-california-based-clinics-laboratory-and-their-owners-pay-10m-false-claims-arising**

- Admera Health LLC (Admera), a biopharmaceutical research and clinical laboratory company, agreed to pay over **$5.5 million** to resolve allegations that it paid commissions to independent contractor marketers who recommended Admera's services to healthcare providers, in violation of the AKS. The relators were two co-founders of a marketing company that allegedly served as one of the third-party marketers for Admera.

  **DOJ's Press Release: https://www.justice.gov/opa/pr/admera-health-agrees-pay-over-5m-settle-false-claims-act-allegations-kickbacks-third-party**

- AccuLab, LLC d/b/a Thoroughbred Diagnostics (Thoroughbred), a clinical laboratory, agreed to pay **$4.9 million** to resolve allegations that it submitted false claims for urine drug testing services to Medicare and Kentucky Medicaid. Specifically, the government alleged that Thoroughbred performed and billed for urine drug tests requested by Edgewater Recovery Center that did not have proper physician orders or despite knowing the tests typically were not used for medical diagnosis or treatment.

  **DOJ's Press Release: https://www.justice.gov/usao-edky/pr/kentucky-lab-agrees-49-million-civil-judgment-and-drug-treatment-center-enters**

- Oncology San Antonio, PA, its affiliated physicians and CorePath Laboratories agreed to pay over **$4 million** to resolve allegations that they entered into a kickback arrangement that paid for each biopsy referred to the lab, in violation of the AKS. As part of the scheme, CorePath Laboratories allegedly agreed to pay $115 for each biopsy referred by Oncology San Antonio and its physicians. The relator was a physician formerly employed by an affiliated Oncology San Antonio physician. One of the settling physicians also entered into a three-year Integrity Agreement.

  **DOJ's Press Release: https://www.justice.gov/usao-wdtx/pr/oncology-practice-physicians-and-reference-laboratory-pay-over-4-million-settle-false**

- Vista Clinical Diagnostics, LLC, Access Dermpath, Inc. and Advanced Clinical Laboratories, Inc. (collectively, "the Labs") agreed to pay **$2.45 million** to resolve allegations that they submitted claims for clinical laboratory services using diagnosis codes that were generated by the Labs and not provided by the beneficiaries' physicians. The Labs also entered into a five-year Corporate Integrity Agreement. The relator in the related *qui tam* action was a former employee of Vista Clinical Diagnostics.

  **DOJ's Press Release: https://www.justice.gov/usao-mdfl/pr/three-clermont-labs-agree-pay-245-million-settle-false-claims-act-liability**

- Two laboratory marketers, their laboratory marketing companies and five physicians across California, South Carolina, Texas, Missouri and Kansas agreed to pay **$1.5 million** to resolve allegations that they offered and received kickbacks for laboratory referrals. The alleged kickbacks involved payments in the form of consulting fees and medical director fees as well as payments through various management service organizations.

  **DOJ's Press Release: https://www.justice.gov/opa/pr/marketers-and-physicians-five-states-agree-pay-over-15-million-settle-laboratory-kickback**

- A laboratory marketer, his laboratory marketing company and three physicians and their respective practices in South Carolina and North Carolina agreed to pay almost **$1.4 million** for allegedly offering or receiving kickbacks for laboratory referrals, in violation of the AKS. The various kickbacks included purported office space

rental and phlebotomy payments to referring physicians as well as commissions the marketers received as independent contractors.

**DOJ's Press Release:** **https://www.justice.gov/opa/pr/laboratory-marketer-and-north-carolina-physicians-agree-pay-over-13m-settle-kickback**

- Avertest, LLC d/b/a Averhealth, a forensic drug testing company, agreed to pay over **$1.3 million** for allegedly knowingly submitting false claims for positive drug tests that were not properly confirmed and did not conform to the terms of the contract for such testing entered into with the government. The relator was Averhealth's former lab director.

  **DOJ's Press Release:** **https://www.justice.gov/usao-edmi/pr/averhealth-pay-over-13-million-resolve-false-claims-act-allegations-related-drug-tests**

- Brandon Eye Associates P.A., an ophthalmology practice, agreed to pay **$1.3 million** to resolve allegations it submitted claims for the technical component of medically unnecessary trans-cranial doppler ultrasounds (TCD) without a supported diagnosis. The government also alleged a kickback arrangement wherein Brandon Eye paid a third-party TCD provider based on the volume or value of tests ordered for Medicare Part B patients and would refer patients to the third party's preferred radiology group for the TCD's professional component, in violation of the AKS.

  **DOJ's Press Release:** **https://www.justice.gov/opa/pr/florida-ophthalmology-practice-agrees-pay-13m-resolve-allegations-fraudulent-claims-0**

- Pacific Toxicology Laboratories, a clinical laboratory, agreed to pay **$1 million** for allegedly double billing Medicare by submitting separate claims for confirmatory urine drug testing that were already included in a bundled payment.

  **DOJ's Press Release:** **https://www.justice.gov/usao-ma/pr/pacific-toxicology-laboratories-agrees-pay-1-million-resolve-allegations-fraudulent#:~:text=For%20Immediate%20Release&text=BOSTON%20%E2%80%93%20A%20California%2Dbased%20laboratory,urine%20drug%20testing%20(UDT)**

## Durable Medical Equipment (DME)

- United Seating and Mobility, LLC, d/b/a Numotion (Numotion), a DME company, agreed to pay **$13.5 million** to resolve allegations that the company violated the FCA by submitting claims to federal health care programs for custom wheelchairs and wheelchair parts using supporting documentation that had been unlawfully authored, signed and/or completed by Numotion employees rather than a qualified medical practitioner. The relators in three related *qui tam* actions were former employees of Numotion.

  **DOJ's Press Release:** **https://www.justice.gov/usao-az/pr/united-seating-and-mobility-llc-dba-numotion-agrees-pay-13500000-resolve-alleged-false**

- Innovasis Inc., a spinal device manufacturer and senior executives, Brent Felix and Garth Felix, agreed to pay **$12 million** to resolve allegations that they violated the FCA in connection with kickbacks paid to seventeen orthopedic surgeons and neurosurgeons to induce use of their Innovasis spinal implants and other devices in procedures on Medicare beneficiaries. The alleged kickbacks were provided in the form of consulting fees, intellectual property acquisition and licensing fees, registry payments and performance shares in Innovasis, travel to luxury ski resorts, fancy dinners and holiday parties. The relator was a former Regional Sales Director for Innovasis.

**DOJ's Press Release: https://www.justice.gov/opa/pr/medical-device-manufacturer-innovasis-inc-and-two-top-executives-agree-pay-12m-settle**

- Hill-Rom Holdings, Inc., Hill-Rom Company, Inc., Hill-Rom Services, Inc., Advanced Respiratory, Inc., (collectively, Hillrom), a durable medical equipment manufacturer and supplier, agreed to pay **$2.1 million** for allegedly improperly billing for certain DME and DME repair time. Specifically, the government alleged Hillrom billed used hospital beds as if they were new, sold certain DME to patients under a miscellaneous code that sometimes resulted in a higher reimbursement. The relator worked as an insurance specialist for Hillrom.

  **DOJ's Press Release: https://www.justice.gov/usao-sc/pr/durable-medical-equipment-companies-pay-millions-false-claims-settlement**

## Long Term Care

- Strauss Ventures LLC, d/b/a The Grand Health Care System, along with 12 affiliated skilled nursing facilities (collectively, Grand Health Care), agreed to pay **$21.3 million** to resolve allegations that they knowingly billed Medicare and Tricare for therapy services that were unreasonable, unnecessary, unskilled or that did not occur as billed. Grand Health Care entered into a five-year Corporate Integrity Agreement.

