POLSINELLI. What a law firm *should* be.™

Health Care Fraud and Abuse
2023 Year in Review

OVERVIEW

AUTHORS

Dayna C. (LaPlante) Staron
Shareholder
Chicago

Kevin M. Coffey
Shareholder
Chicago

Assisting

Meredith E. Eng, Associate
Tessa M. Lancaster, Associate
Rebecca M. Hsu, Associate
Haley Essner, Associate
Christopher I. Kim, Associate
Logan Moore, Associate
Angela C. Powers, Associate

NEXT PAGE ›

Introduction

Polsinelli proudly introduces the Health Care Fraud and Abuse 2023 Year in Review, a comprehensive examination of the evolving landscape surrounding the False Claims Act ("FCA") and fraud & abuse enforcement efforts in the United States. Since its significant amendments in 1986, the FCA has stood as a formidable tool in combating health care fraud, with the Department of Justice reclaiming over $75 billion in allegedly fraudulent proceeds. The focus remains steadfast, with ongoing enforcement initiatives displaying no signs of abating.

The targets of these enforcement actions span a broad spectrum, encompassing hospitals, nursing facilities, physician practices, laboratories, durable medical equipment manufacturers and suppliers, and other various health care providers accused of diverse infractions such as kickbacks, unnecessary care, and overbilling federal health care programs. Navigating this complex terrain demands vigilance and insight, as the regulatory framework continually evolves.

Drawing upon the collective expertise of Polsinelli's seasoned health care litigators, Government Investigations attorneys, False Claims Act specialists, and former Government attorneys, this publication is intended to serve as a valuable resource for industry stakeholders. It aims to provide critical updates, including significant settlements, noteworthy court decisions, and key guidance from agencies like the Centers for Medicare and Medicaid Services and the Office of Inspector General.

We are honored to present this annual report, designed to equip health care providers with the knowledge and understanding necessary to navigate the intricate landscape of health care fraud and abuse enforcement in the United States.

The content that follows is a comprehensive, interactive summary of civil government enforcement activity, litigation, and guidance issued in the False Claims Act space in 2023.

NEXT PAGE ›

False Claims Act Settlements

In 2023, the False Claims Act witnessed a flurry of notable settlements, each offering critical insights into the evolving landscape of government enforcement priorities. This section delves into these significant settlements, highlighting the robustness of government enforcement efforts. Despite not reaching the staggering figures of previous years, the government's recoveries still amounted to an impressive $2.7 billion within a span of just 12 months, marking a substantial 20% increase from the previous year's $2.2 billion. What's particularly striking is the substantial rise in the number of settlements and judgments, with nearly 200 more matters resolved in 2023 compared to the preceding year, constituting a remarkable 55% surge.

Although some settlements reached eye-catching amounts, such as those involving Booze Allen and Community Health, there was a notable absence of billion-dollar single-case settlements. Instead, the focus was on a broader array of cases, spread across 543 settlements and judgments—a significant uptick from the 305 recorded in 2022. This surge can be attributed in part to the government's intensified data-mining efforts, resulting in a record number of FCA actions initiated by the government, surpassing all previous counts. Moreover, the government's commitment to addressing whistleblower cases remains steadfast, with a substantial number of *qui tam* filings recorded.

The majority of these settlements were in the health care sector, spanning a range of industry participants and reflecting a heightened scrutiny on matters related to medical necessity and violations of the Anti-Kickback Statute (AKS) and Stark Law. Notably, the Department of Justice (DOJ) announced its largest-ever FCA settlement based on alleged Stark Law violations, involving an Indianapolis-based health care network's alleged overcompensation of physicians, resulting in a hefty $345 million payment. As government-initiated cases continue to rise, propelled by enhanced data analysis capabilities and a proactive approach to enforcement, the significance of these settlements reverberates across various sectors, underscoring the imperative for heightened compliance and vigilance in navigating the evolving regulatory landscape.

Health Systems and Hospitals

- Community Health Network Inc. ("CHN"), an integrated health system, agreed to pay **$345 million** to resolve allegations that it submitted false claims to Medicare for services referred in violation of the Stark Law. CHN allegedly compensated certain employed physicians above fair market value and provided incentive-based bonuses based on reaching target levels of referrals. The government also alleged that CHN provided its valuation firm with false data to secure a favorable opinion and ignored the firm's warnings on overcompensating physicians. CHN also agreed to a five-year Corporate Integrity Agreement. The relator was CHN's former Chief Financial and Operating Officer.

  DOJ's Press Release: https://www.justice.gov/opa/pr/indiana-health-network-agrees-pay-345-million-settle-alleged-false-claims-act-violations

- Santa Barbara San Luis Obispo Regional Health Authority d/b/a CenCal Health ("CenCal"), a county organized health system, as well as a not-for-profit hospital network, not-for-profit outpatient clinic, and a not-for-profit community health center agreed to pay **$68 million** to resolve allegations that they submitted or caused the submission of false claims for "Enhanced Services" provided to the Adult Expansion population under Medi-Cal that that were not allowable medical expenses, failed to reflect fair market value, and/or were duplicative of services already required. The relator was CenCal's former medical director.

  DOJ's Press Release: https://www.justice.gov/opa/pr/california-county-organized-health-system-and-three-health-care-providers-agree-pay-68

- St. Francis Physician Services Inc., St. Francis Hospital Inc., and Bon Secours St. Francis Health System Inc. (collectively, "St. Francis") agreed to pay **$36.5 million** to resolve allegations that they submitted claims for services in violation of the Stark Law and AKS. St. Francis allegedly made improper bonus payments to an orthopedic and pain management practice that were tied to the volume or value of the practice's referrals to St. Francis. The relator was an orthopedic surgeon.

  DOJ's Press Release: https://www.justice.gov/usao-sc/pr/st-francis-pay-united-states-365-million-settle-allegations-under-false-claims-act

- VHS of Michigan Inc., d/b/a The Detroit Medical Center Inc. ("DMC"), Vanguard Health Systems Inc. ("Vanguard"), and Tenet Healthcare Corporation ("Tenet"), agreed to pay **$30 million** to resolve allegations that they violated the FCA in connection with kickbacks provided to physicians in the form of mid-level practitioner services. Hospitals operated by the DMC allegedly provided the services of DMC-employed mid-level practitioners to 13 physicians at no cost or below fair market value in violation of the AKS. The government alleged that the physicians were selected based on the volume or value of referrals to the hospitals. The relator was a former employed physician of Wayne State University Medical School, which is affiliated with DMC.

  DOJ's Press Release: https://www.justice.gov/opa/pr/detroit-medical-center-vanguard-health-systems-and-tenet-healthcare-corporation-agree-pay

- Clinica Sierra Vista, a non-profit federally qualified health center, agreed to pay nearly **$26 million** to resolve self-disclosed violations it under-reported its income to the government by failing to accurately report capitated payments received from managed care plans, which resulted in higher wrap around payments made by Medi-Cal.

  DOJ's Press Release: https://oag.ca.gov/news/press-releases/attorney-general-bonta-and-us-attorney-talbert-announce-nearly-26-million#:~:text=OAKLAND%20%E2%80%93%20California%20Attorney%20General%20Rob,the%20federal%20False%20Claims%20Act

- Cornerstone Healthcare Group Holding Inc. and CHG Hospital Medical Center LLC, ("Cornerstone"), a hospital and post-acute provider, paid **$21.6 million** to resolve allegations that they submitted claims for services that were worthless, not provided, or provided by unauthorized personnel. The government alleged Cornerstone improperly delegated the provision of services to unlicensed, unauthorized students and sought payment for services that were not performed because the treating physician was out of the country traveling. The relator was a former employed technician of Cornerstone.

  DOJ's Press Release: https://www.justice.gov/usao-sdtx/pr/medical-center-pays-over-21m-settle-alleged-false-claims

- The University of Pittsburgh Medical Center ("UPMC"), an academic hospital; James L. Luketich, M.D., a cardiothoracic surgeon; and the University of Pittsburgh Physicians ("UPP"), UPMC's wholly-owned physician group, agreed to pay **$8.5 million** to resolve allegations that they improperly submitted claims for concurrent surgeries. The government alleged Dr. Luketich failed to participate in the "key and critical" portions of the surgeries and caused patients to undergo medically unnecessary anesthesia time as Dr. Luketich performed other surgeries.

  The parties also agreed to a Corrective Action Plan for Dr. Luketich and to a third-party audit of Dr. Luketich's Medicare claims for physician fee services for a year. Additionally, the settlement agreement allowed UPMC to seek guidance and/or an advisory opinion from CMS regarding the Medicare regulations at issue. The relators were a former UPMC surgeon and a former employee of UPMC.

  DOJ's Press Release: https://www.justice.gov/usao-wdpa/pr/james-l-luketich-md-university-pittsburgh-medical-center-and-university-pittsburgh

- Sibley Hospital and its parent company, Johns Hopkins Health System, paid **$5 million** to resolve allegations that they billed Medicare for designated health services referred by ten cardiologists in violation of the Stark Law. Sibley Hospital allegedly paid the cardiologists compensation in excess of fair market value of the services provided. The parties self-disclosed these arrangements to the Office of the Inspector General of the Department of Health and Human Services.

  DOJ's Press Release: https://www.justice.gov/opa/pr/sibley-hospital-and-johns-hopkins-health-system-settle-allegations-improper-compensation

- Lompoc Valley Medical Center ("Lompoc"), a California Health Care District that operates a hospital and several health care clinics, agreed to pay **$5 million** to resolve allegations that it caused the submission of false claims for "Enhanced Services" provided to the Adult Expansion population under Medi-Cal that

that were not allowable medical expenses, failed to reflect fair market value, and/or were duplicative of services already required. The relator was the former medical director for CenCal, with whom Lompoc contracted.

DOJ's Press Release: https://www.justice.gov/opa/pr/health-care-provider-agrees-pay-5-million-alleged-false-claims-californias-medicaid-program

- Luminis Health Doctors Community Medical Center, Inc. ("Luminis") and Diagnostic Imaging Associates, LLC ("DIA"), a radiology imaging practice, paid **$2 million** to resolve allegations that DIA improperly billed for the technical component of services provided by Luminis, which was not an enrolled provider and not eligible for reimbursement. Luminis and DIA self-disclosed the allegations under CMS' Self-Referral Disclosure Protocol.

