11TH ANNUAL

HEALTHCARE FRAUD & ABUSE REVIEW 2022

BASS BERRY SIMS

A LOOK BACK ... A LOOK AHEAD

We are pleased to bring you our 11th annual *Healthcare Fraud & Abuse Review*. Our Review provides comprehensive coverage of the most significant civil and criminal enforcement issues facing healthcare providers. Each year, we endeavor to cover key enforcement initiatives, analyze important case developments and document healthcare fraud settlements across the industry, and present those topics in a readily digestible format for our readers.

To no one's surprise, healthcare fraud enforcement remains a top priority among government regulators. The filing of *qui tam* lawsuits under the False Claims Act (FCA) involving healthcare providers has continued to dominate the landscape from a civil enforcement standpoint. Over the last 10 years, more than 6,700 FCA *qui tam* lawsuits have been filed by relators and 652 of those lawsuits were filed in the preceding year, reflecting nearly a 10% increase over the prior year.[1] For their efforts, *qui tam* relators have recovered more than $4.6 billion in relator share awards during the last decade, amassing more than $488 million last year, which represents the highest amount in more than five years. Civil enforcement actions initiated by the U.S. Department of Justice (DOJ) continued to increase as well, with 296 such lawsuits filed last year, reflecting nearly a 40% increase over the prior year.

The filing of *qui tam* lawsuits under the False Claims Act involving healthcare providers has continued to dominate the landscape from a civil enforcement standpoint.

Criminal enforcement efforts involving the healthcare industry remained a key area of focus for DOJ. There has been continued pursuit of traditional fraud schemes involving telemedicine, clinical labs, and durable medical equipment (DME), with DOJ announcing an enforcement action in July 2022 involving more than $1.2 billion in intended fraud loss and 36 defendants charged across 13 federal judicial districts.[2] The takedown built on prior telemedicine enforcement actions totaling over $8 billion in alleged fraud.

DOJ also ramped up criminal enforcement efforts involving COVID-19 relief funds and related fraud schemes. In April 2022, DOJ announced a COVID-19 healthcare fraud criminal takedown involving $149 million in COVID-19-related false billings and 21 defendants charged across nine federal judicial districts.[3] This takedown targeted fraudulent testing schemes and misuse of personal identifying information used to submit fraudulent claims for medical services. DOJ also announced the creation of a number of COVID-19 fraud strike force teams—based upon DOJ's long-standing strike force model of partnering with U.S. Attorney's Offices throughout the country—to enhance DOJ's enforcement capabilities in connection with pandemic-related fraud.[4]

Key FCA issues continued to wind their way through the federal court system. Supreme Court watchers and practitioners have paid close attention to the Court's docket as significant FCA-related issues have repeatedly found their way to the Court's doorstep. Not surprisingly and consistent with its prior approach, the Court declined to consider the parameters of Federal Rule of Civil Procedure 9(b)'s pleading requirements for FCA claims.

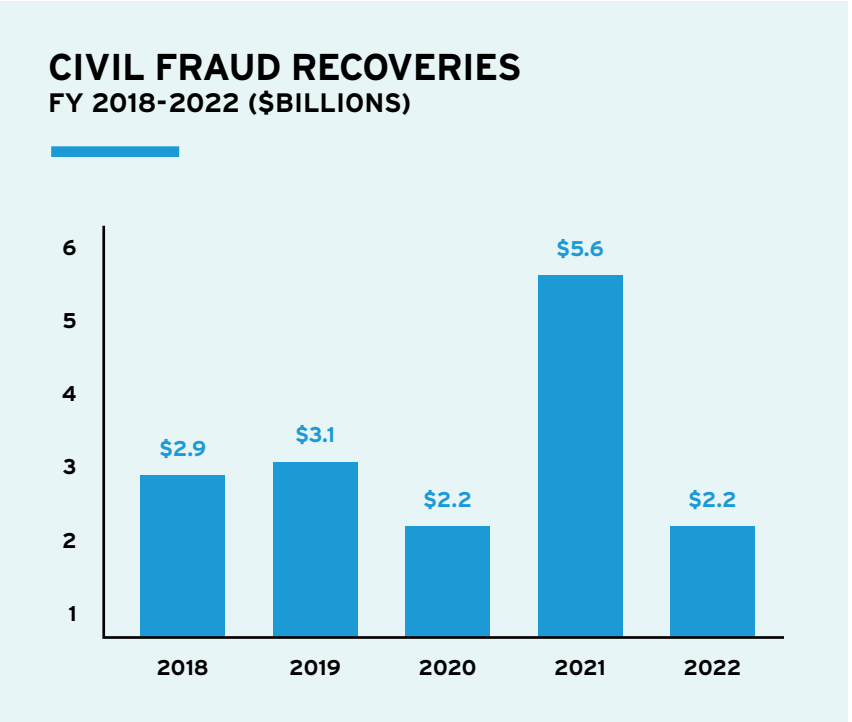
DOJ also ramped up criminal enforcement efforts involving COVID-19 relief funds and related fraud schemes.

1 https://www.justice.gov/opa/pr/false-claims-act-settlements-and-judgments-exceed-2-billion-fiscal-year-2022.
2 https://www.justice.gov/opa/pr/justice-department-charges-dozens-12-billion-health-care-fraud.
3 https://www.justice.gov/opa/pr/justice-department-announces-nationwide-coordinated-law-enforcement-action-combat-health-care.
4 https://www.justice.gov/opa/pr/justice-department-announces-covid-19-fraud-strike-force-teams.

Before the end of this term, however, the Court will address the scope of the government's dismissal authority under the FCA and will consider important legal questions involving the FCA's scienter requirement.

Finally, the Biden administration has continued its rollback of certain policy approaches announced by the prior administration and that reversal may very well have a significant impact on the way DOJ and *qui tam* relators pursue civil FCA enforcement actions. In July 2021, U.S. Attorney General Merrick Garland issued a memorandum revoking what was known as the Brand Memo, which prohibited DOJ from using its enforcement authority to convert non-binding guidance documents into binding rules.[5] In July 2022, the U.S. Department of Health and Human Services (HHS) issued a proposed rule rescinding prior restrictions on the issuance and utilization of sub-regulatory guidance documents.[6] These policy changes may bear directly on the question of what renders a claim for reimbursement false under the FCA and whether healthcare providers acted with the requisite level of intent in submitting false claims to government healthcare programs.

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



5 https://www.justice.gov/d9/2022-12/attorney_general_memorandum_-_issuance_and_use_of_guidance_documents_by_the_doj712021.pdf. This followed the White House's revocation of certain Executive Orders from the prior administration concerning federal regulations. https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-revocation-of-certain-executive-orders-concerning-federal-regulation/.