  **DOJ's Press Release: https://www.justice.gov/opa/pr/grand-health-care-system-and-12-affiliated-skilled-nursing-facilities-pay-213m-allegedly**

- Columbus LTACH d/b/a Silver Lake Hospital (Silver Lake), a long-term care hospital based in Newark, New Jersey, agreed to pay **$18.6 million** to resolve allegations of claiming excessive cost outlier payments from the Medicare program. Specifically, the settlement resolves allegations that Silver Lake manipulated the cost outlier payment system by increasing its charges beyond its costs. The settlement also resolves allegations that Silver Lake transferred millions of dollars in the hospital's money to its investors without receiving equivalent value in return, at a time when the hospital had reason to believe that it would not be able to repay its debts to the Medicare program. The government alleges that such conduct violated the Fair Debt Collection Practices Act.

  **DOJ's Press Release: https://www.justice.gov/opa/pr/new-jersey-hospital-and-investors-pay-united-states-306-million-alleged-false-claims-related**

- RiverSpring Living Holding Corp. and ElderServe Health Inc., d/b/a RiverSpring at Home, a New York not-for-profit corporation that administers a Managed Long Term Care Plan for Medicaid beneficiaries, paid over **$10 million** to resolve allegations that they violated the FCA by failing to provide or failing to adequately document, certain long-term care services as obligated by a contract between RiverSpring and the New York State Department of Health. Relator was a former healthcare compliance professional contractor who conducted compliance audits for RiverSpring.

  **DOJ's Press Release: https://www.justice.gov/usao-sdny/pr/us-attorney-announces-101-million-settlement-managed-long-term-care-plan-improper**

## Hospice, Home Health and Home Care

- Gentiva Health Services, successor to Kindred at Home, a company comprised of several entities that provide health care services, paid nearly **$19.5 million** to resolve allegations that they submitted false

claims and retained overpayments for hospice services provided to patients who were ineligible for Medicare and Medicaid hospice benefits because they were not terminally ill. The nine relators were current and former Gentiva Health Services employees.

**DOJ's Press Release: https://www.justice.gov/opa/pr/kindred-and-related-entities-agree-pay-19428m-settle-federal-and-state-false-claims-act**

- ReNew Health Group LLC and ReNew Health Consulting Services (collectively, ReNew Health), a California based nursing home chain, paid over **$7 million** to resolve allegations of knowingly submitting false Medicare claims for nursing home residents. The government's allegations related to used of 1,135 waivers during the COVID-19 pandemic. The relator was Bay Area Whistleblower Partners. ReNew Health also entered into a five-year Corporate Integrity Agreement.

  **DOJ's Press Release: https://www.justice.gov/opa/pr/california-based-nursing-home-chain-and-two-executives-pay-7m-settle-alleged-false-claims**

- Guardian Health Care Inc., Gem City Home Care LLC and Care Connection of Cincinnati LLC, home health agencies and their owner Evolution Health LLC (collectively, the Companies) agreed to pay nearly **$4.5 million** to resolve allegations that they provided illegal kickbacks in exchange for referrals of Medicare beneficiaries. The Companies allegedly provided lease payments and benefits not limited to wellness health services, sports tickets and meals to various health care providers, assisted living facilities and residents of those facilities in exchange for the Medicare referrals. The Companies self-disclosed their conduct to the government.

  **DOJ's Press Release: https://www.justice.gov/opa/pr/home-health-providers-pay-45m-resolve-alleged-false-claims-act-liability-providing-kickbacks**

- Elara Caring, a parent company which owns and operates hospice service providers, and its wholly owned subsidiaries paid **$4.2 million** for allegedly knowingly submitting false Medicare claims and knowingly retaining overpayments. Elara Caring allegedly submitted false claims on behalf of hospice patients that were ineligible for the Medicare hospice benefit as they were not terminally ill. The relator was a former Elara Caring employee.

  **DOJ's Press Release: https://www.justice.gov/opa/pr/elara-caring-agrees-pay-42-million-settle-false-claims-act-allegations-it-billed-medicare**

- Intrepid U.S.A. Inc., a home healthcare and hospice provider, agreed to pay **$3.85 million** to resolve allegations that it improperly submitted Medicare claims for home healthcare services that patients were not qualified to receive, for patients that were not eligible for Medicare home healthcare benefits, that were not reasonable or medically necessary, that were provided by untrained staff or that were not actually performed. The relators in two related *qui tam* actions were former Intrepid employees, including a former travel nurse, a former Director of Quality Assessment Performance Improvement and New Business Development for Intrepid, a former Director of Clinical Excellence and Integrity and a former Regional Manager of Clinical Excellence for Intrepid.

  **DOJ's Press Release: https://www.justice.gov/opa/pr/nationwide-home-healthcare-and-hospice-provider-pay-385m-resolve-false-claims-act**

## Pharmacy

- Rite Aid Corporation and ten subsidiaries (collectively, Rite Aid) agreed to pay approximately **$409.3 million** to resolve allegations that they had knowingly dispensed opioids prescriptions and sought reimbursement from Medicare and Medicaid for controlled

substances that lacked a legitimate medical purpose, were not issued in the usual course of professional practice, were not valid prescriptions, were not prescribed for a medically accepted indication or were medically unnecessary. The relators in the related *qui tam* action were three previous employees of Rite Aid. Rite Aid entered into a Corporate Integrity Agreement.

**DOJ's Press Release: https://www.justice.gov/opa/pr/rite-aid-corporation-and-affiliates-agree-settle-false-claims-act-and-controlled-substance**

- Rite Aid Corporation and three of its subsidiaries, Elixir Insurance Company, RX Options LLC and RX Solutions LLC, agreed to pay approximately **$121 million** to resolve allegations that they improperly reported rebates received from drug manufacturers to CMS as bona fide service fees. The relator in the related *qui tam* action was a former employee of RX Options.

  **DOJ's Press Release: https://www.justice.gov/opa/pr/rite-aid-corporation-and-elixir-insurance-company-agree-pay-101m-resolve-allegations-falsely**

- Walgreens Boots Alliance Inc. and Walgreen Co. (Walgreens) agreed to pay **$106.8 million** to resolve allegations that they billed the government health care programs for prescriptions its pharmacies processed but never dispensed to beneficiaries. The relators in three separate *qui tam* actions included a former Walgreens pharmacy manager and a former Walgreens district pharmacy supervisor.

  **DOJ's Press Release: https://www.justice.gov/opa/pr/walgreens-agrees-pay-1068m-resolve-allegations-it-billed-government-prescriptions-never**

- Covid Test DMV LLC d/b/a Rapid Health, a pharmacy located in Los Angeles, agreed to pay **$8.2 million** to resolve allegations that it submitted claims for over-the-counter COVID-19 tests provided to non-Medicare beneficiaries. The United States alleged that the pharmacy distributed COVID-19 tests as a part of the OTC COVID-19 Test Demonstration Project.

  **DOJ's Press Release: https://www.justice.gov/opa/pr/rapid-health-agrees-pay-82m-allegedly-billing-medicare-over-counter-covid-19-tests-were-not**

- Jai Shri Krishna LLC, the operator of a Pennsylvania pharmacy called Pennmark Pharmacy and its principal pharmacist (collectively, JSK LLC), agreed to pay nearly **$4 million** to resolve allegations that it billed federal health care programs for prescription medications that were not dispensed to beneficiaries and billed Medicare for high-cost formulations when the pharmacy dispensed lower-cost formulations to beneficiaries. JSK LLC also entered into a three-year Corporate Integrity Agreement.

  **DOJ's Press Release: https://www.justice.gov/usao-edpa/pr/current-and-former-owners-center-city-philadelphia-pharmacy-agree-pay-over-46-million**

## Pharmaceutical Manufacturers and Distributors

- McKinsey & Company (McKinsey), a global management consulting firm, agreed to pay **$650 million** to resolve civil and criminal allegations regarding its advisement and advice to Purdue Pharma L.P. (Purdue), a pharmaceutical company, on the sale and marketing of OxyContin that caused the submission of false claims to the government programs. The government alleged that the company advised Purdue to intensify its OxyContin marketing to health care providers as a way to increase turbocharge sales and "turbocharge" the sales pipeline for the drug. The government also alleged that McKinsey knowingly misled the FDA by assigning consultants to work on both the FDA's Sentinel Initiative, which relates to

monitoring the safety of prescription drugs, and Purdue projects that involved drug research and development and drug related data analytics. The settlement agreement included a five-year deferred prosecution agreement in connection with a criminal Information filed against one of the company's subsidiaries in the Western District of Virginia.