  DOJ's Press Release: https://www.justice.gov/usao-md/pr/acute-care-hospital-and-radiology-imaging-practice-pay-more-2-million-resolve-false

- Doctor's Hospital 1997 L.P. d/b/a United Memorial Medical Center LLC ("UMMC") agreed to pay **$2 million** plus additional contingent payments to resolve allegations that it submitted false claims for cost outlier payments, retained overpayments for such payments, and double-billed for COVID-19 tests. The government alleged UMMC submitted claims for cost outlier payments by rapidly increasing its charges for inpatient care and underreporting its charges on Medicare cost reports. Additionally, UMMC allegedly submitted claims for COVID-19 tests despite being reimbursed for those same services by the State of Texas or the City of Houston. The relator was a former UMMC employee.

  DOJ's Press Release: https://www.justice.gov/opa/pr/united-memorial-medical-center-pay-2-million-plus-additional-contingent-payments-allegedly

Physicians

- Aarti D. Pandya, M.D. P.C., an ophthalmology practice, and its physician owner (collectively, "Pandya") agreed to pay **$1.85 million** to resolve allegations they billed for medically unnecessary services; specifically, cataract extraction surgeries and YAG laser capsulotomies. The government alleged Pandya did not complete these procedures under accepted standards of medical practice, caused injury to some patients, falsely diagnosed patients to bill for testing and treatment, and did not interpret tests in the medical record. Pandya entered into a multi-year Integration Agreement with HHS-OIG. The relator was a former Pandya employee.

  DOJ's Press Release: https://www.justice.gov/usao-ndga/pr/conyers-doctor-pays-1850000-resolve-allegations-she-performed-and-billed-medically

- Mitias Orthopaedics, PLLC, its physician owner, and a subsidiary of Champion Orthopedics, all orthopedic health services providers, agreed to pay **$1.87 million** to resolve allegations they billed for brand name knee injections when a cheaper compounded agent was used. The relator was a medical device sales representative.

  DOJ's Press Release: https://www.justice.gov/usao-ndms/pr/mitias-pay-187-million-settle-false-claims-act-allegations-medicare-and-medicaid

- Psychiatric Solutions, Longview Psychiatric Center, Longview Psychiatric Center, and their physician owner agreed to pay **$3 million** to resolve allegations that they billed for Transcranial Magnetic Stimulation sessions that were medically unnecessary, not performed, or for which no physician supervised the session. The relators were former employees.

  DOJ's Press Release: https://www.justice.gov/usao-sdtx/pr/psychiatrist-settles-claims-unnecessary-brain-stimulation-treatments

- Arlington Ophthalmology Association, P.L.L.C. d/b/a Kleiman Evangelista Eye Centers ("K&E"), an ophthalmology practice, agreed to pay **$2.9 million** to resolve allegations it provided kickbacks to referring optometrists who co-managed patient care wherein K&E paid optometrists for referring cataract patients and guaranteed the referral of the patients back to the optometrists for post-surgical care so that the referring optometrists could receive 20% of Medicare's global payment for the surgery. Additional alleged kickbacks included free continuing education courses, expensive dinners for top-referring optometrists, and invitations for optometrists, their families, and their staff to attend professional sports games in K&E's suite. The relator was an oculofacial plastic surgeon employed at K&E.

  DOJ's Press Release: https://www.justice.gov/usao-edtx/pr/ophthalmology-practice-agrees-pay-over-29-million-settle-kickback-allegations

- Ellis Pain Center, its physician owner, and its manager agreed to pay **$5 million** to resolve allegations that they submitted claims for services not performed and medically unnecessary diagnostic and urine drug tests.

  DOJ's Press Release: https://www.justice.gov/usao-mdga/pr/athens-georgia-pain-medicine-owner-practice-manager-agree-5-million-settlement

- Jason A. Dreyer, D.O., a neurosurgeon, agreed to pay **$1.2 million** to resolve allegations that he caused his health system employer to submit claims for medically unnecessary neurosurgery procedures and services that did not meet federal health care program reimbursement criteria. The government further alleged that the services performed were incentivized by the health system's compensation model that paid Dr. Dreyer based on Work Relative Value Units ("wRVUs"), a personal productivity metric, without a cap for wRVU-based compensation that he could earn. Dr. Dryer also agreed to a nine-year voluntary exclusion.

In 2022, Dr. Dreyer's former hospital employer agreed to pay $22.7 million to resolve allegations that it billed for medically unnecessary neurosurgery procedures performed by Dr. Dreyer and another physician.

DOJ's Press Release: https://www.justice.gov/usao-edwa/pr/former-physician-pay-more-11-million-resolve-allegations-he-performed-medically

- Tower Multi-Specialty Medical Group ("Tower Medical"), two outpatient ambulatory surgery centers, a medical billing company, their physician owner, and the director of revenue cycle management for one of the surgery centers and the CEO of the billing company agreed to pay nearly **$24 million** to resolve allegations that they manipulated the place of service code on claims for skin grafts to maximize reimbursement as well as re-used and billed multiple times for single-use skin graft materials. Tower Medical and each individual also agreed to voluntary exclusions. The relators were employees of the parties.

  DOJ's Press Release: https://www.justice.gov/opa/pr/beverly-hills-plastic-surgeon-agrees-pay-nearly-24-million-settle-false-claims-act

- FA CV Consultants, P.C., a medical practice, and its two physician owner-operators agreed to pay **$1 million** to resolve allegations that they billed for medically unnecessary services, including balance tests, pulmonary function tests, allergy tests, autonomic nervous tests, and cardiology ultrasounds. The relator was a former employee.

  DOJ's Press Release: https://www.justice.gov/usao-nj/pr/medical-practice-and-its-owners-pay-1-million-resolve-false-claims-act-allegations

- Massachusetts Eye and Ear Infirmary, a teaching hospital ("MEEI"); Infirmary Massachusetts Eye and Ear Associates Inc., a physician group of ophthalmologists and otolaryngologists ("MEEI Associates"); and the entities' parent group agreed to pay over **$5.7 million** to resolve allegations that they billed for services referred by employed physicians who received compensation in violation of the Stark Law. MEEI admitted that certain of its compensation models transferred to MEEI Associates a percentage of the operating margins at hospital outpatient departments. Mass General Brigham, which has owned and operated MEEI since 2019, self-disclosed these arrangements to the government during a *qui tam* investigation into related conduct. The relator in that case was a former otolaryngologist at MEEI Associates.

  DOJ's Press Release: https://www.justice.gov/usao-ma/pr/massachusetts-eye-and-ear-agrees-pay-over-57-million-resolve-false-claims-act

- Dr. Vasso Godiali, a vascular surgeon, agreed to pay over **$43 million** to resolve allegations that he billed for vascular stents and arterial thrombectomies that were never performed, created false medical record entries, and improperly used Modifier 59 to unbundle services to increase reimbursement. Dr. Godiali was also criminally prosecuted. The relator was Innovative Solutions Consulting, LLC, a consulting firm.

  DOJ's Press Release: https://www.justice.gov/opa/pr/michigan-vascular-surgeon-sentenced-80-months-prison-health-care-fraud-conviction-and-agrees

- Complete Physician Services and two physicians ("CPS") agreed to pay **$1.5 million** to resolve allegations that they submitted unsupported diagnosis codes to Medicare Advantage plans as well as submitted claims to Medicare Part B for upcoded E&M visits, "incident to" physician assistant services when the physician was out of the country, and other unsupported services. The relators were former CPS employees.

  DOJ's Press Release: https://www.justice.gov/usao-edpa/pr/primary-care-physicians-pay-15-million-resolve-false-claims-act-liability-submitting

- Carolina Heart and Leg Center, a cardiology clinic, and its physician owner agreed to pay **$5 million** to resolve allegations that they performed and billed for medically unnecessary atherectomy procedures without the required arterial blockage and supporting medical records. The physician owner was one of the highest billing cardiologists for this procedure in North Carolina. The relator was an interventional cardiologist who worked at the Carolina Heart and Leg Center.

  DOJ's Press Release: https://www.justice.gov/usao-ednc/pr/fayetteville-cardiologist-agrees-pay-over-5-million-resolve-allegedly-false-medicare

- Skin Cancer & Cosmetic Dermatology Center, an operator of 13 dermatology clinics, and its physician owner ("SCCDC") agreed to pay **$6.6 million** to resolve allegations that they submitted claims for both the surgery and pathology portion of Mohs procedures performed by different providers. The government also alleged SCCDC submitted claims for multiple procedures for the same patient on the same day, in violation of Medicare's "multiple procedure reduction rule." SCCDC also entered into an Integrity Agreement.

  DOJ's Press Release: https://www.justice.gov/usao-edtn/pr/dermatologist-agrees-pay-66-million-settle-allegations-fraudulent-billing-practices

- CRH Healthcare, LLC and Peachtree Immediate Care FP, LLC agreed to pay **$1.6 million** to resolve allegations that they upcoded E&M levels for the treatment and testing of patients with suspected COVID-19 exposure. The relators were CRH's former regional medical director and an employed nurse practitioner.

  DOJ's Press Release: https://www.justice.gov/usao-ndga/pr/georgia-urgent-care-chain-agrees-pay-1600000-resolve-false-claim-act-allegations

- Lags Spine & Sportscare Medical Centers Inc., its subsidiaries, and its physician owner, who collectively owned and operated pain management clinics, ambulatory surgical centers, and a laboratory (collectively, "Lags Medical") agreed to pay **$11 million** to resolve allegations that they submitted claims for medically unnecessary services, such as skin biopsies, spinal cord stimulator implant surgeries, and urine drug testing. Specifically, the government alleged Lags Medical (i) created a team of non-provider staff to order skin biopsies each week without the consent of the patients' treating provider and told patients it would reduce their opioid medications if they refused the biopsy, (ii) paid a psychiatrist to falsely state to insurers that the psychiatrist performed required psychological evaluations of patients prior to them receiving the implant surgery, and (iii) made blanket orders of definitive urine drug testing without regard to patients' individualized need. The settlement amount was based on ability to pay. Dr. Lagattuta also agreed to a five-year voluntary exclusion. The relator was Lag Medical's former operations director and marketing director.

  DOJ's Press Release: https://www.justice.gov/usao-edca/pr/california-doctor-and-medical-practice-agree-pay-114-million-resolve-false-claims-act

- Mile High Psychiatry LLC, a telepsychiatry services provider, and its owner ("Mile High") agreed to pay **$1.9 million** to resolve allegations that they submitted claims for upcoded E&M services. The government alleged that the claims double-counted time spent for E&M and psychotherapy services. The relator was Mile High's compliance manager.