6 https://www.federalregister.gov/documents/2020/12/07/2020-26832/department-of-health-and-human-services-good-guidance-practices.

ISSUES TO WATCH

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

CARES ACT/COVID-19 RELIEF

DOJ has continued to examine the receipt and use of the Coronavirus Aid, Relief, and Economic Security (CARES) Act relief funds by healthcare providers and civil, criminal and administrative enforcement actions have followed. Pandemic-related fraud remains an enforcement priority with the government devoting significant personnel and resources to this effort and investigations and settlements following. In a March 2022 press release, Attorney General Garland made clear that DOJ "remains committed to using every available federal tool – including criminal, civil, and administrative actions – to combat and prevent COVID-19 related fraud."[7]

7 https://www.justice.gov/opa/pr/justice-department-announces-director-covid-19-fraud-enforcement.

In March 2022, DOJ announced the appointment of a Director for COVID-19 Fraud Enforcement to lead the Department's criminal and civil enforcement efforts to combat COVID-19-related fraud.

In March 2022, DOJ announced the appointment of a Director for COVID-19 Fraud Enforcement to lead the Department's criminal and civil enforcement efforts to combat COVID-19-related fraud.

In March 2022, DOJ announced the appointment of a Director for COVID-19 Fraud Enforcement to lead the Department's criminal and civil enforcement efforts to combat COVID-19-related fraud.[8] The newly-appointed director announced the establishment of Strike Force Teams to propel DOJ's next phase of its efforts to fight pandemic fraud and to focus on large-scale actors who sought to profit off the vast relief provided during the pandemic. As of the date of that announcement, DOJ had charged more than 1,000 defendants in COVID-19-related fraud cases and launched civil investigations into more than 1,800 individuals and entities for alleged misconduct in connection with pandemic relief loans.

The number of provider relief enforcement actions against healthcare providers continued to increase. Criminal charges were announced against the owners of two hospice companies for submitting fraudulent Paycheck Protection Program (PPP) loan applications and misusing other COVID-19 relief funds.[9] In April 2022, DOJ announced charges against the owner of a different hospice provider for receiving and then failing to return provider relief payments, which were received more than six months after the center had stopped seeing patients.[10]

DOJ also has continued to prosecute defendants for misappropriating provider relief funds intended for frontline medical providers.[11] In many cases, DOJ has relied on evidence that provider relief funds were directly used for the personal enrichment of the recipients or that the healthcare providers receiving funds made blatant misrepresentations about patient care in their funding applications. As DOJ and its partner agencies continue to scrutinize the use of provider relief funds, we expect that an increasing number of enforcement actions will be pursued in more complex circumstances.

We anticipate a continued focus on FCA healthcare investigations related to COVID-19 funding for years to come, and the government is only in the initial stages of its analysis of specific uses of COVID-19 funding. We likewise expect to see a wave of whistleblower *qui tam* lawsuits stemming from the receipt of pandemic-related relief filed and subsequently unsealed in the future.

8 https://www.justice.gov/opa/pr/justice-department-announces-director-covid-19-fraud-enforcement.

9 https://www.justice.gov/opa/pr/justice-department-announces-new-charges-convictions-and-sentencings-ongoing-initiative.

10 https://www.justice.gov/usao-wdtn/pr/justice-department-announces-nationwide-coordinated-law-enforcement-action-combat.

11 https://www.justice.gov/usao-wdtn/pr/justice-department-announces-nationwide-coordinated-law-enforcement-action-combat; https://www.justice.gov/opa/pr/doj-announces-coordinated-law-enforcement-action-combat-health-care-fraud-related-covid-19.

THE FUTURE OF THE FALSE CLAIMS ACT

In last year's Review, we looked at the FCA's future and many of the issues we considered warrant continued attention. We discussed the proposed FCA Amendments of 2021, which seek to curtail the perceived impact of the Supreme Court's decision in ***Universal Health Services v. U.S. ex rel. Escobar*** on the FCA's materiality requirement, establish limits on the government's ability to dismiss FCA lawsuits, and shift discovery costs to defendants in declined *qui tam* actions in certain situations. The proposed amendments were voted out of committee and are ready for a floor vote in the Senate. A floor vote never occurred in 2022, however, leaving the future of the amendments uncertain.

In July 2022, the Congressional Budget Office (CBO) issued a cost estimate concerning the proposed FCA amendments.[12] As to the impact of the amendments' proposed changes regarding FCA materiality, the CBO estimated that "DOJ would succeed in about three FCA cases each year that would not otherwise have been won." It is unclear from the CBO's estimate how it arrived at such a conclusion, but it hardly endorses U.S. Senator Charles Grassley's view that *Escobar*'s materiality holdings "gutted" the FCA and necessitated these amendments. In addition, while the materiality amendment might help the government's enforcements efforts on the margins, the CBO noted that changes to the bill's government dismissal standard would simultaneously force the government to expend *more* time and money in prolonged litigation. A CBO report is often a key stepping stone in moving legislation forward in Congress. Should the bill proceed to a full Senate vote in 2023, this report will likely be an important part of the debate.

The FCA also has been at the forefront of recent Supreme Court developments, with the Court having opportunities to address several notable issues in FCA litigation. In June 2022, the Supreme Court granted the petition for writ of certiorari stemming from the Third Circuit's decision in ***U.S. ex rel. Polansky v. Executive Health Resources, Inc.***, to address the government's authority to dismiss *qui tam* actions, particularly in declined cases.[13] Oral argument has occurred and a decision is anticipated before the end of the Court's term in June 2023.

In October 2022, the Court declined requests—from both the relators and a defendant healthcare company—to address the pleading standards applicable to FCA claims under Rule 9(b), by denying certiorari petitions in ***Estate of Helmly v. Bethany Hospice & Palliative Care, LLC***, and two other cases.[14] The Court since granted certiorari petitions that concern the objective scienter standard from the Court's opinion in ***Safeco Ins. Co. v. Burr*** and its application to the FCA in determining whether a defendant "knowingly" defrauded the federal government. The petitions, all relator driven, stemmed from opinions issued by the Fourth, Seventh, and Eleventh Circuits, with the most advanced being ***U.S. ex rel. Schutte v. SuperValu, Inc***.[15] A decision concerning this key FCA issue is expected before the end of this Supreme Court term.

> In the past three years, DOJ has initiated more cases each year than at any point since 1995.