**DOJ's Press Release: https://www.justice.gov/opa/pr/justice-department-announces-resolution-criminal-and-civil-investigations-mckinsey-companys**

- Endo Health Solutions Inc. (EHSI), agreed to pay **$475.6 million** to resolve allegations that, from 2011 to 2017, that EHSI targeted healthcare providers that EHSI knew were prescribing Opana ER (an opioid drug) for non-medically accepted indications. The government alleged ESHI ignored or minimized concerns brought by EHSI employees about targeting prescribers believed to be engaged in abuse, diversion or pill mill prescribing and continued to directly market Opana ER to such prescribers. EHSI allegedly used sales goals and contests to ensure that its sales representatives focused on providers who prescribed high volumes of opioids or Opana ER.

  **DOJ's Press Release: https://www.justice.gov/opa/pr/opioid-manufacturer-endo-health-solutions-inc-agrees-global-resolution-criminal-and-civil**

- Teva Pharmaceuticals USA Inc. and Teva Neuroscience Inc. (collectively, Teva), a pharmaceutical manufacturer, agreed to pay **$450 million** to resolve allegations that it paid kickbacks by paying for Medicare patients' co-pays, through donating to co-pay assistance foundations and ensuring those donations were used to pay co-pays for Teva's drug. Separately, the United States also alleged that Teva conspired with competing manufacturers to fix prices and allocate markets for at least three generic drugs, which resulted in remuneration payments in exchange for arranging the sale of the drugs. This settlement was in additional to a criminal penalty paid by Teva Pharmaceuticals USA Inc. under a deferred prosecution agreement.

  **DOJ's Press Release: https://www.justice.gov/opa/pr/drug-maker-teva-pharmaceuticals-agrees-pay-450m-false-claims-act-settlement-resolve-kickback**

- QOL Medical LLC, a pharmaceutical manufacturer, and its CEO agreed to pay **$47 million** to resolve allegations that it offered kickbacks in the form of free Carbon-13 (C-13) breath testing services to induce increased prescriptions for the manufacturer's drug, Sucraid. QOL Medical also agreed to pay an additional $3.4 million to Medicaid participating states.

  **DOJ's Press Release: https://www.justice.gov/opa/pr/pharmaceutical-company-qol-medical-and-ceo-agree-pay-47m-allegedly-paying-kickbacks-induce**

- Glenmark Pharmaceuticals Inc. USA (Glenmark) agreed, without any admission of liability, to pay **$25 million** to resolve allegations that conspired to fix the price of a generic drug in violation of the FCA and the AKS.

  **DOJ's Press Release: https://www.justice.gov/opa/pr/pharmaceutical-company-pays-25m-resolve-alleged-false-claims-act-liability-price-fixing**

- Medisca Inc., a pharmaceutical company, agreed to pay **$21.75 million** to resolve allegations that it established false and inflated average wholesale prices (AWP) for two ingredients used in compound prescriptions to increase the profit its

pharmacy customers would receive from federal reimbursement programs, which rely on reported AWPs to determine claim reimbursement amounts.

**DOJ's Press Release: https://www.justice.gov/archives/opa/pr/compound-ingredient-supplier-medisca-inc-pay-2175m-resolve-allegations-false-and-inflated**

- Precision Lens, an ophthalmic distributor and the estate of its former principal, Paul Ehlen, (collectively, Precision) agreed to pay **$12 million** to resolve allegations that paid ophthalmic surgeons kickbacks to induce their use of Precision products in cataract surgeries reimbursed by Medicare. The relator in the related *qui tam* action was a former employee of an ophthalmology company who allegedly observed Precision inducing doctors to buy products that Precision distributed.

  **DOJ's Press Release: https://www.justice.gov/usao-mn/pr/precision-lens-agrees-pay-12-million-united-states-kickbacks-doctors-violation-false**

- KVK Research Inc., a generic drug manufacturer and its corporate affiliate, KVK Tech (collectively, KVK), agreed to pay **$2 million** and enter into a plea agreement and deferred prosecution agreement to resolve allegations that the company failed to exercise appropriate controls as required by current good manufacturing practice regulations, which caused KVK Tech to introduce into interstate commerce drugs deemed to be adulterated. As part of the deferred prosecution agreement, KVK will be subject to a three-year corporate compliance monitoring program.

  **DOJ's Press Release: https://www.justice.gov/opa/pr/generic-pharmaceuticals-manufacturer-pleads-guilty-agrees-15-million-criminal-penalty**

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- ASD Specialty Healthcare d/b/a Besse Medical, a specialty medical and pharmaceutical products distributor, agreed to pay **$1.6 million** to resolve allegations that it provided kickbacks to retina practices by providing no cost for inventory management systems in exchange for drug purchases. The government alleged that the distributor, after acquiring rights to an inventory management system called PODIS, made PODIS available to customers for zero monetary cost in return for prime vendor agreements that required the customer to purchase a certain percentage of specialty drugs from the company.

  **DOJ's Press Release: https://www.justice.gov/usao-ma/pr/asd-specialty-healthcare-dba-besse-medical-agrees-pay-167-million-allegedly-paying**

- Azon Medical, LLC, a medical equipment supplier, agreed to pay over **$1 million** to resolve allegations of improperly billing for the "ANSiStim" acupuncture device not reimbursable by Medicare.

  **DOJ's Press Release: https://www.justice.gov/usao-edpa/pr/medical-device-distributor-pay-1019000-resolve-false-claims-act-liability-arising**

## Imaging and Monitoring

- Innovasis Inc, a spinal device manufacturer, and two senior executives agreed to pay a total of **$12 million** to resolve allegations that they violated the FCA by paying kickbacks to spine surgeons to induce their use of Innovasis's spinal devices. The alleged kickbacks included consulting fees, intellectual property acquisition and licensing fees, registry payments and performance shares in Innovasis, as well as travel to a luxury ski resort, lavish dinners and holiday parties for surgeons, their office staff and family members. The relator was a former Regional Sales Director for Innovasis.

**DOJ's Press Release: https://www.justice.gov/opa/pr/medical-device-manufacturer-innovasis-inc-and-two-top-executives-agree-pay-12m-settle**

- National Interventional Radiology Partners, PLLC, along with its founder and its CEO (collectively, NIRP) agreed to pay **$8.88 million** to resolve allegations that they illegally paid physicians, with strong volumes of Medicare patients, for referrals to its surgical clinics that provided treatment for peripheral arterial disease throughout the state of Texas. The relator in the related *qui tam* action was a Texas physician who allegedly had knowledge that NIRP approached physicians to invest in the surgical clinics and encouraged these physicians to refer patients to the clinics for higher profits and investment returns.

  **DOJ's Press Release: https://www.justice.gov/usao-sdtx/pr/nirp-and-founder-pay-nearly-9m-resolve-alleged-kickback-referral-violations**

- American Health Imaging, Inc., a radiology company and its former founder and CEO agreed to pay **$5.25 million** to resolve allegations that it caused the submission of false claims as a result of kickbacks. The government alleged the company paid referring physicians various forms of renumeration, including meals, entertainment, gifts, sponsorships and made above fair market value payments through personal service agreements in return for referring patients to the company for diagnostic scans in violation of the AKS leading the submission of false claims to Medicare and Medicaid.

  **DOJ's Press Release: https://www.justice.gov/usao-ndga/pr/american-health-imaging-inc-and-scott-arant-pay-over-5-million-resolve-allegations**

- The Radiology Group LLC (TRG), a teleradiology services company that provides remote diagnostic radiology services and its CEO/co-owner agreed to pay **$2.7 million** to resolve allegations that they billed federal health care programs for radiology services that were rendered by individuals not listed in the claims as the rendering provider, including individuals located in India. The government alleged TRG knew Medicare does not reimburse for medical services provided outside the country. The two relators were the former Director of Operations for TRG from approximately 2014 to 2018 and a Board-certified radiologist who was a former independent contractor for TRG.