  DOJ's Press Release: https://www.justice.gov/usao-co/pr/colorado-psychiatry-practice-and-owner-agree-pay-19-million-settle-allegations-0

- Med First Immediate Care & Family Practice, P.A. ("Med First") agreed to pay almost **$1.5 million** to resolve allegations that it billed for medically unnecessary urine drug testing and upcoded E&M visits. The government alleged that Med First performed both presumptive and definitive urine drug tests on almost all office visits for patients on opioids and frequently disregarded the results. The relator was Med First's former Chief Medical Officer.

  DOJ's Press Release: https://www.justice.gov/usao-mdnc/pr/med-first-agrees-pay-1450000-resolve-health-care-fraud-allegations-south-carolina

- Total Access Urgent Care, P.C. ("TAUC"), an operator of urgent care clinics, agreed to pay **$9.1 million** to resolve allegations that it submitted claims that were upcoded and in violation of the Stark Law. TAUC allegedly submitted claims for physician E&M services performed by a non-physician practitioner and upcoded the level of E&M services. During the government's investigation, TAUC also self-disclosed that it submitted upcoded claims for COVID-19 testing. This settlement also resolved TAUC's self-disclosure to CMS' Self-Referral Disclosure Protocol program that it paid certain employed physicians productivity bonuses determined in a manner that took into account the volume or value of referrals in violation of the Stark Law.

  DOJ's Press Release: https://www.justice.gov/usao-edmo/pr/united-states-reaches-91-million-civil-settlement-total-access-urgent-care-over-false

Laboratories

- Genomic Health, Inc. ("GHI"), which provides genomic-based clinical diagnostic tests for cancer, agreed to pay **$32.5 million** to resolve allegations that it provided kickbacks to referring hospitals and improperly billed for tests ordered within 14 days of a patient's discharge from a hospital, in violation of Medicare regulations. GHI allegedly tried to circumvent this rule by seeking direct reimbursement for tests that the hospital should have billed or were covered as part of the hospital's inpatient reimbursement as well as encouraging ordering providers to cancel and re-order after the 14-day period lapsed. The government also alleged that GHI provided kickbacks by failing to invoice hospitals for laboratory services or writing off unpaid fees in violation of the AKS.

  DOJ's Press Release: https://www.justice.gov/opa/pr/genomic-health-inc-agrees-pay-325-million-resolve-allegations-relating-submission-false

- Laboratory Corporation of America ("LabCorp") agreed to pay **$19 million** to resolve allegations that it provided kickbacks to physicians in the form of free phlebotomy services for patients referred to other laboratories for testing. Relators also alleged that LabCorp conspired with these laboratories by facilitating their kickbacks to referring physicians disguised as sham "processing fee" arrangements. The relators were an owner of a medical services billing company used by one of the induced physicians and a nurse employed by one of the induced physicians.

  DOJ's Press Release: https://www.justice.gov/usao-sc/pr/labcorp-pay-united-states-19-million-settle-allegations-under-false-claims-act

- Genotox Laboratories, Ltd. ("Genotox"), a reference laboratory, agreed to pay **$5.9 million** to resolve allegations that it paid commissions to independent contractor sales representatives or marketing firms to arrange or recommend orders for urine drug tests, in violation of the AKS. The alleged commissions were based on a percentage of revenue received from billing insurers, including federal health care programs. The settlement

also resolves allegations that Genotox submitted claims for laboratory tests that were medically unnecessary or not covered, including blanket and standing drug testing orders for all patients in a provider's practice. Genotox admitted it offered providers order forms wherein the provider pre-selected tests to order for all or nearly all of the provider's patients. Genotox also entered into a five-year Corporate Integrity Agreement. The relator was Genotox's former billing manager.

DOJ's Press Release: https://www.justice.gov/opa/pr/texas-laboratory-agrees-pay-59-million-settle-allegations-kickbacks-third-party-marketers-and

- Laboratory Corporation of America ("LabCorp") agreed to pay **$2.1 million** to resolve allegations it double or triple billed genetic tests conducted by a third-party reference lab that LabCorp used under Department of Defense contracts, overcharged the Department of Defense by failing to reconcile what the reference lab charged compared to what LabCorp billed, and improperly billed for services without evidence of a requisition form, test result and/or invoice. The relator was a former employee of LabCorp.

  DOJ's Press Release: https://www.justice.gov/usao-md/pr/laboratory-corporation-america-agrees-pay-2100000-settle-false-claims-act-allegations

- Aspirar Medical Lab LLC, a medical laboratory, and its owner ("Aspirar") agreed to pay **$2 million** to resolve allegations that they submitted claims for urine drug tests that were medically unnecessary and a result of kickbacks in violation of the AKS. The government alleged that the tests were neither patient-specific nor reflective of a provider's determination of need. Additionally, Aspirar allegedly paid a medical consulting company for each urine drug test that the company referred to Aspirar.

  DOJ's Press Release: https://www.justice.gov/usao-wdnc/pr/north-carolina-laboratory-and-owner-agree-pay-more-19-million-resolve-false-claims-0

- Blue Waters Assessment and Testing Services, LLC and VerraLab JA, LLC. d/b/a BioTap Medical, both involved in performing urine drug tests, agreed to pay almost **$1.5 million** to resolve allegations they improperly billed for court-ordered urine drug tests to Medicare and Medicaid. Medicare and Medicaid do not cover these tests, because they were performed to satisfy a court order not for medical diagnosis or treatment.

  DOJ's Press Release: https://www.justice.gov/usao-edky/pr/drug-testing-companies-agree-collectively-pay-17-million-resolve-false-claims-act

- Thyroid Specialty Laboratory Inc. d/b/a TEN Healthcare, a clinical testing lab; Ten Healthcare 3890 Management LLC, the lab's management company; and Ten Marketing LLC, a subsidiary that employs marketing and sales staff (collectively, "TEN"), agreed to pay **$1.9 million** and **relinquish almost $7 million in escrow** to resolve allegations that they billed for medically unnecessary tests. TEN allegedly created a requisition form for providers to use in ordering certain panels, which included medically unnecessary and unreasonable PCR tests. When Medicare began rejecting certain billing codes for lack of medical necessity, TEN allegedly used other codes to circumvent the rejections. The government also alleged that TEN separately billed for urine drug tests contemporaneously with bundled codes that included such tests.

  DOJ's Press Release: https://www.justice.gov/usao-edmo/pr/missouri-laboratory-owners-agree-pay-19-million-and-relinquish-7-million-escrow

- Genesis Reference Laboratories LLC ("Genesis"), a clinical laboratory, agreed to pay over **$1 million** to resolve allegations that the marketing companies it hired paid kickbacks to physicians to induce urine drug testing referrals in violation of the AKS. The marketing companies allegedly used management service organizations to pay kickbacks disguised as investment returns.

  DOJ's Press Release: https://www.justice.gov/opa/pr/florida-laboratory-agrees-pay-over-11-million-settle-kickback-allegations

Durable Medical Equipment ("DME")

- Lincare Holdings, Inc. ("Lincare"), a DME supply company, agreed to pay **$29 million** to resolve allegations that it billed for oxygen equipment rentals in excess of coverage limits. Lincare allegedly lacked controls to ensure such rentals were billed properly and its officials allegedly instructed staff to keep billing for the rentals after staff raised concerns about the billing practices. Lincare also agreed to enter into a five-year Corporate Integrity Agreement. The relators were former Lincare employees.

  DOJ's Press Release: https://www.justice.gov/usao-edwa/pr/lincare-holdings-agrees-pay-29-million-resolve-claims-overbilling-medicare-oxygen

- DePuy Synthes, Inc. ("DePuy"), an orthopedic device manufacturer, agreed to pay **$9.75 million** to resolve allegations that it caused the submission of false claims as a result of kickbacks provided to a physician. DePuy sales representatives allegedly provided a surgeon with free DePuy implants and instruments worth over $100,000 that the surgeon used on patients overseas (who were not federal health care beneficiaries) in order to induce the surgeon to use DePuy products in his surgeries performed in the United States, in violation of the AKS. The relator was a former DePuy sales representative.

  DOJ's Press Release: https://www.justice.gov/opa/pr/depuy-synthes-inc-agrees-pay-975-million-settle-allegations-concerning-kickbacks-paid

- United Seating and Mobility, LLC, d/b/a Numotion ("Numotion"), a DME supplier, agreed to pay **$7 million** to resolve allegations it made false statements in claims submitted to Medicaid and Medicaid MCOs by failing to disclose discounts received from or actual costs paid to DME manufacturers. This resulted in allegedly higher reimbursement received, as the Medicaid payors "manually priced" the DME based on the cost Numotion actually paid to manufacturers. Numotion also entered into a five-year Corporate Integrity Agreement. The relator was a former Numotion employee.

  DOJ's Press Release: https://www.justice.gov/usao-edky/pr/medical-equipment-company-pays-7-million-resolve-false-claims-act-allegations

- AdaptHealth LLC, a DME provider, agreed to pay **$5.3 million** to resolve allegations it submitted upcoded claims for higher reimbursed non-invasive ventilators when a patient was actually prescribed a BiPAP machine. The government also alleged AdaptHealth billed for ventilators after patients no longer needed or ceased using them and double billed federal payors for ventilator rentals. The relator was a former employee.

  DOJ's Press Release: https://www.justice.gov/usao-edpa/pr/plymouth-meeting-pa-company-pay-53-million-resolve-false-claims-act-allegations

- Spacelabs Healthcare, LLC ("Spacelabs"), a medical equipment manufacturer, paid **$2.5 million** to resolve allegations that it failed to comply with price reduction clauses in contracts with the Department of Veterans Affairs and Department of Defense, thereby causing the government to overpay. The clause required that the government receive lower prices for patient monitoring equipment if such lower prices were offered to another customer. The relators were a former government business specialist and accounts manager for Spacelabs.

  DOJ's Press Release: https://www.justice.gov/opa/pr/spacelabs-healthcare-llc-agrees-pay-25-million-settle-allegations-it-overcharged-federal-0

- Philips Respironics ("Respironics"), a DME manufacturer, agreed to pay **$2.4 million** to resolve allegations that it caused DME suppliers to submit false claims for products used to treat sleep disorders referred in violation of the AKS. Respironics allegedly provided kickbacks in the form of free masks to sleep laboratories to induce physicians associated with the labs to prescribe Respironics-brand masks from suppliers.

  DOJ's Press Release: https://www.justice.gov/usao-sdca/pr/phillips-respironics-pays-24-million-allegedly-giving-kickbacks

Long Term Care

- Paksn Inc., a skilled nursing facility management company; its owner; and six owned or operated SNFs agreed to pay **$45.6 million** to resolve allegations they entered into sham medical directorship agreements in violation of the AKS. The SNFs allegedly paid medical directors proportional to the number of expected referrals, hired physicians who promised in advance to refer patients, and terminated physicians who failed to so refer. The relator was Paksn's former Vice President of Operations and Chief Operating Officer.