Finally, while most of the government's FCA recoveries continue to stem from *qui tam* lawsuits, recent enforcement trends suggest that could be changing. In fact, in the past three years, DOJ has initiated more cases each year than at any point since 1995. As for whether this trend continues, there are several reasons indicating that it could. The government is dedicating significant resources to data analytics and data mining, which should enable the government to more easily identify outliers and trends on its own. The government also has a number of current enforcement initiatives (*e.g.*, COVID-19-related fraud, telehealth) through which it is proactively initiating investigations and lawsuits and pursuing new theories of liability. Better coordination between government agencies pursuing these cases appears to be on the horizon as well, with HHS Office of Inspector General (OIG) establishing a dedicated FCA working group with this objective in mind. While the FCA remains the foremost enforcement tool for pursuing healthcare fraud, whether the statute's *qui tam* provisions remain the primary driver of those efforts in the years to come is worth monitoring.

INTERSECTION OF ENFORCEMENT AND PRIVATE EQUITY

The past several years have seen a tremendous increase in private equity investment in the healthcare industry and with that investment has come a new focus on private equity firms from an enforcement perspective. Private equity companies have now faced FCA liability in several cases in recent years stemming from their ownership, control, and management of healthcare companies. For instance, in ***U.S. ex rel. Mandalapu v. Alliance Family of Companies, Inc.***, and several related cases, the minority owner in an EEG testing company agreed to pay $1.8 million in addition to what was paid by its portfolio company to resolve allegations that it discovered the portfolio company's alleged wrongdoing during due diligence but failed to take action to stop that wrongdoing.[16] And, in ***U.S. ex rel. Martino-Fleming v. South Bay Medical Health Ctrs.***, the relator survived summary judgment sought by a private equity firm when the firm's majority participation on a healthcare company's board of directors meant it "had the power to fix the regulatory violations which caused the presentation of false claims but failed to do so."[17]

12 https://www.cbo.gov/system/files/2022-07/s2428.pdf.

13 No. 21-1052 (U.S.); *see also* 17 F.4th 376 (3d Cir. 2021).

14 *Helmly*, 853 F. App'x 496 (11th Cir. 2021), *cert. denied*, 143 S. Ct. 351 (2022); *see also U.S. ex rel. Owsley v. Fazzi Associates, Inc.*, 16 F.4th 192 (6th Cir. 2021), *cert. denied*, 143 S. Ct. 362 (2022); *United States v. Molina Healthcare of Illinois, Inc.*, 17 F.4th 732 (7th Cir. 2021), *cert. denied*, 143 S. Ct. 352 (2022).

15 *SuperValu.*, 9 F.4th 455 (7th Cir. 2021), *cert. granted*, No. 21-1326; *U.S. ex rel. Proctor v. Safeway, Inc.*, 30 F.4th 649 (7th Cir. 2022), *cert. granted*, No. 22-111; *U.S. ex rel. Olhausen v. Arriva Med. LLC*, 2022 WL 1203023 (11th Cir. Apr. 22, 2022); *U.S. ex rel. Sheldon v. Allergan Sales, LLC*, 24 F.4th 340 (4th Cir.), opinion vacated on reh'g en banc, 49 F.4th 873 (4th Cir. 2022).

16 *U.S. ex rel. Mandalapu, et al. v. Alliance Family of Companies, Inc.*, No. 4:17-cv-00740 (S.D. Tex.); *U.S. ex rel. Fuller v. Respiratory Sleep Solutions*, No. 4:17-cv-01197 (S.D. Tex.); *U.S. ex rel. Calcanis v. Alliance Family of Companies, Inc.*, No. 4:19-cv-1497 (S.D. Tex.); *U.S. ex rel. Jane Doe v. Alliance Family of Companies, LLC*, No. 4:19-cv-1213 (S.D. Tex.); *U.S. ex rel. McKay v. Alliance Family of Companies, LLC*, No. 4:18-cv-1949 (S.D. Tex.); and *U.S. ex rel. Krasnov v. Alliance Family of Companies, LLC*, No. 4:19-cv-4886 (S.D. Tex.).

17 540 F. Supp. 3d 103 (D. Mass. 2021).

"When a private equity firm invests in a company in a highly-regulated space like healthcare or the life sciences, the firm should be aware of the laws and regulations designed to prevent fraud. Where a private equity firm takes an active role in illegal conduct by the acquired company, it can expose itself to liability under the False Claims Act."

Last year, a *qui tam* complaint alleging violations of the Anti-Kickback Statute (AKS) against specialty pharmacies and their private equity owners was unsealed in ***U.S. ex rel. Webster v. BioMatrix Holdings, LLC***.[18] The relator, a former vice president for one of the defendant specialty pharmacies, alleged that the pharmacies employed regional care coordinators (RCCs) specifically to recruit hemophilia patients to use the specialty pharmacies' services and the RCCs were improperly compensated based on the number of patients referred to the pharmacies and the volume of prescriptions filled. The relator alleged that the private equity owners were aware of the scheme, including participating in board meetings where lucrative "referral source relationships" were discussed.

DOJ investigated the matter for three and a half years, but ultimately declined to intervene. Although the private equity owners were alleged to have been informed about "referral source relationships" generally, the relator's *qui tam* complaint did not allege more specific knowledge of the purported kickback scheme, or more direct management of, or participation in, the portfolio company's operations, which may have diminished DOJ's interest in the case. The relator did not pursue the *qui tam* claims on behalf of the government and filed a notice of voluntary dismissal.

Nonetheless, we expect to see continued FCA enforcement against private equity companies in the years to come. After all, DOJ has warned: "When a private equity firm invests in a company in a highly-regulated space like healthcare or the life sciences, the firm should be aware of the laws and regulations designed to prevent fraud. Where a private equity firm takes an active role in illegal conduct by the acquired company, it can expose itself to liability under the False Claims Act."[19] If the past couple of years are any indication, private equity companies should expect the prospect of continued FCA scrutiny going forward.

18 No. 2:18-cv-09333-PSG-PLA (C.D. Cal. Oct. 31, 2018).
19 https://www.justice.gov/civil/speech/principal-deputy-assistant-attorney-general-ethan-p-davis-delivers-remarks-false-claims.

As the United States emerges from the COVID-19 pandemic, the opioid epidemic continues to rage throughout the country, with over 75,000 Americans dying as a result of overdoses in the past year.

OPIOID ENFORCEMENT

As the United States emerges from the COVID-19 pandemic, the opioid epidemic continues to rage throughout the country, with over 75,000 Americans dying as a result of overdoses in the past year.[20] To help combat this widespread problem, DOJ has sought to continue to uphold its "solemn promise to employ every tool at our disposal to address the opioid crisis." This toolkit has involved several high profile criminal enforcement actions, as well as civil and regulatory actions resulting in millions of dollars in penalties. DOJ also has intervened in *qui tam* complaints in which whistleblowers allege that companies along the controlled substance distribution line have violated their obligations under federal regulations. Notably, DOJ's enforcement actions have been aimed at participants across the entire spectrum of the controlled substance distribution line, targeting manufacturers, distributors, pharmacies, and individual prescribers.