  **DOJ's Press Release: https://www.justice.gov/usao-sdny/pr/us-attorney-announces-31-million-false-claims-act-settlement-radiology-company-and-its**

- Dr. Mohammad Athari, a Houston-area doctor and his diagnostic facilities agreed to pay **$1.8 million** to resolve allegations that Dr. Mohammad Athari and United Neurology P.A. billed for medically unnecessary services and billed diagnostic imaging procedures in violation the Physician Self-Referral Law by referring his patients to diagnostic centers he owned.

  **DOJ's Press Release: https://www.justice.gov/usao-sdtx/pr/physician-pays-18m-settle-false-claims-act-liability**

- Assure Holdings Corp. and Assure Neuromonitoring LLC (collectively, Assure), an outsourced intraoperative neurophysiological monitoring services provider and its subsidiaries, agreed to pay **$1 million** to resolve allegations based on a whistleblower complaint that it paid remuneration to surgeons through joint ventures to induce the surgeons to order services for their surgical patients, resulting in false claims billed to Medicare and Medicaid. The relator was a software developer who had a business relationship with Assure.

**DOJ's Press Release: https://www.justice.gov/usao-co/pr/2-million-resolves-kickback-allegations-relating-denver-neuromonitoring-company**

## Behavioral Health Facilities

- Acadia Healthcare Company Inc. (Acadia), an inpatient behavioral health facilities owner and operator, agreed to pay **$19.85 million** to settle allegations that it violated the FCA by admitting patients who were not eligible for inpatient treatment and failing to properly discharge patients when they no longer needed inpatient treatment. The relators in the related *qui tam* action were three former employees of Acadia.

  **DOJ's Press Release: https://www.justice.gov/archives/opa/pr/acadia-healthcare-company-inc-pay-1985m-settle-allegations-relating-medically-unnecessary**

- Southeastern Behavioral Healthcare Services, Inc., a behavioral health care agency, and its owners agreed to pay **$2.5 million** to resolve allegations that it had falsely billed North Carolina Medicaid for services that were not necessary, had insufficient medical records supporting medical necessity or were not actually performed. In some instances, bills were allegedly submitted for patients that were incarcerated or deceased on the date the services were billed for. Southeastern Behavioral Healthcare Services also agreed to enter into a Corporate Integrity Agreement.

  **DOJ's Press Release: https://www.justice.gov/usao-ednc/pr/lumberton-based-behavioral-health-provider-agrees-pay-over-25-million-settle-medicaid**

- Edgewater Recovery Center, LLC (Edgewater), an operator of multiple residential and outpatient drug rehab facilities, agreed to pay **$2.24 million** to resolve allegations it caused the submission of false claims for urine drug tests. Specifically, the government alleged that Edgewater requested the same weekly, complex panel of urine drug tests for its patients from a clinical lab without considering individual patient need and did not use the tests for medical diagnosis or treatment. The relator was the Program Director for one of Edgewater's facilities. Edgewater also entered into a five-year Corporate Integrity Agreement.

  **DOJ's Press Release: https://www.justice.gov/usao-edky/pr/kentucky-lab-agrees-49-million-civil-judgment-and-drug-treatment-center-enters**

- Evergreen Treatment Services, a not-for-profit corporation that provides substance use disorder treatment and social services, agreed to pay nearly **$1.5 million** for allegedly submitting claims for bundled drug treatment services that were previously submitted to and paid by Medicare, resulting in double billing.

  **DOJ's Press Release: https://www.justice.gov/usao-wdwa/pr/doj-and-evergreen-treatment-services-settle-allegations-regarding-double-billing**

## Other

- Insight Global LLC, a staffing company, agreed to pay **$2.7 million** dollars to resolve allegations that it inadequately implemented measures to secure and protect personal health information obtained during COVID-19 contact tracing. The government also alleged that Insight Global knew the information was unsecure and failed to remediate the issue for months. The relator was a former Insight Global staff member who worked on the contact tracing at issue.

  **DOJ's Press Release: https://www.justice.gov/opa/pr/staffing-company-pay-27m-alleged-failure-provide-adequate-cybersecurity-covid-19-contact**

# Court Decisions

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

## First Circuit Cases

- ***United States v. Regeneron Pharmaceuticals Inc.*, Case no. 23-2086 (1st Cir.) and *Flanagan v. Fresenius Medical Care Holdings, Inc.*, Case no. 23-1305 (1st Cir.).**
  The First Circuit recently heard arguments in two cases concerning the causation standard for AKS-based liability under the FCA. In *United States v. Regeneron Pharmaceuticals Inc.* (case no. 23-2086), the district court held that the FCA's causation standard under the AKS requires a direct link between a defendant's alleged kickback and the claims submitted to a government program, applying the strict "but-for" standard. In oral argument, the government argued for a contextual reading of the AKS while counsel for defendant maintained that the "but-for" standard was appropriate. The First Circuit considered this same issue in *Flanagan v. Fresenius Medical Care Holdings, Inc.* (case no. 23-1305). Both cases underscore the ongoing review surrounding the level of causation required to establish FCA liability based on underlying AKS violations. Critically, there is a circuit split on this issue: The Sixth and Eighth Circuits have required "but-for" causation, while the Third Circuit has only required a link between alleged kickbacks and remuneration to constitute a violation of the FCA. It will be interesting to see which way the First Circuit goes and review by the Supreme Court may be necessary to resolve the disagreement between the Circuits.

## Second Circuit Cases

- ***United States ex rel. Hart v. McKesson Corp.*, 96 F.4th 145 (2nd Cir. 2024)**
  The Second Circuit affirmed the dismissal of relator's FCA claim. Relator filed a *qui tam* action alleging that McKesson Corporation (McKesson) violated the AKS by providing free business management tools to oncology practices to induce them to purchase pharmaceuticals from McKesson. The Second Circuit held that to act "willfully" under the AKS, a defendant must act with knowledge that their conduct is unlawful, even if they are not aware that it specifically violates the AKS. A general awareness of the illegality of the conduct is sufficient to meet the "willfully" standard and a defendant acts "willfully" under the AKS when acting with a "bad purpose." Based on this interpretation, the Second Circuit concluded that relator's allegations did not plausibly suggest that McKesson acted with the requisite knowledge of unlawfulness. The Supreme Court denied relator's petition for a writ of *certiorari*, leaving the Second Circuit's decision as the standard in its jurisdiction.

- ***United States ex rel. Askari v. PharMerica Corp.*, 2024 WL 1132191 (2nd Cir. 2024)**
  The Second Circuit affirmed the district court's dismissal of the relator's FCA complaint for failure to state a claim. The relator alleged that various pharmacies and their executives engaged in schemes that resulted in the submission of false claims for prescription drugs to Medicaid and Medicare in violation of the FCA and analogous state statutes by operating without the required licenses. The relator claimed these schemes violated state licensing

laws, federal laws requiring compliance with state licensing for government reimbursements, federal regulations on National Provider Identifier (NPI) usage and resulted in overbilling. The district court held that the amended complaint failed to identify any law, regulation or rule that prohibited the defendants' conduct and further held that the relator had failed to allege that any alleged false claims by the defendants were material to Medicare's decision to reimburse the defendants. In affirming the district court's ruling, the Second Circuit reasoned that even if the schemes violated state licensing laws, the relator failed to plead with particularity how the defendants' alleged false claims or practices regarding their NPIs were material to the government's payment decision. Specifically, the Second Circuit noted that, while the relator alleged that the CMS Medicare Fraud Handbook discusses the unlawfulness of claims filed by persons precluded by reimbursement and generally suggests the importance of filing claims under the proper NPI, those allegations do not indicate the materiality to the government's payment decision of using just one pharmacy's NPI where, as in this case, the one pharmacy assists in the preparation of the prescription and another pharmacy reviews and delivers the medication to the patient.