  DOJ's Press Release: https://www.justice.gov/opa/pr/california-skilled-nursing-facilities-owner-and-management-company-agree-456-million-consent

- The Saratoga Center for Rehabilitation and Skilled Nursing Care ("Saratoga Center"), its landlord, and other individuals and entities involved in operating Saratoga Center agreed to pay **$7.2 million** to resolve allegations that they submitted or caused the submission of false claims to Medicaid for worthless services. Following a financial dispute, Saratoga Center's landlord allegedly required the legally licensed operators to surrender control of the nursing facility after which the landlord replaced them with unlicensed operators. The government alleged that, under the care of the unlicensed parties, Saratoga Center delivered worthless services to residents, citing allegations of the facility's physical deterioration in violation of state and federal regulations, inadequate staffing, inadequate maintenance of hot water, inadequate linen inventory, inconsistent waste disposal, and harm to residents. Saratoga Center was placed on CMS' "Special Focus Facility List" during that time. While Saratoga Center closed after the government initiated its investigation, the parties voluntarily agreed to exclusion from federal health care program participation for timeframes between ten to twenty years.

  DOJ's Press Release: https://www.justice.gov/opa/pr/landlord-and-former-operators-upstate-new-york-nursing-home-pay-7168000-resolve-false-claims

- Watermark Retirement Communities LLC ("Watermark"), an operator of 79 long-term care facilities, agreed to pay **$4.25 million** to resolve allegations that it caused a home health agency operator (the "HHA Operator") to submit false claims for services referred in violation of the AKS. Watermark owned a home health company, Watermark at Home, and allegedly solicited the HHA Operator to purchase Watermark at Home for an above fair market value price in exchange for Watermark referring its residents. The relator was the former director of strategic growth for the HHA Operator.

  DOJ's Press Release: https://www.justice.gov/opa/pr/watermark-retirement-communities-pay-425-million-allegedly-receiving-kickback-violation

- Alta Vista Healthcare & Wellness Centre, LLC ("Alta Vista"), a skilled nursing facility, and its management company agreed to pay **$3.8 million** to resolve allegations they submitted claims

for services referred as a result of kickbacks in violation of the AKS. Alta Vista allegedly induced referrals by gifting physicians expensive dinners, golf trips, massages, e-reader tablets, limousine rides, and gift cards of up to $1,000 and paying physicians monthly stipends between $2,500 and $4,000 for medical director services. The settlement amount was based on ability to pay. The relator was a former Alta Vista accounting employee.

DOJ's Press Release: https://www.justice.gov/opa/pr/california-skilled-nursing-facility-and-management-company-agree-pay-3825-million-settle

Hospice, Home Health, & Home Care

- 1st Adult N Pediatrics Healthcare Services ("1st Adult") agreed to pay **$3 million** to resolve allegations it billed Medicaid for home health and personal care services that were never performed, including for services while patients were hospitalized at the time. The relators were two parents whose children were patients of 1st Adult.

  DOJ's Press Release: https://www.justice.gov/usao-wdva/pr/1st-adult-pediatrics-healthcare-pay-3-million-settle-false-claims-act-allegations

- Summit Hospice agreed to pay **$1 million** to resolve allegations that it billed for medically unnecessary hospice services that were unsupported by medical record documentation of a terminal illness.

  DOJ's Press Release: https://www.justice.gov/usao-ut/pr/summit-hospice-pay-over-1m-settle-false-claims-liability

Pharmacy

- BioTek reMEDys Inc. ("BioTek"), a specialty pharmacy, and its CEO agreed to pay **$20 million** to resolve allegations that they routinely waived copayments without considering patient financial need and provided kickbacks to physicians. The alleged kickbacks were gifts, dinners, and free practice management and clinical support services. The settlement amount was based on an ability to pay. The relators were two former employees of BioTek.

  DOJ's Press Release: https://www.justice.gov/opa/pr/united-states-settles-kickback-allegations-biotek-remedys-inc-chaitanya-gadde-and-dr-david

- Smart Pharmacy, Inc., SP2, LLC, and their owner (collectively, "Smart Pharmacy") agreed to pay at least **$7.4 million** to resolve allegations that they routinely waived copayments without regard to patient need and adding drugs approved for oral use to topical compounded pain creams to increase reimbursement. The relators were former employees of Smart Pharmacy.

  DOJ's Press Release: https://www.justice.gov/opa/pr/two-jacksonville-compounding-pharmacies-and-their-owner-agree-pay-least-74-million-resolve

- Walgreen Co. ("Walgreens") agreed to pay **$7 million** to resolve allegations that it submitted claims for Hepatitis C medication dispensed to TennCare beneficiaries who did not meet the clinical coverage criteria. Specifically, the government alleged that a former pharmacist and store manager at Walgreens' specialty pharmacy falsified prior authorization requests and supporting

clinical records for 65 program beneficiaries. Walgreens also allegedly retained the overpayments from TennCare after discovering the pharmacist/manager's conduct.

DOJ's Press Release: https://www.justice.gov/usao-edtn/pr/walgreen-co-pays-7-million-settle-allegations-under-false-claims-act

- Dr. Gisele Thao Nguyen, a pharmacist, agreed to pay **$3.9 million** to resolve allegations that she billed Medicare Part D for medications that were never dispensed by the community pharmacy she owned. The government alleged the pharmacy had not purchased enough of the medications from distributors to fill the amount of prescriptions billed.

  DOJ's Press Release: https://www.justice.gov/opa/pr/california-pharmacist-agrees-settle-allegations-fraud

Pharmaceutical Manufacturers

- Nostrum Laboratories Inc. ("Nostrum"), a pharmaceutical manufacturer, and its CEO agreed to pay up to **$50 million** to resolve allegations that they underpaid rebates to state Medicaid programs under the Medicaid Drug Rebate Program. Nostrum repriced a drug from $474.75 to $2,3292.32 per bottle, which triggered higher rebates. The final settlement amount will be based upon the parties' financial conditions.

  DOJ's Press Release: https://www.justice.gov/opa/pr/drugmaker-nostrum-and-its-ceo-agree-pay-50-million-settle-false-claims-act-claims

- Ultragenyx Pharmaceutical Inc. ("Ultragenyx"), a pharmaceutical manufacturer, agreed to pay **$6 million** to resolve allegations that it induced prescriptions of its drug in violation of the AKS. Ultragenyx admitted it paid a genetic testing laboratory to conduct genetic tests needed for insurance to reimburse its drug, Crysvita, at no cost to prescribing providers or patients and provided the results to prescribers for diagnostic purposes. Ultragenyx also admitted that it paid the lab to secure the test results, which allowed sales personnel to market the drug to providers. The relator was a Patient Diagnosis Liaison for Ultragenyx.

  DOJ's Press Release: https://www.justice.gov/opa/pr/pharmaceutical-company-ultragenyx-agrees-pay-6-million-allegedly-paying-kickbacks-induce

Imaging & Monitoring

- Cardiac Imaging Inc., a medical imaging company, and its CEO ("Cardiac Imaging") agreed to pay over **$85 million** to resolve allegations that they paid above fair market value fees to cardiologists for supervising mobile PET scans of the patients they referred in violation of the AKS and Stark Law. The fees were allegedly for $500 or more per hour, compensated for services not provided, and compensated for time when the cardiologist was providing care to other patients. Cardiac Imaging also allegedly contracted with cardiologists to refer exclusively to Cardiac Imaging and increased the hourly rate in competitive markets or for higher referring physicians. The government also alleged that Cardiac Imaging knew the FMV analysis it relied upon was

ultimately withdrawn by the authoring consultant and was based on fundamental inaccuracies. Cardiac Imaging agreed to a five-year Corporate Integrity Agreement. The relator was Cardiac Imaging's former billing manager.

DOJ's Press Release: https://www.justice.gov/opa/pr/mobile-cardiac-pet-scan-provider-and-founder-pay-85-million-resolve-allegedly-unlawful

- BioTelemetry Inc. and its subsidiary LifeWatch Services Inc. ("LifeWatch") agreed to pay **$14.7 million** to resolve allegations that they submitted claims for medically unnecessary services or upcoded claims for remote cardiac monitoring that inflated the level of monitoring ordered. The government alleged LifeWatch developed an enrollment portal for its monitoring device that led clinical staff to select the most expensive level of monitoring services. One of the relators was employed by a LifeWatch customer.

  DOJ's Press Release: https://www.justice.gov/opa/pr/biotelemetry-and-lifewatch-pay-more-z147-million-resolve-false-claims-act-allegations

Health Care Technology

- NextGen Healthcare Inc. ("NextGen"), an electronic health record ("EHR") technology vendor, agreed to pay **$31 million** to resolve allegations that it misrepresented its EHR software capabilities and provided kickbacks to users in violation of the AKS. Specifically, the government alleged that NextGen falsely obtained a certification that its EHR met HHS' certification criteria when the software lacked certain functionalities. NextGen also allegedly provided credits up to $10,000 to existing customers after the customers' recommendation led to a new sale of the EHR software. The relators were health care professionals at a facility that used NextGen's software.

  DOJ's Press Release: https://www.justice.gov/opa/pr/electronic-health-records-vendor-nextgen-healthcare-inc-pay-31-million-settle-false-claims

- Capital Technology Information Services, Inc. ("CTIS"), a health care information technology company, agreed to pay **$1.7 million** to resolve allegations that it billed unallowable costs to the National Institutes of Health in the form of luxury vehicles, residential mortgage payments, housekeeping, the cost of a wedding, and for work that was unreasonable or not performed. NIH awarded CTIS a contract and grant for a health data analytics project and to provide IT support, reimbursing CTIS only for allowable expenses. The relators were CTIS employees.

  DOJ's Press Release: https://www.justice.gov/usao-md/pr/health-care-information-technology-contractor-agrees-pay-more-17-million-resolve-false

Medical Transport

- Air Methods Corporation, an air medical transport service, agreed to pay **$1 million** to resolve allegations that it failed to return overpayments for medically unnecessary flights. Air Methods allegedly performed an internal review that identified 100 flights lacked medical necessity and should have been ground transports, but did not repay. The relator was a nurse for Air Methods.