In May 2022, DOJ announced the results of its 2022 Opioid Enforcement Action.[21] Through its Appalachian Regional Prescription Opioid (ARPO) Strike Force, DOJ brought criminal charges against 14 individuals, including 12 medical professionals, in eight federal districts who were accused of the unlawful distribution of over 5.1 million opioid pills. In addition to the criminal charges, the Centers for Medicare & Medicaid Services' (CMS) Center for Program Integrity took administrative actions against six providers for their involvement in these opioid investigations.

The 2022 Opioid Enforcement Action is a continuation of ARPO's efforts to prosecute medical professionals and others involved in the illegal prescription and distribution of opioids. In the three years since its inception, ARPO efforts – which have focused primarily in the states of Alabama, Kentucky, Ohio, Virginia, Tennessee, and West Virginia – have resulted in charges against 111 defendants for the unlawful prescriptions of over 115 million controlled substance pills.

ARPO's success within its geographic footprint led DOJ to expand the strike force approach by establishing the New England Prescription Opioid (NEPO) Strike Force in June 2022.[22] DOJ has announced that NEPO's primary purpose will be to "identify and investigate health care fraud schemes in the New England region, and to effectively and efficiently prosecute

20 https://www.justice.gov/opa/speech/assistant-attorney-general-kenneth-polite-jr-delivers-remarks-2022-opioid-enforcement.
21 https://www.justice.gov/opa/pr/justice-department-announces-enforcement-action-charging-12-medical-professionals-opioid.
22 https://www.justice.gov/opa/pr/justice-department-s-criminal-division-creates-new-england-prescription-opioid-strike-force.

individuals involved in the illegal distribution of prescription opioids and other prescribed controlled substances." Like ARPO, the NEPO Strike Force will primarily target "criminal conduct by physicians, pharmacists, and other medical professionals, focusing upon both health care fraud and drug diversion offenses."

DOJ was not limited to criminal enforcement actions in combating opioid issues and brought or settled several significant civil actions against corporations and pharmacies for violations of the Controlled Substances Act (CSA). In March 2022, McKesson Corporation entered into a settlement agreement and will pay a $1 million civil penalty to resolve at least 700 separate alleged recordkeeping violations and alleged overages, or excess quantities of drugs on hand, for eight controlled substances.[23] According to the settlement, McKesson's packaging subsidiary RxPak engaged in a continuing pattern of recordkeeping deficiencies, including a failure to: (1) take an initial inventory of controlled substances received; (2) maintain complete and accurate records of controlled substances; and (3) maintain complete and accurate Drug Enforcement Administration (DEA)-222 forms.

In August 2022, Allegheny Pharma LLC and its subsidiary Dunn Meadow LLC entered into a settlement agreement and will pay as much as $50 million over the next five years to resolve various claims under the FCA and the CSA.[24] According to the settlement, Dunn Meadow dispensed "highly addictive and dangerous transmucosal immediate-release fentanyl (TIRF) medications" to patients throughout the United States via mail. Despite several obvious red flags and warnings from various third parties, Dunn Meadow continued to fill TIRF prescriptions without a legitimate medical purpose and for patients exhibiting drug-seeking and suspicious behavior. Dunn Meadow also engaged in kickbacks by providing meals and social events to induce providers and pharmaceutical companies to send TIRF prescriptions to Dunn Meadow. Dunn Meadow agreed to be excluded from Medicare, Medicaid, and all other federal healthcare programs for 30 years.

In December 2022, DOJ announced that it had filed a civil complaint against one of the largest wholesale pharmaceutical distributors in the country, AmerisourceBergen Corporation and two of its subsidiaries, alleging that the companies contributed to the opioid epidemic via hundreds of thousands of violations of the CSA.[25] The complaint alleges that AmerisourceBergen failed to report hundreds of thousands of suspicious orders of controlled substances, including from pharmacies AmerisourceBergen allegedly knew were likely facilitating diversion of prescription opioids. The complaint also alleges that AmerisourceBergen relied upon inadequate internal systems to monitor and identify suspicious orders. If found liable for all of the alleged violations, AmerisourceBergen could face billions of dollars in civil penalties.

DOJ is not alone in bringing claims against opioid manufacturers and providers, as several relators have brought FCA claims which have resulted in major settlements for the government and the relators. In March 2022, pharmaceutical company Mallinckrodt ARD LLC agreed to pay $260 million to resolve FCA allegations that the company: (1) underpaid quarterly rebates to state Medicaid programs for its drug; and (2) knowingly used a foundation as a conduit to pay illegal kickbacks in the form of co-pay subsidies to providers and patients.[26] The $260 million settlement resolved *qui tam* complaints in which the government had intervened. As a result of this settlement, DOJ announced that the whistleblowers in these cases would receive $4.9 million and $24.7 million for bringing their cases.

Similarly, in July 2022, Solera Specialty Pharmacy entered into a deferred prosecution agreement and a civil settlement agreement with DOJ after it agreed to pay $1.31 million to resolve FCA allegations related to the distribution of the anti-overdose drug Evzio.[27] The whistleblower, a former employee of the pharmaceutical manufacturer Kaléo, brought a *qui tam* complaint alleging that the pharmacy would complete prior authorization forms for Evzio, the highest priced naloxone product on the market, without any consultation from a physician. The complaint also alleged that Solera submitted prior authorization requests with false clinical information in an attempt to bill for the expensive anti-overdose drug. As a part of the settlement, Solera also agreed to abide by the terms of a three-year integrity agreement (IA), which requires Solera to implement additional measures to ensure its claims meet all statutory and regulatory requirements for prior authorizations and to submit to periodic reviews by an independent reviewer. This action was closely related to the $12.7 million settlement DOJ had reached with Kaléo in November 2021.

The government's commitment to combatting the opioid epidemic through criminal, civil, and administrative actions has resulted in several high profile indictments, civil complaints, and settlements. Companies and individuals involved in the manufacturing, distribution, and prescribing of controlled substances, particularly opioids, should take great care to ensure they are abiding by all statutory and regulatory requirements related to their products.

Companies and individuals involved in the manufacturing, distribution, and prescribing of controlled substances, particularly opioids, should take great care to ensure they are abiding by all statutory and regulatory requirements related to their products.

23 https://www.justice.gov/opa/pr/mckesson-agrees-pay-1-million-resolve-recordkeeping-violations-under-controlled-substances.

24 https://www.justice.gov/usao-nj/pr/new-jersey-pharmacy-admits-illegal-distribution-prescription-opioids-and-kickback-scheme.

25 https://www.justice.gov/opa/pr/justice-department-files-nationwide-lawsuit-against-amerisourcebergen-corp-and-subsidiaries.

26 https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-260-million-settle-lawsuits-alleging-underpayments-medicaid-drug.