- ***United States ex rel. Omni Healthcare Inc. et al. v. U.S. Oncology, Inc.*, 2024 WL 4751635 (2nd Cir. 2024)**
  The Second Circuit affirmed the district court's dismissal of the amended *qui tam* complaint on the basis of the public disclosure bar. The relator, a medical company specializing in oncology and hematology treatment, alleged that the defendant specialty pharmacy harvested the "overfill" of injectable oncology drugs to fill and sell unapproved syringes to other medical providers and profited from providers' administration of these overfill drugs to patients by submitting fraudulent reimbursement claims to CMS in violation of the AKS. The Second Circuit reasoned that the claims were barred by the FCA's public disclosure bar because substantially similar allegations were publicly disclosed in two prior federal actions and held that the relator did not qualify for the original source exception because it failed to plead sufficient facts to establish direct and independent knowledge of the alleged fraud, a voluntary disclosure to the government or a material addition to the prior public disclosures. With respect to the "voluntary" nature of the disclosure, the Second Circuit noted that the relator's pleading explicitly referenced the FCA's mandatory disclosure provision and the district court rejected the relator's argument that a mandatory disclosure may simultaneously be voluntary if a relator discloses information prior to a public disclosure. The Second Circuit agreed with the district court, noting that a disclosure is not "voluntary" simply because it is made prior to a public disclosure, as to hold otherwise would nullify the provision's voluntariness requirement.

## Third Circuit Cases

- ***United States ex rel. Krahling v. Merck & Co., Inc.*, Case no. 23-2553 (3rd Cir. 2024)**
  The Third Circuit affirmed the district court's grant of summary judgment in favor of the defendant concluding the relator failed to establish materiality under the FCA. The relator alleged that Merck misled the CDC by omitting, concealing and misrepresenting material information regarding its mumps vaccines, violating the FCA. Specifically, the Relators claimed Merck made false representations about the potency and efficacy of its MMR-II and ProQuad vaccines. The Third Circuit concluded that even if Merck made false claims, no reasonable jury could find that the defendant's alleged misrepresentations were material to the CDC's purchasing decision because the government: (1) had actual knowledge of the facts concerning potency, shelf-life and the like;

(2) satisfied itself as to the effectiveness of the vaccine based on real world studies, which it acknowledged showed lower effectiveness rates than the efficacy that the defendant reported from clinical trials; (3) entered into contracts with the defendant that required the product to have only a twelve-month shelf-life (and there is no evidence that the defendant's vaccine did not meet this condition); and (4) continued to purchase the defendant's vaccine, even when another option became available.

## Fifth Circuit Cases

- ***United States ex rel. Aldridge v. Corporate Mgmt., Inc.*, 2024 WL 983560 (5th Cir. 2024)**
  The Fifth Circuit vacated and remanded the district court's approval of the relator's attorneys' fees and litigation costs. In the underlying FCA lawsuit filed in 2016, the relator alleged that the defendants engaged in Medicare fraud, including fake cost-reporting practices, "swing bed" manipulation and improper waivers of copays and deductibles. The government later intervened and the case ultimately went to trial, where a jury found the defendants liable for nearly $11 million in damages, which tripled to $32 million after applying the FCA's trebling provision. After the verdict, the relator moved for attorneys' fees and costs, which the district court approved in an amount exceeding $550,000 and defendants also subsequently appealed. On appeal for attorneys' fees, the Fifth Circuit noted that it recently issued an opinion modifying the district court's judgment in part in the underlying FCA case on the merits, holding that the FCA's six-year statute of limitations barred the government's claims accruing prior to 2009, reducing the total judgment by over half. Accordingly, because the district court's decision on attorney's fees was based on the original judgment that was subsequently modified, the Fifth Circuit vacated the district court's ruling and remanded.

## Seventh Circuit Cases

- ***Stop Illinois Health Care Fraud, LLC v. Sayeed*, 100 F.4th 899 (7th Cir. 2024)**
  The Seventh Circuit affirmed the district court's judgment that the defendants were liable for violating the AKS and FCA after a bench trial. The Seventh Circuit held that the nearly $6 million judgment was not constitutionally excessive under the Eighth Amendment. However, the Seventh Circuit found that the district court erred in calculating damages based on Medicare claims that may not have been directly related to the kickback scheme. The court underscored the text of the AKS, which provides that "a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim" for purposes of the FCA. The phrase "resulting from" requires that there be some causal nexus between the allegedly false claims and the underlying kickback violation. Because the district court's damages award broadly included all Medicare claims submitted by defendants during the time period in which they engaged in the kickback scheme, regardless of whether they resulted from the scheme, the Seventh Circuit found this approach to be inconsistent with the AKS's directive. Consequently, the Seventh Circuit reversed the damages award in part and remanded the case for the district court to clarify which specific Medicare claims resulted from the illegal conduct.

## Eighth Circuit Cases

- ***United States ex rel. Zorn*, 107 F.4th 782 (8th Cir. 2024)**
  The Eighth Circuit held the amount of treble damages imposed as punitive sanction violated the Eighth Amendment's Excessive Fines Clause. Relator filed a *qui tam* lawsuit alleging that the defendants submitted false claims violating the FCA. Following a bench trial, the district court found the defendants liable for submitting 1,050

false claims and imposed a combined award of 26 times the amount of treble damages and 78 times the amount of actual damages. On appeal, the Eighth Circuit held that the Excessive Fines Clause applies to penalty awards in FCA cases, even when the government has not intervened. The court also determined that the district court committed two errors in its Excessive Fines analysis. First, the district court improperly inflated the compensatory damages by using the entire amount of treble damages as its baseline, when it should have instead removed the punitive portion from its analysis. Second, a punitive sanction 26 times the amount of treble damages and 78 times the amount of actual damages was excessive given the relatively small amount of only economic loss caused by the defendants. The Eighth Circuit noted that double-digit multipliers were generally reserved in cases where defendants engaged in tortious conduct that evinced an indifference to the health or safety of others.

- ***United States ex rel. Holt v. Medicare Medicaid Advisors, Inc.*, 115 F.4th 908 (8th Cir. 2024)**
  The Eighth Circuit affirmed the district court's ruling that dismissed the *qui tam* for failure to plead a FCA violation with particularity and failure to allege that a claim was submitted to CMS or the regulatory violations were material. Relator's *qui tam* alleged that defendant Medicare Medicaid Advisors (MMA), which is an insurance broker that marketed Medicare Advantage (MA) plans, caused the submission of false claims to CMS by violating regulations governing the marketing of such plans while submitting MA enrollments to the defendant MA insurers. The defendant MA insurers then allegedly violated the FCA by knowingly submitting such enrollment applications to CMS and paying commissions to MMA. The Eighth Circuit focused exclusively on materiality and adopted three non-exhaustive factors that sister circuits have outlined from the Supreme Court's decision in *Escobar*; namely,
    1. *"whether the government has expressly designated the legal requirement at issue as a condition of payment;*
    2. *whether the alleged violation is minor or insubstantial or instead goes to the essence of the bargain between the contractor and the government; and*
    3. *whether the government made continued payments, or does so in the mine run of cases, despite actual knowledge of the violation."*

  Looking to these factors, the held that MMA's alleged violations were immaterial because the regulations do not expressly state compliance is a condition of payment, the regulatory text dictates that noncompliance can be insubstantial and the regulations do not require sanctions when a violation occurs.

## Ninth Circuit Cases

- ***Silbersher v. Valeant Pharmaceuticals International, Inc.*, 89 F.4th 1154 (9th Cir. 2024)**
  The Ninth Circuit reversed the district court's dismissal based on the public disclosure bar of the FCA. The relator alleged that pharmaceutical companies fraudulently obtained drug patents to prolong monopolies, charged the federal government artificially inflated prices under the Medicare and Medicaid programs and falsely certified that the prices were fair and reasonable. The Ninth Circuit held that the public disclosure bar did not apply because *inter partes* review (IPR) proceedings do not qualify as public disclosures under the FCA and the remaining qualifying public disclosures did not collectively disclose a combination of facts sufficient to permit a reasonable inference of fraud. In reaching this decision, the Ninth Circuit distinguished IPR from patent prosecution—which did qualify as a public disclosure—because the government was not a "party" to IPR. Additionally, IPR did not

qualify as "other Federal . . . hearings" because its primary function was adjudicatory and not investigative. The Ninth Circuit also reaffirmed its historic interpretation of the "substantially the same" prong of the public disclosure bar—revised by Congress in the FCA's 2010 amendments—as equivalent to the "based upon" standard.