  DOJ's Press Release: https://www.justice.gov/usao-edky/pr/air-medical-transport-company-agrees-pay-1-million-resolve-allegations-false-claims

Medicare Advantage

- The Cigna Group ("Cigna"), an owner and operator of Medicare Advantage organizations, agreed to pay over **$172 million** to resolve allegations that it submitted inaccurate diagnosis codes to CMS resulting in inflated reimbursement. Through a chart review program, Cigna allegedly identified additional inaccurate diagnosis codes to submit and failed to withdraw previously submitted diagnosis codes that the chart review found were unsupported. The government also alleged that Cigna reported unsupported diagnosis codes based only on in-home assessments of plan enrollees from vendors that Cigna hired who did not perform or order the diagnostic testing needed to diagnose the reported conditions. The relator for the in-home visit allegations was a former part-owner of a vendor Cigna retained.

  https://www.justice.gov/opa/pr/cigna-group-pay-172-million-resolve-false-claims-act-allegations

- Martin's Point Health Care Inc. ("Martin's Point"), an operator of Medicare Advantage plans, agreed to pay **$22.5 million** to resolve allegations that it submitted inaccurate diagnosis codes to CMS resulting in inflated reimbursement. Martin's Point allegedly performed chart reviews to identify additional diagnosis codes to submit, which were unsupported by the medical records. The relator was a former manager in Martin's Point's Risk Adjustment Operations group.

  https://www.justice.gov/opa/pr/martins-point-health-care-inc-pay-22485000-resolve-false-claims-act-allegations

Notable Court Decisions

This section delves into notable cases involving the FCA, spanning opinions rendered in U.S. District Courts, federal appellate courts, and the Supreme Court of the United States. Among these, two key Supreme Court decisions stand out: the court's rulings in *United States ex rel. Schutte v. Supervalu Inc.* and *United States ex rel. Polansky v. Executive Health Resources*. These important decisions have significant implications for FCA enforcement and interpretation.

In addition to these pivotal Supreme Court decisions, other notable FCA court cases offer valuable insights into evolving legal standards, enforcement trends, and judicial interpretations surrounding FCA claims.

United States Supreme Court Cases

- ***United States ex rel. Schutte v. SuperValu Inc.*, 598 U.S. 739 (June 1, 2023)**
  In assessing the FCA's critical scienter element, the Supreme Court held that scienter refers to a defendant's knowledge and subjective beliefs, not to what an objectively reasonable person may have known or believed. In the two underlying Seventh Circuit cases for which the Supreme Court granted certiorari, relators brought qui tam actions alleging that defendant pharmacies violated the FCA by (i) underreporting their "usual and customary" drug prices through failing to include lower pricing that the pharmacies offered in discount programs and (ii) knowingly submitted claims to the government in amounts higher than such prices. In both cases, the district court granted, and the Seventh Circuit affirmed, summary judgment in favor of defendants, holding that they could not have acted knowingly under the scienter standard articulated in *Safeco Insurance Co. of America v. Burr*, 551 U.S. 47 (2007) because their actions were consistent with an objectively reasonable interpretation of "usual and customary." The Supreme Court explicitly rejected applying the Safeco standard in an FCA case, holding that "[t]he FCA's scienter element refers to a defendant's knowledge and subjective beliefs – not to what an objectively reasonable person may have known or believed." Accordingly, the Court concluded that the requisite scienter under the FCA may be established by showing that defendants (i) actually knew that their claims were false, (ii) were aware of a substantial risk that their claims were false and intentionally avoided learning whether they were accurate, or (iii) were aware of such a substantial and unjustifiable risk that the claims were false but submitted them anyway.

- ***United States ex rel. Polansky v. Executive Health Resources, Inc.*, 599 U.S. 419 (June 16, 2023)**
  In addressing the government's authority to seek dismissal of a *qui tam*, the Supreme Court held that the government may move to dismiss whenever it has intervened and courts should assess dismissal pursuant to Federal Rule of Civil Procedure 41.

The relator alleged that defendant billing company enabled their hospital clients to charge inpatient rates for outpatient services in order to obtain higher reimbursement amounts. The government declined to intervene while the case was under seal but filed a motion to dismiss, over relator's objection, after deciding the burdens of the suit outweighed its potential value. The Supreme Court held that the government may move to dismiss an FCA action under 31 U.S.C. § 3730(c)(2)(A) whenever it has intervened, whether during the seal period or afterwards. The Court reasoned that the government's interest in obtaining a dismissal does not diminish in importance if the government waited to intervene, as Congress intended the government to be able to reassess litigation as it progresses and change its mind as to intervention. The Court also held that Rule 41 governs the government's motion to dismiss, which permits the voluntary dismissal of a case (i) by the plaintiff if defendant has not served an answer or a summary judgment motion or (ii) by court order on terms that the court deems proper. In assessing whether Rule 41 is satisfied, the Court signaled that the government's views are "entitled to substantial deference." As the Court stated, "[i]f the government offers a reasonable argument for why the burdens of continued litigation outweigh its benefits, the court should grant the motion." Under this standard, the Court affirmed the dismissal, concluding that the government identified the significant costs of future discovery and explained in detail why relator had a low likelihood of success on the merits.

Second Circuit Cases

- ***Doe 1 v. EviCore Healthcare MSI, LLC,* No. 22-530-CV, 2023 WL 2249577 (2d Cir. Feb. 28, 2023)**
  The Second Circuit affirmed the dismissal of relators' FCA claim because relators failed to plead fraud with sufficient particularity. The relators alleged that defendant medical benefits management company, which contracted with managed care plans to provide reimbursement determinations, violated the FCA by failing to provide individualized determinations of medical necessity, thereby causing the plans to bill the government for unnecessary and fraudulently approved services. Specifically, defendant allegedly (i) auto-approved" requests related to certain providers, therapies, or populations without regard for standards of clinical practice, evidence-based decision making, and the reviewers' own clinical judgment, and (ii) utilized artificial intelligence to approve certain requests based on flawed criteria that was not manually reviewed. In holding relators did not plead fraud under Rule 9(b), the Second Circuit concluded that relators' general assertion that the volume of auto-approvals made fraud inevitable was insufficient without identifying a particular instance where defendant approved a procedure that was fraudulent or medically unnecessary. Likewise, relator's allegations that defendant breached contracts with the managed care plans did not plead fraud with particularity as relator failed to allege any contracts that governed the relationship or any provisions of the contracts that defendant allegedly breached.

- ***Piacentile v. U.S. Oncology, Inc.*, No. 22-18, 2023 WL 2661579 (2d Cir. Mar. 28, 2023)**
  The Second Circuit upheld dismissal under the FCA's public disclosure bar. The relators alleged that U.S. Oncology, an owner and operator of oncology physician practices and freestanding cancer centers, submitted claims on behalf of physicians that prescribed drugs manufactured by Amgen, which paid kickbacks to the defendant and the prescribing physicians in the form of drug rebates and discounts. The Second Circuit held that the pre-2010 public disclosure bar applied because three complaints filed prior to relators' case already disclosed the existence of the kickback scheme at issue even though the complaints did not expressly identify U.S. Oncology by name. Additionally, the Second Circuit affirmed that the relators were not original sources of the relevant information sufficient to preclude the public disclosure bar, because their allegations were based on indirect knowledge that one relator (a physician who was never employed by Amgen or U.S. Oncology) procured through interviews of Amgen and the defendant's executives.

- ***Brutus Trading, LLC v. Standard Chartered Bank*, No. 20-2578, 2023 WL 5344973 (2d Cir. Aug. 21, 2023), *petition for cert. docketed***
  The Second Circuit affirmed the district court's grant of a motion to dismiss filed by the government. The relator alleged that the defendant bank somehow violated the FCA by facilitating illegal transactions on behalf of institutions sanctioned by the federal government and defrauding the government through concealing the extent of its illegal activities in a deferred-prosecution agreement. The government intervened and moved to dismiss because the factual assertions were unsupported, the legal theory was not cognizable, and continuation would waste government resources. In applying the Supreme Court's decision in *Polansky* to uphold dismissal, the Second Circuit concluded that relator was provided with an opportunity for a hearing on the government's motion to dismiss as required by the FCA but failed to oppose it.

- ***Federal Deposit Insurance Corporation v. Fifth Third Bank*, No. 23-209-CV, 2023 WL 7130553 (2d Cir. Oct. 30, 2023)**
  The Second Circuit affirmed dismissal under Rule 12(b)(6) for the relator's failure to allege falsity, knowledge, and materiality. The relator alleged that the defendant bank, which purchased a portfolio of loans from the Federal Deposit Insurance Corporation ("FDIC"), made false claims to the FDIC by failing to minimize the FDIC's losses and maximize its recovery in managing the loans and submitting claims to the FDIC for loans that were ineligible for reimbursement under defendant's agreements with the FDIC. The Second Circuit declined to address the district court's dismissal on public disclosure bar grounds, instead affirming the dismissal under Rule 12(b)(6). Specifically, the Second Circuit concluded that relator did not sufficiently allege (i) falsity, as the complaint did not expressly identify a false claim or false record that defendant submitted to the FDIC nor allege any specific representation that the defendant made to the FDIC to support an implied false certification theory, (ii) knowledge, as the general allegation that defendant knew certain loans were ineligible for reimbursement was merely conclusory without any supporting facts and allegations related to defendant's motive or opportunity to commit fraud, and (iii) materiality, as the complaint did not

identify any regulatory or contractual provision that conditions payment on defendant's supposed obligation to maximize returns and minimize losses, did not claim that the alleged violations went to the essence of the agreements at issue, and did not plead the government took action against other banks who engaged in similar conduct.

- ***United States ex rel. Weiner v. Siemens AG,* No. 22-2656, 2023 WL 8227913 (2d Cir. Nov. 28, 2023)**
  The Second Circuit reversed the district court's dismissal for insufficient service of process. The relator alleged that defendants, who were contractors on public construction projects, made misrepresentations to the New York City Department of Environmental Protection with the intention of securing payment or approval by the federal government. The government filed several extensions of the sealing period but ultimately declined to intervene, and the case was unsealed. The district court never ordered relator to serve the complaint. After years of inaction, the district court dismissed relator's FCA claim for failure to effectuate service of process. The Second Circuit reversed, holding that the FCA unambiguously instructs that relators may not serve process without a court order authorizing service.

Third Circuit Cases

- ***United States ex rel. Johnson v. AmeriHealth Insurance Company of New Jersey,* No. 22-1542, 2023 WL 3221746 (3d Cir. May 3, 2023)**
  The Third Circuit affirmed dismissal of relator's qui tam for failure to plead falsity. The relator alleged that the defendants, who sold health insurance through New Jersey's federally-operated insurance exchange, knowingly submitted false calculations to conceal that they were charging policyholders copays in excess of a maximum set by state regulation. The Third Circuit held relator did not plead falsity because the state regulation at issue, and the defendants' alleged noncompliance, did not apply to New Jersey's federally-operated exchange.