27 https://www.justice.gov/opa/pr/solera-specialty-pharmacy-agrees-enter-deferred-prosecution-agreement-company-and-ceo-pay-131.

TELEMEDICINE ENFORCEMENT

In recent years, government agencies have devoted considerable resources toward alleged schemes involving companies and individuals that purport to provide telehealth services and exploit the increased adoption of telehealth. These efforts have resulted in numerous coordinated enforcement actions, including DOJ's July 2022 announcement of criminal charges against 36 defendants in 13 federal districts across the country for more than $1.2 billion in alleged telemedicine, cardiovascular and cancer genetic testing, and DME schemes.[28]

On the same day that DOJ announced its nationwide criminal healthcare fraud takedown, HHS-OIG issued a Special Fraud Alert concerning telehealth arrangements.[29] The Special Fraud Alert encourages practitioners to exercise caution when entering into certain telehealth arrangements and identifies a handful of suspect characteristics that may suggest that an arrangement presents a heightened risk of fraud and abuse. The suspect characteristics largely concern limited practitioner-patient relationships (such that the practitioner lacks sufficient information to meaningfully assess the medical necessity of the items or services that the practitioner orders); how the patient comes to the practitioner (often through the telehealth company or a marketer paid by the telehealth company); how the telehealth company pays the practitioner (namely, payments based on the volume of items or services ordered or prescribed, or based on some proxy therefor, like the number of medical records the practitioner reviews); and the often limited scope of items or services furnished by the telehealth company (e.g., DME, genetic testing, diabetic supplies, prescription creams).

HHS-OIG went out of its way to state that the Special Fraud Alert is not intended to discourage legitimate telehealth arrangements, including many of the arrangements that practitioners have entered into to provide medically necessary care to their patients during the COVID-19 public health emergency. Nevertheless, the Special Fraud Alert, as well as the government's sustained focus on investigating telehealth and related arrangements, serve as important reminders for healthcare providers to carefully consider the risks telehealth arrangements may pose under the fraud and abuse laws, including the AKS and FCA.

In addition, government agencies have begun conducting significant oversight work assessing telehealth services, including the impact of the flexibilities implemented in response to the public health emergency. In September 2022, HHS-OIG issued a data brief analyzing program integrity risks associated with Medicare telehealth services during the first year of the pandemic.[30] And, in November 2022, the Pandemic Response Accountability Committee released a report examining the emerging program integrity risks identified by six participating Offices of Inspectors General related to the expansion of telehealth across federal programs during the pandemic.[31] Rapid changes in telehealth payment policies and a dramatic increase in the use of telehealth all but ensure a continued emphasis on telehealth arrangements by government enforcement agencies.

On the same day that DOJ announced its nationwide criminal healthcare fraud takedown, HHS-OIG issued a Special Fraud Alert concerning telehealth arrangements. The Special Fraud Alert encourages practitioners to exercise caution when entering into certain telehealth arrangements and identifies a handful of suspect characteristics that may suggest that an arrangement presents a heightened risk of fraud and abuse.

28 https://www.justice.gov/opa/pr/justice-department-charges-dozens-12-billion-health-care-fraud.

29 HHS-OIG, Special Fraud Alert: OIG Alerts Practitioners to Exercise Caution When Entering into Arrangements with Purported Telemedicine Companies (July 20, 2022), available at https://oig.hhs.gov/documents/root/1045/sfa-telefraud.pdf.

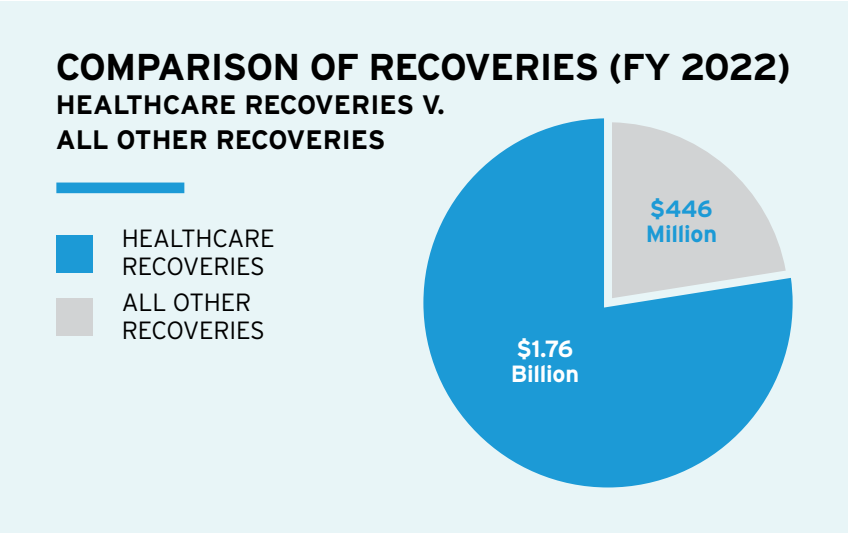
30 HHS-OIG, Medicare Telehealth Services During the First Year of the Pandemic: Program Integrity Risks, OEI-02-20-00720 (Sept. 2, 2022), available at https://oig.hhs.gov/oei/reports/OEI-02-20-00720.pdf.

31 Pandemic Response Accountability Committee, Insights on Telehealth Use and Program Integrity Risks Across Selected Health Care Programs During the Pandemic (Nov. 30, 2022), available at https://www.pandemicoversight.gov/media/file/telehealthfinal508nov30pdf.

NOTEWORTHY SETTLEMENTS

As in recent years, resolutions in healthcare fraud cases accounted for the vast majority of all FCA recoveries in FY 2022. Of the $2.2 billion total in settlements and judgments, recoveries from matters involving the healthcare industry amounted to nearly $1.8 billion (80%). This is the 14th consecutive year that recoveries in federal civil healthcare fraud matters have exceeded $1.5 billion.

Newly filed *qui tam* complaints accounted for the majority of the new civil fraud matters initiated in FY 2022, in line with past years, although the number of government-initiated and data-driven FCA actions continue to rise. Whistleblowers filed 652 *qui tam* lawsuits in FY 2022 and recoveries from these and earlier filed lawsuits accounted for nearly $2 billion of the $2.2 billion recovered. Settlements associated with *qui tam* lawsuits where the government intervened or otherwise pursued the allegations comprised more than $641 million of the recoveries from healthcare companies. Settlements and judgments in cases where the government declined to intervene amounted to more than $1 billion and far exceeded prior years, largely resulting from a settlement with a federal share of more than $853 million agreed to by pharmaceutical company Biogen, Inc., to resolve allegations that it violated the FCA by paying kickbacks to physicians to induce them to prescribe Biogen drugs. The ***Appendix*** to our Healthcare Fraud & Abuse Review contains a detailed breakdown of key settlements from the past year, many of which are referenced within this section of the Review.