- ***Stein v. Kaiser Found. Health Plan, Inc.*, 115 F.4th 1244 (9th Cir. 2024)**
  On rehearing, the Ninth Circuit reversed the district court's dismissal for lack of jurisdiction and held that FCA's first-to-file rule is not jurisdictional. Relators filed suit against Kaiser Foundation Health Plan, Inc., alleging Medicare fraud. The district court dismissed the lawsuit as barred by the FCA's first-to-file rule because it "related" to earlier-filed, pending FCA action against the same defendants. The FCA's first-to-file rule states: "When 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." Historically, the Ninth Circuit labeled this rule "jurisdictional." Based on this precedent, a three-judge panel of the Ninth Circuit affirmed the district court's dismissal. Upon en banc review, the Ninth Circuit overruled its prior precedents, *United States ex rel. Hartpence v. Kinetic Concepts, Inc.*, 792 F.3d 1121 (9th Cir. 2015) and *United States ex rel. Lujan v. Hughes Aircraft Co.*, 243 F.3d 1181 (9th Cir. 2001). The court concluded that the first-to-file rule is not jurisdictional, aligning with the Supreme Court's directive that a statutory bar is jurisdictional only if Congress clearly states it as such. Because the text of the FCA does not use the term "jurisdictional" and does not speak to the court's adjudicatory authority, the Ninth Circuit determined it should not be treated as affecting the court's jurisdiction.

- ***United States ex rel. Stenson v. Radiology Limited, LLC*, 2024 WL 1826427 (9th Cir. 2024)**
  The Ninth Circuit affirmed in part and reversed in part the district court's dismissal of the relator's complaint. The relator alleged that the defendant radiology facility violated the FCA by submitting false claims to CMS for diagnostic readings that did not qualify for Medicare reimbursement because they were conducted on non-medical grade Dell computer monitors. The Ninth Circuit affirmed the district court's dismissal of the complaint to the extent it alleged that the claims were false because the Dell Monitors lacked FDA approval, as the monitors were not furnished in violation of any CMS rule, regulation or standard. The defendant could not misrepresent its compliance with CMS rules that did not exist. However, the Ninth Circuit reversed the district court regarding the general Medicare statute's "reasonable and necessary" requirement, finding that the relator sufficiently pled falsity and materiality under this requirement by alleging the use of non-medical grade monitors resulted in diagnostic readings that fell below the federally mandated minimum standard of care.

## Notable District Court Cases

- ***United States ex rel. Zafirov v. Florida Medical Associates, LLC*, Case No. 8:19-cv-01236, 2024 WL 4349242 (M.D. Fla. Sept. 30, 2024)**
  A federal judge in the Middle District of Florida ruled that the FCA's *qui tam* enforcement provision is unconstitutional, concluding that relators operate as "Officers" of the executive branch of the United States who must be properly appointed pursuant to Article II of the U.S. Constitution. The relator alleged that the defendants, certain medical providers, submitted false claims by misrepresenting patients' medical conditions to Medicare. The defendant providers

filed a motion for judgment on the pleadings raising several constitutional challenges to the FCA's *qui tam* provision. In finding that an FCA relator is an "Officer" under Article II, the court concluded that a relator's power to institute and prosecute a suit on behalf of the federal government qualified as exercising "significant authority" under federal law. In doing so, the court focused on a relator's ability to file an FCA case without prior oversight by the federal government that seeks "daunting," "substantial" or "punitive" penalties. The court also found that a relator holds a "continuing position," even though he or she ordinarily only prosecutes a single action. Accordingly, because the relator was an Article II Officer who was not properly appointed, the court concluded she lacked authority to prosecute the case and dismissed it with prejudice.

- ***United States ex rel. Kyer v. Thomas Health Sys.*, 2024 WL 4165082 (S.D.W. Va. Sept. 12, 2024).**
  In a FCA case pending in the Southern District of West Virginia, the court ordered supplemental briefing on the effect of the Supreme Court's ruling in *Loper Bright Enterprises v. Raimondo* on the Stark Law claim. The relator, who worked as a nurse at the defendant hospital for years, brought a *qui tam* action against her former employer and related entities alleging violations of the FCA, Stark Law and the AKS. The defendants filed a motion to dismiss, arguing that the complaint should be dismissed because the relator (1) failed to file her claim under seal and (2) failed to plead her FCA allegations with the level of particularity required by Federal Rule of Civil Procedure 9(b). In addressing the motion to dismiss, the court expressed concern over interpreting the Stark Law's regulatory scheme in light of *Loper Bright*. The court noted the complexity of the Stark Law and regulations and questioned whether the Stark Law regulations' definitions of financial relationships are consistent with congressional authorization and the statute. Accordingly, the court ordered the parties to submit briefs addressing the impact of *Loper Bright* on the pending claim.

## Advisory Opinions

- **Advisory Opinion 23-12 (Jan. 3, 2024)** is a favorable opinion regarding two hospitals request to provide a one-time voluntary redemption offer (Redemption Offer) for retiring physician partners aged 67 to have partnership units repurchased by the partnership for a two-year period premised upon retiring. OIG advised the arrangement is low risk under the AKS for several reasons including the Redemption Offer is based on specific criteria rather than referrals or business generated by the physician partners and the remuneration paid will not likely result in unfair competition. The six-month period allows physician partners to refer patients to the medical center, the hospitals and physician partners is time-limited for winding down the physician's practice and thus, will not alter referrals to benefit any of the entities.

  **https://oig.hhs.gov/documents/advisory-opinions/1144/AO-23-12.pdf**

- **Advisory Opinion 23-13 (Jan. 3, 2024)** is a favorable opinions with identical fact pattern regarding Medicare Supplemental Insurance (Medigap) policy and preferred hospital organization (PHO) request to discount Medigap Plan patients on the Medicare Part A inpatient deductible as a $100 credit the Medigap plan covers for inpatient care at a hospital within the PHO network. The OIG advised the arrangement was low risk as the Network Hospitals' deductible and the premium credit were unlikely to result in overutilization or increased costs for federal healthcare program, the discount was not limited to "discriminatory eligibility criteria" and patient choice was not impacted because coverage by Medigap inpatient deduction is not based on choice of Network Hospital or non-Network hospital. The OIG noted that even though administrative fee by Medigap to PHO is based on volume or value of the business, it is sufficiently low risk of driving overutilization of a federal healthcare program.

  **https://oig.hhs.gov/documents/advisory-opinions/1145/AO-23-13.pdf**

  **https://oig.hhs.gov/documents/advisory-opinions/1146/AO-23-14.pdf**

- **Advisory Opinion 23-15 (Jan. 3, 2024)** is a favorable opinion regarding consultant requesting to offer their current customer physician practice clients the provision of gift cards for referring new potential physician practice customers. For successful recommendations, the consultant would provide the customer another $50 gift card. The OIG highlighted three potential streams of remunerations: (i) consultant gift cards to clients for recommended customers; (ii) client payment to consultant for services; and (iii) client potentially receiving a higher Medicare's Merit-Based Incentive Payment System (MIPS) reimbursement from Medicare from consultant's services. The OIG concluded the first stream would not implicate the AKS because the gift card is not in return for "referrals of, purchasing, arranging for, or recommending services" that are reimbursed by the Federal healthcare programs. Additionally, the OIG concluded the second and third streams would not implicate the AKS because even if the consultant receives payment from physician practices for its services, the services do not involve recommendation the customer purchase, lease or order items or services in which payment is in whole or part reimbursed by the Federal healthcare programs. Finally, even if the consulting

services result in higher MIPS related payments, any customer remuneration is not due to return in referrals, purchase of or arranging to or recommending purchase of item or service payable by the federal healthcare program.