- ***United States v. Care Alternatives*, 81 F.4th 361 (3d Cir. Aug. 25, 2023)**
  The Third Circuit vacated the district court's grant of summary judgment in favor of defendants, concluding that a reasonable jury could find materiality. The relators alleged that defendant hospice care provider submitted claims for Medicare reimbursement despite inadequate clinical documentation to support the patients' hospice eligibility in violation of Medicare regulations. The district court granted summary judgment to defendant for lack of materiality because the government continued to reimburse defendant even after being made aware of defendant's insufficient documentation. Applying the *Escobar* materiality framework, the Third Circuit concluded that (i) the applicable documentation requirement is a condition of payment, which jurors should be permitted to weigh alongside *Escobar's* other factors; (ii) a reasonable jury could conclude that the defendant's noncompliance was not an isolated incident nor "minor or insubstantial" violations, but went to the patients' medical need for hospice case, i.e. the "essence of the bargain;" and, (iii) the government's continued payment of funds despite its awareness of fraud allegations was not conclusive of immateriality.

Fourth Circuit Cases

- ***United States v. Walgreen Co.*, 78 F.4th 87 (4th Cir. Aug. 15, 2023)**
  The Fourth Circuit vacated the district court's dismissal, holding that the government plausibly alleged materiality. Specifically, the government alleged that the defendant pharmacy's manager falsified patient records and other documents so that beneficiaries of Virginia's Medicaid program appeared eligible to receive expensive Hepatitis C drugs. To support materiality, the Fourth Circuit pointed to allegations that the government initially rejected claims when patients truthfully acknowledged they did not satisfy Virginia's eligibility requirements but ultimately approved the same patients' claims after defendant doctored documents and lied to indicate compliance. The Fourth Circuit also rejected defendant's argument that it could not be liable under the FCA because Virginia's eligibility requirements violated the Medicaid Act by restricting coverage of medically necessary drugs beyond permissible restrictions, concluding that civil-fraud defendants cannot escape liability by arguing that their fraudulent statements related to illegal requirements.

Fifth Circuit Cases

- ***United States ex rel. Beck v. St. Joseph Health System*, No. 22-10137, 2023 WL 1433614 (5th Cir. Feb. 1, 2023), *cert. denied* 144 S. Ct. 193 (Oct. 2, 2023)**
  The Fifth Circuit granted defendants-appellees' motion to dismiss on the grounds that the court lacked jurisdiction of relator's untimely appeal. The relator alleged that defendants violated the FCA through alleged schemes to compensate physicians employed by a defendant physician practice in excess of fair market value to induce them to refer to another defendant hospital, in violation of the Stark Law and AKS. After the district court granted defendants' motion for summary judgment, relator filed a motion to alter or amend the judgment pursuant to Federal Rule of Civil Procedure 59(e) on December 10, 2021. On December 14, 2021, the court denied the motion for failure to include a certificate of conference. That same day, Relator filed a second identical motion to alter or amend the judgment with the required certificate of conference. The court denied his second motion on January 12, 2022. Relator filed a notice of appeal with the Fifth Circuit on February 9, 2022, and defendants filed a motion to dismiss the appeal as untimely. In granting the motion, the Fifth Circuit held that a successive identical post-judgment motion does not toll the time to appeal; the 30-day time for appeal ran from the district court's denial of Relator's first Rule 59(e) motion on December 14, 2021.

- ***United States ex rel. Toledo v. HCA Holdings, Inc.*, No. 21-20620, 2023 WL 2823899 (5th Cir. Apr. 7, 2023)**
  The Fifth Circuit affirmed the grant of defendants' motion for summary judgment on relator's retaliation claim. The relator alleged that defendants, a nationwide network of health care providers and one of its affiliated hospitals, violated the FCA's anti-retaliation provision by terminating her from her position as a payment coordinator after she complained to various supervisors that she was asked to engage in fraudulent activity—namely, to allegedly backdate missing admissions orders or ignore other regulatory violations. In upholding summary judgment, the Fifth

Circuit concluded that there was no dispute of material fact that defendants were unaware of relator's alleged protected activity and that there was no evidence that the protected activity contributed to her termination.

- ***United States v. Corporate Management, Inc.*, 78 F.4th 727 (5th Cir. Aug. 21, 2023)**
  After a jury trial finding defendants liable under the FCA, the Fifth Circuit rejected defendants' challenge to materiality and scienter. The relator alleged that defendants (a critical access hospital ("CAH"), its management company, and the management company's owner and executives inflated management and compensation costs on the hospital's cost reports, which are used by Medicare to reimburse CAHs on a cost-basis. The Fifth Circuit affirmed the jury's finding of materiality on the grounds that that (i) the government's pay-and-chase practice, through which the government paid Medicare claims to CAHs upon submission and then recouped overpayments afterwards, was necessary to keep the rural hospital in operation, (ii) the defendants' misrepresentations were substantial, amounting $10 million dollars over 12 years, and (iii) the cost reports and statements defendants submitted to Medicare went to the "essence of the bargain" because they were the basis for determining reimbursement amounts owed. In affirming the jury's finding of scienter, the court rejected defendants' assertion that the FCA required "objective falsity" and concluded that the evidence showing the top executives performed very little reimbursable work but knowingly sought reimbursement for inflated compensation was sufficient to establish scienter. Despite these findings, the Fifth Circuit reduced the damages because the FCA's statute of limitations barred additional allegations made in the government's complaint-in-intervention that did not relate back to relator's original complaint and was not tolled due the government's failure to timely intervene despite an expert's recommendation to intervene.

- ***United States ex rel. Miniex v. Houston Housing Authority*, No. 21-20435, 2023 WL 6174416 (5th Cir. Sept. 22, 2023)**
  The Fifth Circuit partially upheld dismissal of relator's FCA claims for failure to plead the submission of false claims with particularity and, for certain defendants, vicarious liability. The relator alleged that the defendants, the City of Houston and its housing authority along with several property management companies, submitted false claims to the Department of Housing and Urban Development that falsely certified compliance with regulations requiring performance of cost estimates before engaging in certain services. The Fifth Circuit affirmed the dismissal of the FCA claims against the city and the property management companies, concluding that the city was not vicariously liable for the housing authority's claims under an agency theory and that relator did not plead fraud under Rule 9(b) by failing to allege when the property management companies submitted false claims or when any specific conduct occurred. However, the Fifth Circuit reversed the dismissal of the FCA claim against the housing authority, holding that: (i) dismissal was not appropriate under the government action prong of the public disclosure bar because an OIG audit is not a civil suit or administrative civil monetary penalty proceeding; (ii) the complaint satisfied Rule 9(b) as it outlined repeated requests for federal funding and specific details regarding the housing

authority's failure to conduct cost estimates; and, (iii) relator stated a claim for relief and alleged that the housing authority's false statements were material by attaching a copy of an OIG audit showing that the government sought recoupment for services that did not comply with the cost-estimate regulations.

- ***United States v. Daniels*, No. 23-50423, 2023 WL 7443272 (5th Cir. Nov. 9, 2023)**
  The Fifth Circuit affirmed the district court's grant of summary judgment in favor of the government, holding that no reasonable jury could find in favor of the defendant on any element of the FCA claim. The government alleged that defendant helped an owner of a school obtain approval to receive benefits under the Post 9/11 GI Bill for classes taught to veterans by falsely certified that the school operated as an educational institution for at least two years. For falsity, the Fifth Circuit concluded that defendant's application for funds clearly misrepresented that the school had been open for two years when it had not. For scienter, the court concluded that defendant's submission of student records from another school, combined with the fact that the application expressly stated compliance with the two-year requirement, sufficiently proved defendant's knowledge of the requirements. For materiality, the court determined that the two-year rule is an express requirement for eligibility under the statute, making it essential to the government's payment of funds.

- ***United States ex rel. Vaughn v. Harris County Hospital District*, No. 22-20659, 2023 WL 8649876 (5th Cir. Dec. 14, 2023)**
  The Fifth Circuit upheld the district court's dismissal of relator's FCA claim under the public disclosure bar. The relator alleged that a county and its hospital district, several medical schools, and private health care organizations engaged in a scheme to obtain inflated Medicaid "matching" funds from the federal government. Specifically, relator alleged that private hospitals paid inflated medical staffing costs and expenses provided by medical schools to county hospitals disguised as donations. The county then used the donations to fund the state/local government share of the Medicaid program. The federal government matched the state/local government share, and the increased funds were given to the private hospitals involved in the scheme as supplemental Medicaid payments intended to reimburse Medicaid providers at rates closer to the actual cost of providing care. Under the public disclosure bar, the Fifth Circuit held that the complaint was substantially the same as allegations publicly disclosed in multiple news articles that reported that federal officials were investigating the scheme alleged by relator. The court also concluded that relator was not an original source of the information despite the county employing relator and relator providing additional allegations than those in the news articles, because relator's allegations did not materially add to the publicly disclosed conduct.

Sixth Circuit Cases

- ***United States ex rel. Martin v. Hathaway*, 63 F.4th 1043 (6th Cir. Mar. 28, 2023), *cert. denied* 144 S. Ct. 224 (Oct. 2, 2023)**
  The Sixth Circuit upheld the dismissal of relators' FCA complaint based on underlying AKS allegations for failure to plead remuneration and causation. The relators (an ophthalmologist and her husband) alleged that the defendant hospital rejected relator's employment as a hospital-based ophthalmologist in

exchange for the other defendants (a competing ophthalmologist and ophthalmology practice) to refer surgeries to the hospital in violation of the AKS. The Sixth Circuit held relators failed to plead remuneration, concluding that the hospital's decision not to hire the relator-ophthalmologist was not a payment or transfer of value to the other defendants. Additionally, the court held that relators failed to plead the submission of claims for items or services "resulting from" the AKS violation. In applying a but-for causation standard, the court concluded relator did not plausibly allege causation because the alleged scheme "did not change anything" given that the defendants were the only local hospital and ophthalmologist in town and naturally would have referred patients to one another even without an illegal agreement.