HOSPITALS AND HEALTH SYSTEMS

There were several notable settlements involving hospitals and health systems resolving FCA allegations, many of which related to alleged violations of the Stark Law or AKS. Improper compensation arrangements with physician referral sources remained a key area of scrutiny with inappropriate remuneration taking on various forms, including kickbacks disguised as sham medical director payments[32] and free call coverage service.[33] Certain of these settlements were based on self-disclosures by the hospital or health system.[34]

Hospitals and health systems also resolved several cases related to medical necessity issues, including allegations of submitting claims for medically unnecessary genetic testing,[35] medically unnecessary medical device battery replacement surgeries,[36] and medically unnecessary neurosurgery procedures.[37] A number of settlements involved

32 https://www.justice.gov/usao-nh/pr/catholic-medical-center-agrees-pay-38-million-resolve-kickback-related-false-claims-act.
33 https://www.justice.gov/usao-ma/pr/steward-health-care-system-agrees-pay-47-million-resolve-allegations-false-claims-act.
34 *See, e.g.*, https://www.justice.gov/usao-ndwv/pr/west-virginia-hospital-pay-15-million-settle-allegations-concerning-impermissible-0.
35 https://www.justice.gov/opa/pr/uc-san-diego-health-pays-298-million-resolve-allegations-ordering-unnecessary-genetic-testing.
36 https://www.justice.gov/usao-edny/pr/new-york-presbyterianqueens-hospital-settles-allegations-federal-health-care-fraud-over.
37 https://www.justice.gov/usao-edwa/pr/providence-health-services-agrees-pay-227-million-resolve-liability-medically.

general failures to adhere to reimbursement or coverage requirements,[38] services that were not properly supervised by physicians,[39] and services allegedly rendered and billed without the appropriate physician authorization.[40]

In the year's largest series of settlements involving hospitals and health systems, multiple California-based hospitals agreed to pay a combined total of $93.2 million to California's Medicaid program, Medi-Cal, to resolve FCA allegations that they submitted or caused the submission of false claims for "additional" or "enhanced services" to Adult Expansion Medi-Cal members that were contractually not allowed, duplicative of other required services, and/or did not reflect the fair market value (FMV) of the services provided.[41] Most of the settling entities entered into a corporate integrity agreement (CIA) with HHS-OIG as part of their respective resolution.

COMPARISON OF TOTAL RECOVERIES:
INTERVENED V. DECLINED CASES
SETTLEMENTS AND JUDGMENTS (FY 2018-2022)

YEAR	INTERVENED CASES	DECLINED CASES
2018	$2.00 billion	$135.22 million
2019	$1.94 billion	$305.52 million
2020	$1.51 billion	$193.88 million
2021	$1.19 billion	$479.01 million
2022	$776.75 million	$1.18 billion

38 *See, e.g.*, https://www.justice.gov/usao-ndca/pr/sutter-health-agrees-pay-13-million-settle-false-claims-act-allegations-improper.

39 https://www.justice.gov/usao-md/pr/university-maryland-shore-regional-health-agrees-pay-296870-settle-federal-false-claims.

40 https://www.justice.gov/usao-wdok/pr/oklahoma-city-hospital-pays-over-11-million-settle-allegations-submitting-false-claims.

41 https://www.justice.gov/usao-cdca/pr/ventura-county-s-organized-health-system-and-3-medical-providers-agree-pay-707-million; https://www.justice.gov/opa/pr/three-health-care-providers-agree-pay-225-million-alleged-false-claims-california-s-medicaid.

LONG-TERM CARE PROVIDERS

The vast majority of settlements in the home health, hospice, skilled nursing, and nursing home provider sector in FY 2022 involved allegations of medically unnecessary services and admissions.[42] Moreover, over a quarter of the total settlements in this sector resolved allegations of Medicaid fraud against Massachusetts' Medicaid program, MassHealth, most involving allegations of medically unnecessary home health services.[43]

This sector of the healthcare industry also saw settlements related to novel fraud schemes, including allegations related to various providers' failures of response or misuse of appropriated funds related to the COVID-19 emergency.[44] A number of other long-term care settlements involved general failures to adhere to reimbursement or coverage requirements.[45] Others involved fraudulent attempts to circumvent applicable rules, including double-billing for skilled nursing facilities (SNF) services for patients who had already been moved to hospice,[46] failure to pay home health aides the state-required minimum wage,[47] and modifying patients' insurance coverage to receive higher reimbursement without their knowledge or consent.[48]

In the year's largest settlement involving a long-term care provider, a home health provider, its former CEO, and its former COO agreed in October to pay more than $22 million to resolve FCA allegations that they paid physicians sham medical director payments to induce patient referrals, in violation of the AKS. As part of the resolution, the provider entered into a five-year CIA with HHS-OIG and the two former officers were excluded from participating in federal healthcare programs for five years.[49] In a separate resolution later in the same month, the same provider and former officers agreed to pay more than $7 million to resolve FCA allegations that they billed Medicare for medically unnecessary therapy services.[50]

42 *See, e.g.*, https://www.justice.gov/usao-wdky/pr/home-health-company-operating-florida-pays-21-million-resolve-false-claims-allegations; https://www.justice.gov/usao-sdtx/pr/hospice-agrees-pay-nearly-1m-settle-false-claims-liability; https://www.justice.gov/usao-sdtx/pr/hospice-agrees-pay-nearly-1m-settle-false-claims-liability.

43 *See* https://www.mass.gov/news/ag-healey-secures-630000-from-home-health-care-company-to-resolve-false-billing-allegations; https://www.mass.gov/news/home-health-agency-agrees-to-pay-653-million-to-masshealth-to-resolve-allegations-of-fraud; https://www.mass.gov/news/ag-healey-secures-550000-from-home-health-care-company-to-resolve-false-billing-allegations; https://www.mass.gov/news/ag-healey-secures-430000-from-springfield-home-health-agency-to-resolve-fraudulent-billing-allegations; https://www.mass.gov/news/ag-healey-reaches-settlement-with-rowley-nursing-home-over-pandemic-response-failures.

44 https://www.justice.gov/opa/pr/morselife-nursing-home-health-system-agrees-pay-175-million-settle-false-claims-act; https://www.mass.gov/news/ag-healey-reaches-settlement-with-rowley-nursing-home-over-pandemic-response-failures.

45 *See* https://www.justice.gov/usao-sdoh/pr/ohio-home-healthcare-provider-agrees-pay-500000-part-false-claims-act-settlement; https://www.justice.gov/usao-ndca/pr/concord-nursing-home-pay-23-million-settle-allegations-grossly-substandard-care.