**https://oig.hhs.gov/documents/advisory-opinions/1147/AO-23-15.pdf**

- **Advisory Opinion 24-01 (Feb. 26, 2024)** is a favorable opinion regarding Medigap plan arrangement with PHO to incentivize inpatient care from hospital in PHO network by covering a $100 premium credit for policyholder per Medicare Part A benefit period. The OIG concluded all three distinct streams: (i) Network hospitals' discounts to Medigap Plan on policyholder Medicare Advantage inpatient deductibles; (ii) premium credit offered by Medigap to policyholders; and (ii) administrative fee to PHO by Medigap plan implicated the AKS and the premium credit to policyholders would implicate the beneficiary inducements CMP. However, the OIG considered the arrangement low risk given the two streams are unlikely to result in overutilization, potential for patient harm was minimal and remuneration unlikely to significantly impact competition. Further, the OIG noted the administrative fee to the PHO implicated the AKS but was low risk as it was fair market value and distinguishable from other arrangements because the compensation set by volume or value was tied to the Medigap plan savings not revenue of the network hospitals, would be contrary for Medigap plan to seek to drive overutilization for Medicare Part A inpatient services and the Medigap plan certified they would not pass along or shift cost of PHO administrative fee to federal healthcare program. Note, this Advisory Opinion largely mirrors previous Advisory Opinions from this year – Advisory Opinion 23-13 and Advisory Opinion 23-14.

  **https://oig.hhs.gov/documents/advisory-opinions/1153/AO-24-01.pdf**

- **Advisory Opinion 24-02 (Apr. 11, 2024)** is a favorable opinion regarding a non-profit seeking to establish a patient assistance program (PAP) funded primarily by pharmaceutical manufacturers for twelve specific diseases. OIG concluded while the arrangement implicated the AKS, there were sufficient safeguards including that funds defined by established diseases states, awards are not contingent on treatment regimen prescribed to a patient, available to all individuals regardless of payor status, required an application to determine financial ability and funds used more than two-thirds of overall donations to pay for goods and services outside drugs manufactured by donors to ensure independence and avoid patient steering. Additionally, the OIG concluded the PAP did not implicate the beneficiary inducement CMP because eligibility is not continent on selecting a certain provider or pharmacy and thus, will not induce a beneficiary to select a certain provider, practitioner or supplier for items or services reimbursed by the federal healthcare programs.

  **https://oig.hhs.gov/documents/advisory-opinions/9864/AO-24-02.pdf**

- **Advisory Opinion 24-03 (Jun. 17, 2024)** is a favorable opinion regarding pharmaceutical manufacturer request to provide travel, lodging and related assistance to patients meeting certain criteria including at or below 600 percent of the Federal Poverty Level receiving gene therapy for two severe genetic diseases. The OIG concluded while this implicates the AKS it is sufficiently low risk given it a one-time curative treatment and the arrangement has other safeguards as not limiting the eligibility if as patient has other options available to secure treatment, does not require certain physicians/treatment centers exclusively prescribe their product and does not offer the arrangement as marketing tool. Further, the arrangement promotes access to medically necessary curative care by removing barrier to the treatment center, complies with the drug

label instructions by having patients remain in the hospital to be monitored for potential complications and as a one-time treatment is unlikely to result in additional referrals. OIG also determined the arrangement implicates the Beneficiary Inducements CMP provision but satisfies the Promotes Access to Care Exception reasoning: (i) arrangement improves the beneficiaries access to services payable by the federal healthcare programs by removing financial and geographical barriers; (ii) poses low risk as the arrangement seeks to increase patient safety with patient monitoring and is unlikely to raise patient safety or quality of care concerns or result; and (iii) is unlikely to result in overutilization as it is one-time curative treatment.

**https://oig.hhs.gov/documents/advisory-opinions/9914/AO-24-03.pdf**

- **Advisory Opinion 24-04 (Jun. 20, 2024)** is a favorable opinion regarding a pharmaceutical manufacturer request for a limited-time refund and discount program for high-cost one-time use rare drug. The arrangement seeks to waive or refund treatment center for 100% of the wholesale acquisition cost of the drug if insurer refuses to reimburse dispute initially approving for patient or delay payment for drug if reimbursement delays from insurer for a patient. The OIG concluded the arrangement implicates the AKS but was low risk because the refund program had a limited narrowly tailored purpose with one-time use, would not interfere with clinical decision make because the drug had no therapeutic alternatives, would not cause overutilization as it was not a mass-produced drug and used for small patient population and would not increase federal healthcare expenditures because it was a curative drug aimed to reduce the cost of palliative care for patients with this condition. Additionally, the arrangement implicates the CMP beneficiary inducement prohibition but is low risk because it was unlikely to influence beneficiary provider selection as the treatment center was only authorized facility for the drug and patients learn about the refund program after receiving drug and receiving delays or insurer coverage issues.

  **https://oig.hhs.gov/documents/advisory-opinions/9915/AO-24-04.pdf**

- **Advisory Opinion 24-05 (Jul. 22, 2024)** is a favorable in part and unfavorable in part regarding a biotechnology company request for patient assistance for travel, lodging, meals, and associated expenses and fertility services for patients receiving one of two gene therapy treatments. OIG provided a favorable opinion for the proposed travel assistance and unfavorable opinion for the fertility treatment services. OIG concluded the travel assistance had sufficiently low risk of fraud and abuse due to removing travel barriers to patients to access treatment centers, facilitating compliance with the drug label instructions for patient monitoring, is a one-time treatment drug unlikely to impact referrals and includes safeguards to reduce risk of fraud and abuse. The OIG did not issue a favorable opinion for the assistance with fertility services noting the arrangement implicated the AKS and did not fit within a safe harbor. OIG concluded they lacked sufficient data to evaluate factors for whether the arrangement posed a fraud and abuse risk. Further, the fertility services assistance also implicated the beneficiary inducement CMP as remuneration that was likely to influence patients and future data may allow the arrangement to qualify for the "Promotes Access to Care Exception."

  **https://oig.hhs.gov/documents/advisory-opinions/9936/AO-24-05.pdf**

- **Advisory Opinion 24-06 (Jul. 23, 2024)** is an unfavorable opinion regarding pharmaceutical manufacturer request to provide $70,000 in financial support for patients receiving gene therapy treatment for fertility services for patients meeting certain criteria including income at or below 670% of the Federal Poverty Line. OIG failed to approve the arrangement under the AKS or CMP noting more information could yield a different result in the future as they lacked sufficient information to consider the arrangement low risk. OIG reasoned for the AKS: (i) the difficulty of accepting an arrangement with the unknowns about cell and gene therapy and optimal arrangement for access to the product; (ii) the arrangement creates remuneration to patients to induce to purchase the product; and (ii) the arrangement creates remuneration for the company-approved hospital treatment centers and/or treating physicians that could include them to recommend their product over competitors due to their opportunity to receive fees related to the treatment by the product. For the CMP, OIG suggested with more data the arrangement could qualify for the "Promotes Access to Care Exception."

  **https://oig.hhs.gov/documents/advisory-opinions/9940/AO-24-06.pdf**

- **Advisory Opinion 24-07 (Aug. 23, 2024)** is a favorable opinion regarding a non-profit requesting to establish a PAP for cost-sharing diabetes treatments for low-income individuals enrolled in Medicare Part D. The non-profit was created from sale proceeds from a non-profit hospital and receives occasional donations from pharmaceutical companies. The OIG determined the risk of fraud and abuse was low because the PAP is independent of pharmaceutical manufacturers influence and limits concerns the PAP is a "conduit for payments by a pharmaceutical manufacturer." Additionally, the arrangement limits concerns of patient steering towards a certain drug because patients have an existing diagnosis and treatment plan and allowing patients to avoid out-of pocket costs does not impact clinical decision-making or risks of overutilization.

  **https://oig.hhs.gov/documents/advisory-opinions/9971/AO-24-07.pdf**

- **Advisory Opinion 24-08 (Sept. 13, 2024)** is an unfavorable opinion regarding an arrangement for Medicaid Advantage Organization offering Employer Group Waiver Plans to share percentage of its savings with contracted group health plans. The OIG concluded the arrangement implicated the AKS and would not qualify for a safe harbor and did not present a sufficiently low risk for a favorable opinion citing to (i) concerns of patient steering impacting competition with other plans; and (ii) that steering concerns are not outweighed by other benefits for beneficiaries. The OIG also noted CMS's beneficiary rebate regulations (42 C.F.R. § 422.266) do not expressly permit gainshare payments and likewise, they may still implicate the AKS.