Seventh Circuit Cases

- ***United States ex rel. Calderon v. Carrington Mortgage Services., LLC,* 70 F.4th 968 (7th Cir. June 14, 2023), *cert. denied* 144 S. Ct. 331 (Oct. 16, 2023)**
  The Seventh Circuit upheld the district court's grant of summary judgment for defendant, concluding that relator failed to establish causation under the FCA. The relator alleged that defendant mortgage lender falsely certified to the Department of Housing and Urban Development that prospective borrowers met the minimum standards of HUD's underwriting guidelines in applications for insurance coverage from the Federal Housing Administration. Although the Seventh Circuit disagreed with the district court's materiality analysis and found that relator provided enough evidence that HUD may not have endorsed the loans for federal insurance had it known of the defects, the court held that relator did not offer evidence that the false representations caused HUD to suffer a monetary loss.

Eighth Circuit Cases

- ***United States ex rel. Kraemer v. United Dairies, L.L.P.,* 82 F.4th 595 (8th Cir. Sep. 20, 2023)**
  Following a bench trial, the Eighth Circuit upheld the district court's decision that relator failed to prove scienter under the FCA. The relator, who was a former general partner of one of the defendants, alleged that the defendant dairy farms falsely certified the intended use of certain corn crops to obtain greater crop insurance coverage and associated payments under federal agriculture programs. The Eighth Circuit held that defendants did not have the requisite scienter because (i) the relator's supposed knowledge of the falsity did not impute to defendants, (ii) relator's "actual knowledge" was simply his opinion; and (iii) there was no evidence suggesting that defendants had a culpable state of mind. The Eighth Circuit also concluded that relator failed to prove materiality because the evidence established that the insurers who contracted with the government regularly paid this type of claim in full despite actual knowledge of the intended-use violations. Last, the Eighth Circuit upheld the district court's decision to vacate its judgment in favor of relators on their unjust enrichment claim after the government moved to vacate, because the government, as the party in interest in an FCA case, has the right to notify the court that the relator lacks standing to seek certain relief.

Ninth Circuit Cases

- ***Gharibian ex rel. United States v. Valley Campus Pharmacy,* No. 21-56253, 2023 WL 195514 (9th Cir. Jan. 17, 2023)**
  The Ninth Circuit upheld dismissal in favor of defendants, concluding relator failed to plead a false claim made to a government payor and materiality. The relator alleged that defendant pharmacies made false representations to private insurance providers to fraudulently obtain prior authorizations for prescription medications. Specifically, relator claimed that defendants instructed their employees to identify themselves as representatives of physicians' offices, rather than pharmacy employees. As to falsity, the Ninth Circuit concluded that relator did not plead false claims because she either alleged statements made to private insurers or pled the submission of claims to government payor on information and belief only. As to materiality, the Ninth Circuit concluded that relator fails to plausibly plead that defendants' supposed practice of instructing employees to misrepresent the identity of their employers was material to the grant of a prior authorization.

- ***Hendrix ex rel. United States v. J-M Manufacturing Co,* 76 F.4th 1164 (9th Cir. Aug. 8, 2023)**
  The Ninth Circuit upheld a jury verdict imposing FCA liability against the defendant and the district court's decision that plaintiffs were not entitled to damages. The relator and the government alleged that the defendant manufacturer falsely represented that its PVC pipes, which were used in state and local water and sewer systems, were compliant with government standards. In phase one of the jury trial, the jury found that defendant violated the FCA on 26 different projects. But, in phase two, the district court granted judgment as a matter of law in favor of defendant on damages after the jury was unable to reach a verdict. The Ninth Circuit concluded there was sufficient evidence that defendant violated the FCA because defendant knew that it changed its manufacturing processes and its products no longer satisfied industry standards. As for statutory penalties, the Ninth Circuit affirmed the district court's imposition of statutory penalties per project – as opposed to penalties per each piece of pipe manufactured. The Ninth Circuit also agreed plaintiffs were not entitled to damages because (i) recovery of the entire amount paid would impose a strict liability standard not found in the FCA, and (ii) plaintiffs did not provide enough evidence to show the difference in value or longevity between the pipes received and compliant pipes to adequately assess damages.

- ***Williams v. Medical Support Los Angeles,* No. 22-55979, 2023 WL 8798089 (9th Cir. Dec. 20, 2023)**
  The Ninth Circuit upheld the district court's dismissal in favor of defendants for failure to plead falsity and on public disclosure grounds. The relator alleged that the defendant medical services organization, which contracted with the Department of Veterans Affairs ("VA") for payment of services provided to veterans, defrauded the VA by (i) sending to medical disability exam examiners only certain records rather veterans' entire files before requesting payment, (ii) permitting improperly credentialed staff to schedule ancillary testing, and (iii) failing to "lock" medical

disability exam reports so that its staff could not subsequently edit the documents. The Ninth Circuit concluded relator's complaint contained no facts that defendant made an express or implied false statement to the VA and, at most, alleged a breach of contract. Other allegations were precluded by the public disclosure bar, as the Ninth Circuit concluded they were disclosed in a VA OIG report.

- ***Salgado ex rel. United States v. TruConnect,* No. 22-55721, 2023 WL 8866563 (9th Cir. Dec. 22, 2023)**
  The Ninth Circuit affirmed both the district court's dismissal of the FCA claim for failure to meet Rule 9(b) and grant of summary judgment in favor of the defendant on the FCA retaliation claim. The relators alleged that defendant cellphone network operator falsely certified its compliance with requirements of a Federal Communications Commission's ("FCC") phone subsidy program by using third-party vendors to sign up subscribers without confirming their eligibility and submitting false usage minutes to circumvent the FCC's usage requirements. Relators also alleged that defendant terminated them in retaliation for their objections to the alleged fraudulent conduct. The Ninth Circuit held that relators failed to meet the heightened pleading standard under Rule 9(b), because they did not allege that defendant was responsible for determining initial subscriber eligibility or failed to receive proper documentation for subscribers, that defendant's billings violated FCC regulations, or any details about how, when, or who at defendant manipulated its usage data. On the retaliation claim, the Ninth Circuit concluded that there was insufficient evidence that the executives who terminated relators had knowledge of relators' supposed protected activity or that their complaints alleged fraud.

Tenth Circuit Cases

- ***United States ex rel. Barrick v. Parker-Migliorini International, LLC,* 79 F.4th 1262 (10th Cir. Aug. 22, 2023)**
  The Tenth Circuit upheld judgment in favor of relator on his retaliation claim. The relator alleged that defendant terminated his employment in retaliation for relator's cooperation with the government's investigation into defendant's practices. The Tenth Circuit held that there was enough evidence for a reasonable jury to infer that defendant had notice relator was engaged in a protected activity because (i) relator raised his concerns to the defendant's CFO, (ii) the FBI questioned defendant's executives regarding the exact issues raised by relator, and (iii) relator repeatedly asked questions about the fraudulent practices even after he was provided an answer (in an effort to record the statements as an FBI informant).

Eleventh Circuit Cases

- ***United States ex rel. Carver v. Physicians Pain Specialists of Alabama, P.C.,* No. 22-13608, 2023 WL 4853328 (11th Cir. July 31, 2023)**
  Relying on the Supreme Court's recent decision in *Polansky*, the Eleventh Circuit affirmed the district court's grant of a motion to dismiss and intervene filed by the government. The relator alleged a variety of fraudulent schemes against a pain-management clinic and two of its doctors. The government declined to intervene but separately indicted and obtained a jury verdict against the doctors on several fraud-based charges. Following several years of status hearings and discovery motions, the government filed,

and the district court granted, a motion to intervene and dismiss relator's *qui tam* case. The Eleventh Circuit affirmed dismissal, concluding that relator made very little progress on obtaining a judgment against defendants, despite repeated prompting by both the government and the district court to seek default judgment, and did not set forth or support a fair assessment of damages for her claim.

- ***United States ex rel. 84Partners, LLC v. Nuflo, Inc.*, 79 F.4th 1353 (11th Cir. Aug. 17, 2023)**
  The Eleventh Circuit affirmed dismissal of relator's complaint for failure to allege fraud with particularity. The relator alleged that defendant military contractors recklessly disregarded their oversight responsibilities and delivered defective materials for installation in submarines for the United States Navy, which were included in allowable costs paid for by the Navy. In upholding dismissal, the Eleventh Circuit acknowledged the complaint alleged "egregious underlying misconduct" with particularity but concluded relator failed to plead the actual submission or payment of a false claim as well as a connection between the misconduct and one or more actual claims.

- ***In re Issac*, No. 23-11210, 2023 WL 6568122 (11th Cir. Oct. 10, 2023)**
  The Eleventh Circuit affirmed dismissal of relator's retaliation claim. The relator alleged that defendant, a defense contractor, retaliated against him in his employment after he complained to his supervisor, contacted the Occupational Safety and Health Administration, and filed a *qui tam* suit alleging that defendant engaged in practices that caused employees to become sick and violated defendant's government contracts and Department of Defense protocols. In upholding dismissal, the Eleventh Circuit concluded that relator failed to allege that defendant was aware of his protected activity and therefore could not allege a causal link between his filing of a *qui tam* suit and the adverse employment actions taken against him.

Advisory Opinions

In 2023, the Office of Inspector General released several advisory opinions assessing proposed arrangements, providing guidance on AKS compliance. A notable number of unfavorable opinions likely reflects requests from parties with vested interests in obtaining negative evaluations from OIG, potentially to deter providers in the same space from engaging in business practices with a higher risk profile that may provide competitors with a business advantage. These opinions, discussed in this section, are helpful in evaluating compliance risks and navigating health care regulations.