46 https://www.justice.gov/usao-sdin/pr/us-attorney-s-office-recovers-over-55-million-civil-false-claims-settlement-american.

47 https://www.justice.gov/usao-edny/pr/home-healthcare-agencies-settle-fraud-claims-54-million-and-agree-pay-wages-and; https://www.justice.gov/usao-edny/pr/home-health-care-agency-settles-fraud-claims-126-million-and-agrees-pay-2-million-wages.

48 https://www.justice.gov/usao-sdny/pr/us-attorney-announces-785-million-settlement-citadel-skilled-nursing-facility-bronx.

49 https://www.justice.gov/usao-wdok/pr/oklahoma-city-home-health-company-and-two-former-corporate-officers-agree-pay-229.

50 https://www.justice.gov/opa/pr/carter-healthcare-affiliates-and-two-senior-managers-pay-7175-million-resolve-false-claims.

As in recent years, many of the larger settlements in these sectors involved alleged AKS violations, while others related to alleged violations of industry-specific program regulations.

PHARMACEUTICAL AND DEVICE

The pharmaceutical and medical device industries continued to be significant sources of enforcement recoveries within the healthcare industry last year. As in recent years, many of the larger settlements in these sectors involved alleged AKS violations, while others related to alleged violations of industry-specific program regulations.

Several significant settlements in the pharmaceutical and medical device industries involved alleged violations of specific program requirements. In March 2022, a pharmaceutical company agreed to pay $260 million to resolve allegations that it underpaid drug rebates to Medicaid by miscalculating the rebates, in addition to allegations that it used a foundation to fund co-pay subsidies.[51] In September 2022, a pharmaceutical company agreed to pay $7.9 million to resolve allegations that it delayed seeking U.S. Food and Drug Administration (FDA) approval to switch three medications from prescription-only status to over-the-counter medications and continued to sell generic versions using prescription packaging, in violation of Medicare regulations.[52] And, in December 2022, a provider of cardiac equipment agreed to pay more than $44 million to resolve allegations that it submitted claims for tests that were performed outside the United States and in some cases by technicians that were not qualified to perform such tests.[53]

The government continued a focus on individual actors including licensed and credentialed healthcare providers, whom it views as important gatekeepers with respect to federally funded healthcare.

51 https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-260-million-settle-lawsuits-alleging-underpayments-medicaid-drug.
52 https://www.justice.gov/usao-ma/pr/pharmaceutical-company-akorn-operating-company-llc-agrees-pay-79-million-resolve.
53 https://www.justice.gov/opa/pr/cardiac-monitoring-companies-pay-more-448-million-resolve-false-claims-act-liability-relating.

The government continued to pursue cases involving alleged kickbacks in the pharmaceutical and medical device industries, including three notable settlements announced in September 2022. A DME manufacturer agreed to pay $24.75 million to resolve FCA allegations that it provided physician prescribing data to suppliers to assist with the suppliers' marketing efforts in exchange for equipment orders from the suppliers, in violation of the AKS.[54] The manufacturer also entered into a five-year CIA with HHS-OIG as part of the resolution. The same month, a pharmaceutical manufacturer and related entities agreed to pay $40 million to settle two *qui tam* cases alleging that they paid kickbacks to physicians and hospitals to persuade them to use their drugs along with other FCA violations.[55] In one of the largest settlements, another pharmaceutical company agreed to pay $900 million to resolve allegations that it paid speaker honoraria, training fees, and other compensation to healthcare professionals in attempts to persuade them to prescribe specific drugs, in violation of the AKS.[56]

Other settlements of AKS violations included a device manufacturer that allegedly paid physicians for training events in excess of what was necessary,[57] a manufacturer of optical lenses that allegedly created programs to provide remuneration to eye care providers[58] and a pharmaceutical distributor that allegedly provided upfront discounts to physicians without tying the rebates to specific purchases, in violation of HHS-OIG guidance on rebates.[59]

LABORATORY SERVICES

Several laboratory and diagnostic service providers settled allegations that they billed Medicare for unnecessary testing, including for confirmatory urine drug screening where presumptive results were not yet available[60] and biopsy tests where a pathologist had not determined that further testing was warranted.[61] Three other clinical laboratories settled allegations relating to AKS violations, with the alleged improper remuneration taking such forms as leases from physician practices at above market rate[62] and payments to marketers that were based on revenue obtained from tests they solicited.[63]

54 https://www.justice.gov/opa/pr/philips-subsidiary-pay-over-24-million-alleged-false-claims-caused-respironics-respiratory.
55 https://www.justice.gov/usao-nj/pr/bayer-corp-pay-40-million-resolve-alleged-use-kickbacks-and-false-statements-relating.
56 https://www.justice.gov/usao-ma/pr/biogen-inc-agrees-pay-900-million-settle-false-claims-act-allegations-related-improper.
57 https://www.justice.gov/opa/pr/medical-device-manufacturer-biotronik-inc-agrees-pay-1295-million-settle-allegations-improper.
58 https://www.justice.gov/usao-edpa/pr/essilor-agrees-pay-164-million-resolve-false-claims-act-liability-paying-kickbacks.
59 https://www.justice.gov/usao-ma/pr/cardinal-health-agrees-pay-more-13-million-resolve-allegations-it-paid-kickbacks.
60 https://www.justice.gov/usao-ma/pr/radeas-llc-agrees-pay-116-million-resolve-allegations-fraudulent-billing; https://ncdoj.gov/attorney-general-josh-stein-reaches-3-6-million-medicaid-settlement-with-radeas/.
61 https://www.justice.gov/usao-ma/pr/inform-diagnostics-agrees-pay-16-million-resolve-false-claims-act-allegations-medically.
62 https://www.justice.gov/opa/pr/bioreference-laboratories-and-parent-company-agree-pay-985-million-resolve-false-claims-act.
63 https://www.justice.gov/usao-nj/pr/two-clinical-labs-and-their-owners-agree-pay-57-million-resolve-false-claims-and-kickback.

INDIVIDUAL PROVIDERS AND PRACTICE GROUPS

The government continued to focus on individual actors including licensed and credentialed healthcare providers whom it views as important gatekeepers with respect to federally funded healthcare. In one notable set of cases, 32 physicians agreed to pay a total of more than $5.3 million to resolve allegations that they received kickbacks from management services organizations (MSOs).[64] The government alleged that the payments were disguised as investment returns when in fact they were based on the doctors' referrals.