  **https://oig.hhs.gov/documents/advisory-opinions/9992/AO-24-08.pdf**

- **Advisory Opinion 24-09 (Nov. 25, 2024)** is a favorable opinion for a municipal emergency medical services (EMS) provider to county residents requesting to bill patient's insurance and waive co-payment for treatment-in-place (TIP) EMS. The EMS provider would charge based on level of care provided not to exceed amounts furnished for same care within an ambulance transport and imposed regardless of public or private insurance status. The OIG reasoned the arrangement implicated both the AKS and CMP without fitting within an exception to the definition for

"remuneration" for the CMP or safe harbor for the AKS. However, the arrangement posed low risk because (i) the cost sharing was equally applied to all individuals regardless of payor status; (ii) neither Medicare Part B or State Medicaid currently covers TIP; (iii) even if or when a federal payor covers TIP, the arrangement is unlikely to increase the costs to federal programs and may ensure appropriate care when TIP can eliminate unnecessary emergency department transports; and (iv) the cost sharing and providing the TIP at no charge would be unlikely to impact patient's decision to use the EMS reimbursable by federal program in future.

**https://oig.hhs.gov/documents/advisory-opinions/10067/AO-24-09.pdf**

- **Advisory Opinion 24-10 (Dec. 12, 2024)** is a favorable opinion regarding medical and dental supplies distributor's request to expand their customer loyalty program to update certain terms allowing customers to earn points on dental-related items and services that can be redeemed to reduce payments for other dental-related items and services and creation of a tiered program. The OIG concluded both streams of revenue, remuneration by requestor and participating entities to member through points on certain purchases to redeem and tiered benefits to members based on those qualifying purchases, did not fit within any AKS safe harbors, which generally means the discount is high risk and considered suspect under AKS. However, OIG found the points arrangement was low risk as the dollar value of each point was low that helped mitigate risk of steering members, the points may only cover 50% of the items or services not allowing free items or services in exchange for purchases of federally reimbursement items or services, and member terms for redemption of points reduce risk of steering and overutilization. Additionally, OIG concluded the tiered benefit was also low risk as the benefits offered reduced risk of improper steering of customers to requestor or unfair competition, was unlikely to drive overutilization or impact medical decision-making, design reduced overall risk of selectively rewarding only particular members or for certain types of purchases.

  **https://oig.hhs.gov/documents/advisory-opinions/10093/AO-24-10.pdf**

- **Advisory Opinion 24-12 (Dec. 17, 2024)** is a favorable opinion regarding a drug manufacturer's request to create a program to sponsor genetic testing and counseling and disease awareness-based education aimed at certain hereditary conditions causing kidney stones. The OIG noted the arrangement implicates the AKS and beneficiary inducement CMP by providing remuneration with free genetic tests, potential free Assay and free genetic counseling, creating opportunity for providers to bill for services with an additional patient visit describing test results and risk that lab and subsidiary could be referral sources for the drug. However, the OIG concluded the arrangement posed low risk given safeguards to limit how the patient obtains the genetic counseling or test reduces risk of overutilization or inappropriate utilization based on the narrow eligibility criteria, limited risk of skewing clinical decision-making and limited concerns of patient safety or quality. Further, OIG expressed that remuneration to the lab or subsidiary poses low risk because of limitation in structing the arrangement with fixed fees for services, limitations on the genetic counselors not discussing treatment and limiting lab and subsidiaries access to data on the providers and patients.

  **https://oig.hhs.gov/documents/advisory-opinions/10117/AO-24-12.pdf**

- **Advisory Opinion 24-13 (Dec. 31, 2024)** is a favorable opinion regarding pharmaceutical manufacturer's provide qualifying patients airfare and ground transportation, lodging and other support for associated expenses during the treatment center stay while receiving a cell therapy product manufactured by Requestor. The OIG concluded the risk presented under the AKS is low because the arrangement removes barriers to access to the treatment center for the 11 day phase of the drug, is for access to a one-time curative treatment and includes additional safeguards such as not providing for other expenses reimbursable by other insurances or charities. Additionally, OIG noted the facts implicate the Beneficiary Inducement CMP but satisfies the Promote Access to Care Exception by improving beneficiaries access to the limited treatment centers allowing for the 11 day for treatment phases and poses low risk to program given it is unlikely to skew clinical decision making, otherwise increase costs to the federal healthcare program and does not pose patient safety or quality concerns.

  **https://oig.hhs.gov/documents/advisory-opinions/10148/AO-24-13.pdf**

## Other Fraud and Abuse Developments

- **DOJ Corporate Whistleblower Program** In April 2024, the DOJ Criminal Division launched a Corporate Whistleblower Awards Pilot Program. This program is intended to serve a "gap filling" purpose and cover federal health care offenses not covered by the Federal False Claims Act—such as fraud on private or non-public health care benefit programs.

  This creates a more formal structure for whistleblower awards in criminal actions. Whistleblowers can receive significant awards, including up to 30% of the first $100 million in net proceeds forfeited and 5% of proceeds forfeited between $100 million and $500 million. In fact, if the whistleblower

  1. is not culpable,
  2. does not unreasonably delay,
  3. does not interfere with the investigation, or
  4. is not management, there is a presumption that they will receive the maximum 30% of the first $10 million forfeited.

  Companies have 120 days from receiving an internal whistleblower report to investigate and report to DOJ. If they self-report before being contacted by DOJ, a company will receive a presumption of declination. Accordingly, companies should ensure existing compliance programs include internal whistleblower reporting systems, refresh compliance training to ensure employee awareness of reporting mechanisms and timely review any reports they receive.

  **https://www.justice.gov/criminal/criminal-division-corporate-whistleblower-awards-pilot-program**

- **New CMS Rule on Medicare Overpayment Disclosure Timing** On November 1, 2024, CMS finalized a new rule that will go into effect on January 1, 2025 regarding the Physician Fee Schedule, which governs Medicare payments for the services of physicians and healthcare professionals.

  The new so-called "60-Day Overpayment" Rule implemented the statutory requirement for reporting and returning overpayment to avoid liability under the False Claims Act.

  In short, in the 2025 Medicare Physician Fee Schedule Final Rule, CMS outlined the following general changes:

  1. Replaces the "reasonable diligence" period with the "knowing" and "knowingly" standard from the False Claims Act. This change better reflects the statutory standard, but the effect is to bring forward the time at which an overpayment is "identified" for purposes of triggering the 60-Day clock, even if you have not yet quantified the total overpayment.
  2. An overpayment is "identified" thus triggering the 60-Day clock begins when the "knowing" or "knowingly" standard is met, even if the amount of the overpayment is not yet quantified in its entirety.
  3. Allows the 60-Day clock to be suspended for up to 180 days while you complete a good faith investigation. Because the 60-Day clock now starts with the identification of the initial overpayment, any delay in beginning the investigation, thus suspending the clock, will result in less time to report and return the overpayment after the investigation is complete.

https://public-inspection.federalregister.gov/2024-25382.pdf

- **HHS-OIG's Nursing Facility Industry-Specific Compliance Program Guidance** In November 2024, HHS-OIG released a new and lengthy reference guide on compliance programs for Nursing Facilities. This the first industry-specific compliance program guidance and is part of the OIG's larger modernization initiative that began with OIG publishing its General Compliance Program Guidance in November 2023.

**The guidance addresses the following key areas of compliance risk for nursing facilities:**

- Quality of care and quality of life
- Medicare and Medicaid billing requirements
- Federal anti-kickback statute
- Other risk areas (related-party transactions; physician self-referral law; anti-supplementation; Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy, Security and Breach Notification Rules; and civil rights)

**https://oig.hhs.gov/documents/compliance/10038/nursing-facility-icpg.pdf**

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