- **Advisory Opinion 23-01 (Feb. 17, 2023)** is a favorable opinion regarding a drug manufacturer's request to provide financial assistance for transportation, lodging, and meals to financially needy pediatric patients and their caregiver(s) in connection with treatment that uses the manufacturer's drug. The OIG advised the arrangement is low risk under the AKS for several reasons, including that the drug has a one-time usage for patients with extremely rare conditions, the drug must be obtained from a specific treatment center, and the patient must meet several criteria to be eligible for the assistance provided. Unlike problematic seeding programs, the OIG focused on the drug in question being a one-time treatment to conclude the arrangement is not likely to induce patients to continue purchasing the drug.

  https://oig.hhs.gov/documents/advisory-opinions/1103/AO-23-01.pdf

- **Advisory Opinion 23-02 (Feb. 23, 2023)** is a favorable opinion for a pharmaceutical company's provision of a free 14-day supply of a drug, for a limited time, to patients who experience a delay in their insurance approval process. The OIG advised the arrangement is low risk under the AKS for several reasons, including that the free 14-day supply would be unlikely to result in overutilization, the prescriber receives no financial benefit, and no costs are submitted to a federal health care program under the arrangement.

  https://oig.hhs.gov/documents/advisory-opinions/1104/AO-23-02.pdf

- **Advisory Opinion 23-03 (Mar. 29, 2023)** is a favorable opinion for a manufacturer of an at-home DNA colorectal cancer screening test to provide certain individuals prepaid gift cards, worth up to $75, including federal health care program beneficiaries, to encourage those individuals to return the test's sample collection kit. The OIG determined that the provision of gift cards would qualify as a Preventative Care Exception under the Beneficiary Inducements CMP, including because the value of the gift cards was not disproportionately large in relation to the value of the test and the test would not be tied to the provision of additional services. The OIG also concluded the arrangement is low risk under the AKS because the proposal was unlikely to improperly increase costs to federal health care programs and was unlikely to influence the frequency at which any test prescriber orders tests.

  https://oig.hhs.gov/documents/advisory-opinions/1109/AO-23-03.pdf

- **Advisory Opinion 23-04 (July 11, 2023)** is a favorable opinion for a health technology company's proposal regarding certain marketing activities. Specifically, the requestor proposed (i) allowing federal health care program beneficiaries to use its online health care directory to search for and book medical appointments with providers and the deployment of sponsored advertisements targeting such beneficiaries on the directory and third-party websites and (ii) enacting certain changes to the functionality of the directory including the removal of providers who have reached their spending caps from the directory. The OIG concluded the arrangement is low risk under the AKS, including because the advertising activities do not specifically target federal health care program beneficiaries, the per-booking fees that the requestor charges providers are set in advance and reflect fair market value of requestor's services, and requestor is not a health care provider or supplier so it is not engaging in problematic "white coat" marketing by health care professionals.

  https://oig.hhs.gov/documents/advisory-opinions/1127/AO-23-04.pdf

- **Advisory Opinion 23-05 (Aug. 28, 2023)** is an unfavorable opinion for a proposed intraoperative neuromonitoring ("IONM") joint venture whereby the requestor would form and operate a turnkey entity that would perform IONM services owned by the physicians to whom the requestor proposes to assist. The physician owners would have limited participation in the turnkey entity's day-to-day operations and instead contract with the requestor through (i) a billing services agreement for the administrative services and (ii) a personal services agreement to enable the turnkey entity's neurologists and neurophysiologists to provide their services. The OIG concluded this arrangement would generate prohibited remuneration through discounts under the personal services agreement, potential profit earned by the turnkey entity, and investment returns realized by the physicians who hold interest in the turnkey entity. In emphasizing the OIG's special bulletin on contractual joint ventures, the OIG also expressed concerns that the proposed arrangement would allow the requestor to indirectly pay surgeon owners a portion of the profits from the referrals for IONM services that could be reimbursed under the federal health care programs.

  https://oig.hhs.gov/documents/advisory-opinions/1128/AO-23-05.pdf

- **Advisory Opinion 23-06 (Sept. 28, 2023)** is an unfavorable opinion for a proposed arrangement between the requestor laboratory to perform the professional component of anatomic pathology services, pay third party laboratories a fair market value per specimen fee for the performance of the technical component of such services, and bill commercial insurers as the in-network provider for both the technical and professional components. In concluding there was risk this arrangement would violate the AKS, the OIG reiterated its longstanding concern about arrangements that "carve out" federal health care program business. Here, the OIG reasoned that arrangement could provide significant incentives for the third-party laboratories to refer federal health care program business back to the requestor laboratory, in the form of remuneration for technical component services that the requestor laboratory could perform itself.

  https://oig.hhs.gov/documents/advisory-opinions/1131/AO-23-06.pdf

- **Advisory Opinion AO 23-07 (Oct. 10, 2023)** is a favorable opinion regarding a multi-specialty physician practice's proposed payment of bonuses to its physician-employees based on net-profits for outpatient procedures they performed at two ambulatory surgery centers operated by the practice. The OIG concluded the bonus compensation is protected by the AKS' bona bide employee safe harbor. In acknowledging safe harbor protection, however, the OIG noted that similar bonus payments to independent contractors or other non-employees as well as through a different corporate structure may raise AKS concerns.

  https://oig.hhs.gov/documents/advisory-opinions/1132/AO-23-07.pdf

- **Advisory Opinion AO 23-08 (Oct. 20, 2023)** is an unfavorable opinion regarding a DMEPOS supplier's proposal to provide free hearing aids to patients who were candidates for "bimodal hearing," wherein the patient has a hearing aid in one ear and a cochlear implant and sound processor in the other. The requestor manufactures the cochlear implant and sound processor. The OIG determined the arrangement could pose risk under the AKS because it might result in inappropriate patient steering to the requestor over a competitor as patients are able to choose the manufacturer from which their provider orders the cochlear implant and sound processor. Additionally, the OIG determined this arrangement did not fall within the AKS safe harbor for patient engagement and support because the price of the hearing aid is well above the $570 ceiling of the safe harbor.

  https://oig.hhs.gov/documents/advisory-opinions/1133/AO-23-08.pdf

- **Advisory Opinion 23-09 & 23-10 (Dec. 13, 2023)** is a favorable opinion for an insurer of Medicare Supplemental Health Insurance ("Insurer") and a preferred hospital organization's ("PHO") proposed arrangement to incentivize Medigap policyholders to seek inpatient care from a hospital within the PHO's network by providing discounts on the Medicare Part A inpatient deductible that the Insurer otherwise would cover for any policyholder. In return, the Insurer would provide a premium credit of $100 off to policyholders who use an in-network hospital for an inpatient stay and would pay the PHO an administrative fee. The OIG determined the proposal posed low risk of violating the AKS because there was minimal potential for patient harm, the remuneration would be unlikely to significantly impact competition, and the remuneration would be unlikely to incentivize policyholders to utilize inpatient care considering patients generally do not control whether they are admitted as an inpatient.

  https://oig.hhs.gov/documents/root/1141/AO-23-09.pdf

- **Advisory Opinion AO 23-11 (Dec. 21, 2023)** is a favorable opinion regarding a medical device manufacturer subsidizing up to a maximum of $2,000 per study participant's Medicare cost-sharing obligations for a clinical trial of its FDA-approved cardiac pulse generator system. The manufacturer would pay the cost-sharing directly to the trial site and investigator. The OIG concluded there was low risk the arrangement violated the AKS, including because the cost-sharing subsidy might be essential to enrolling a sufficient number of participants to complete the study and there was low risk of overutilization of services payable by federal health care programs. While the arrangement

would also implicate the Beneficiary Inducements CMP, the OIG concluded it would not impose sanctions "in an exercise of [its] discretion."

https://oig.hhs.gov/documents/advisory-opinions/1143/AO-23-11.pdf

- **Advisory Opinion 23-12 (Dec. 28, 2023)** is a favorable opinion regarding a proposed arrangement between a physician partnership and a medical center to offer to repurchase partnerships units from physician partners reaching the age of 67 contingent upon the physician partners' agreement to retire from the practice of medicine. The OIG concluded the proposal posed low risk of violating the AKS because the repurchase offer is based on an objective basis (age) unrelated to the volume or value of referrals or business generated by the physician partners and prohibits a physician from referring to the medical center for a set period of time.

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

- **Advisory Opinion 23-13 & 23-14 (Dec. 28, 2023)** is a favorable opinion regarding an arrangement between a licensed offeror of Medigap policies ("Medigap Plan") and a PHO to offer discounts on Medicare Part A deductible for inpatient hospital stays at network hospitals and a $100 premium credit to policyholders who chose a network hospital for a Medicare Part A covered inpatient hospital stay. Additionally, the Medigap Plan would pay a monthly fair market value administrative fee to the PHO based on a percentage of the aggregate savings the Medigap Plan would realize from the network hospital's discounts on policyholders' Medicare Part A inpatient deductibles in a given month. The OIG concluded the arrangement poses minimal risk under the AKS because it is unlikely to result in overutilization considering the Medigap Plan has financial responsibility for the policyholder's costs covered under the plan, minimal risk of any patient harm, and is unlikely to impact competition considering the discounts/premiums would not be advertised nor would the arrangement limit the patient's choice in selecting a hospital.

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

- **Advisory Opinion 23-15 (Dec. 28, 2023)** is a favorable opinion regarding a physician consulting company's proposal to give $25 gift cards to current physician practice customers for recommending the company's consulting services to potential physician practice customers, and an additional $50 gift card if the recommendation is successful. Part of the consulting services offered by the company include Medicare Merit-Based Incentive Payment System services ("MIPS"). The OIG concluded this remuneration does not implicate the AKS because the gift cards provided, and any MIPS related remuneration, would not be in return for the physician practices making referrals of, purchasing, arranging for, or recommending services that are reimbursable in whole or in part by a federal health care program. Further, the company does not recommend to any customer the purchasing, leasing, or ordering of any item or service for which payment may be made in whole or in part under a federal health care program.

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

Other Fraud and Abuse Developments

- **DOJ's Voluntary Self-Disclosure Policy.** On February 22, 2023, DOJ released a voluntary self-disclosure policy for corporate criminal enforcement that codifies previous guidance. Companies that voluntarily self-disclose misconduct to the DOJ will receive more favorable terms for resolution provided the company fully cooperates in the government's investigation and timely and appropriately remediated the criminal conduct.

  For this policy to apply, the disclosure must:

  1. Be voluntarily and not subject to any preexisting obligations to disclose;
  2. Be timely made, which includes disclosure prior to the misconduct being publicly disclosed or otherwise known to the government and within a "reasonably prompt" time after the company became aware of the misconduct; and,
  3. Include "all relevant facts" concerning the misconduct that the company knows at the time of the disclosure.

  https://www.justice.gov/usao-edny/press-release/file/1569406/download

- **HS-OIG's General Compliance Program Guidance.** In November 2023, HHS-OIG released a new and lengthy reference guide on compliance programs for the health care industry. The guidance maintains the OIG's seven elements of an effective compliance program, revising the elements slightly to include:

  1. Written policies and procedures;
  2. Compliance leadership and oversight;
  3. Training and education;
  4. Effective lines of communication with the Compliance Officer and disclosure programs;
  5. Enforcing standards: consequences and incentives;
  6. Risk assessment, auditing, and monitoring; and,
  7. Responding to detected offenses and developing corrective action initiatives.

  https://oig.hhs.gov/documents/compliance-guidance/1135/HHS-OIG-GCPG-2023.pdf

POLSINELLI® | What a law firm *should* be.™

Am Law 100 firm | 1,000 attorneys nationwide | 20+ offices from LA to NY | 170+ services/industries