The government resolved a number of FCA cases with medical providers in which DOJ alleged the providers had misrepresented services rendered in a manner that increased the reimbursement or permitted the providers to bill for services that were not reimbursable. These cases included a physician who allegedly billed for services rendered by unlicensed staff as if they had been performed by the physician herself,[65] a podiatrist who allegedly submitted claims for more complex procedures than she had performed,[66] and a dentist who allegedly submitted claims for services provided by uncredentialed dentists.[67]

Finally, there were also multiple settlements by individuals relating to services that were allegedly either medically unnecessary or not rendered at all, including ultrasounds,[68] hysterectomies and chemotherapy treatment,[69] ENT procedures,[70] and orthopedic treatments.[71] In one such case, an ophthalmologist and his practice agreed to pay more than $900,000 to resolve allegations that he administered injections to patients that were not medically necessary.[72] The government alleged those injections were not medically necessary because the patients in question did not have treatable conditions that would have warranted the invasive treatment.

OTHER ENTITIES AND PROVIDERS

Multiple other entities and providers settled FCA allegations that they caused the submission of false claims. In one notable high-dollar settlement, a pain management practice, its founder, and its chief marketing officer agreed to pay $24.5 million to resolve allegations they billed for urine drug tests and genetic testing that were medically unnecessary, and paid physicians a portion of the profits from those tests, in violation of the Stark Law.[73] As part of the settlement, the practice also entered into a five-year CIA with HHS-OIG. Another significant settlement included six medical practices and their owner who agreed to pay more than $7.4 million to settle allegations that they billed for the use of implanted neurostimulators when instead they used acupuncture devices that are not eligible for reimbursement.[74]

Following similar announcements in prior years, yet another large settlement was reached with an electronic health record (EHR) vendor, which agreed to pay $45 million to resolve allegations that it recommended a specific laboratory to its customers in exchange for payments from that laboratory.[75] The government also alleged that the vendor worked with the laboratory to donate its EHR program to providers, increasing its user base while also increasing the number of orders the lab received.

64 https://www.justice.gov/usao-edtx/pr/seven-texas-doctors-and-hospital-ceo-agree-pay-over-11-million-settle-kickback; https://www.justice.gov/usao-edtx/pr/ten-texas-doctors-and-healthcare-executive-agree-pay-over-168-million-settle-kickback; https://www.justice.gov/opa/pr/fifteen-texas-doctors-agree-pay-over-28-million-settle-kickback-allegations.

65 https://www.justice.gov/Usao-wdmi/pr/2022_0608_Peterson.

66 https://www.justice.gov/usao-sdtx/pr/podiatrist-pays-six-figures-settle-allegations-involving-false-procedure.

67 https://www.justice.gov/usao-edtn/pr/dental-provider-agrees-settle-allegations-improper-billing-tenncare.

68 https://www.justice.gov/usao-sdtx/pr/physician-pays-over-half-million-settle-allegations-concerning-ultrasound-billing.

69 https://www.justice.gov/opa/pr/michigan-doctor-pay-775000-resolve-false-claims-act-allegations.

70 https://www.justice.gov/usao-wdny/pr/dansville-physician-agrees-pay-more-600000-resolve-allegations-he-fraudulently-billed.

71 https://www.justice.gov/usao-edca/pr/los-angeles-doctor-pay-95-million-resolve-allegations-fraud-against-medicare-and-medi.

72 https://www.justice.gov/usao-sdwv/pr/united-states-attorney-announces-90707464-health-care-fraud-settlement.

73 https://www.justice.gov/opa/pr/physician-partners-america-pay-245-million-settle-allegations-unnecessary-testing-improper.

74 https://www.justice.gov/usao-edny/pr/surgery-centers-and-medical-offices-brooklyn-and-new-jersey-settle-allegations-federal.

75 https://www.justice.gov/opa/pr/modernizing-medicine-agrees-pay-45-million-resolve-allegations-accepting-and-paying-illegal.

FALSE CLAIMS ACT UPDATE

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

ESCOBAR'S "RIGOROUS" MATERIALITY REQUIREMENT

Courts analyzing the FCA's "rigorous" and "demanding" materiality element continue to be guided by the Supreme Court's landmark 2016 decision in ***Universal Health Services v. U.S. ex rel. Escobar***.[76] In *Escobar*, the Supreme Court explained that materiality "looks to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation," and identified several non-exclusive factors for courts to consider in assessing materiality.

76 579 U.S. 176 (2016).

In *Escobar*, the Supreme Court explained that materiality "looks to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation," and identified several non-exclusive factors for courts to consider in assessing materiality.

These factors include: (1) whether compliance with a particular statute, regulation, or other requirement is an express condition of payment; (2) whether the violation of the relevant requirement goes to the essence of the bargain or instead is only "minor" or "insubstantial"; and (3) whether the government consistently pays, or refuses to pay, claims in the "mine run of cases" where it has knowledge of noncompliance. Courts have applied these factors in several notable decisions this past year.

Past Payment Patterns

As in previous years, the government's track record of making or refusing payment after learning of alleged noncompliance — either by the defendant or others — was the focus of several key materiality decisions.

In ***U.S. ex rel. Hartpence v. Kinetic Concepts, Inc.***, the Ninth Circuit reversed a district court order granting summary judgment where a relator alleged that a medical device manufacturer violated the FCA by falsely certifying that certain Medicare payment criteria were satisfied.[77] The manufacturer allegedly did so by using a billing modifier that triggered automatic payment, rather than submitting claims without the modifier, which would instead have led to a multi-level administrative review process. Disagreeing with the district court, the Ninth Circuit held that the allegedly false use of the modifier was material to payment. It considered extensive evidence of the government's history of reviewing claims submitted without the modifier and concluded that the government often denied such claims. Because the government had denied a significant portion of unmodified claims in what was considered to be the "mine run of cases," the Ninth Circuit held that there was a genuine issue of material fact as to whether the use of the modifier to evade the administrative review process amounted to a material misrepresentation.

Employing a similar analysis in ***U.S. ex rel. Taylor v. Boyko***, the Fourth Circuit affirmed a district court's order dismissing an FCA complaint where the relator alleged that two physicians, five medical companies, and an accounting firm violated the FCA by submitting claims to Medicare despite knowing that the medical license of one of the companies had been administratively revoked for failure to pay an annual registration fee.[78] The Fourth Circuit held that the revocation of the license was not material to payment because the relator could not point to any instances where Medicare had denied claims under similar

77 44 F.4th 838 (9th Cir. 2022).
78 39 F.4th 177 (4th Cir. 2022).

District courts have also considered whether a violation can be material where the paying government entity has employed an alternate mechanism for addressing similar violations, rather than denying payment.

circumstances. It observed that all but one of the examples that the relator cited had involved individual physicians' licenses. The one case that did involve a company involved substantive fraud and not failure to pay a minor registration fee.[79]

District courts have also considered whether a violation can be material where the paying government entity has employed an alternate mechanism for addressing similar violations, rather than denying payment. One example is ***U.S. ex rel. Holt v. Medicare Medicaid Advisors, Inc.***, where the district court dismissed on materiality grounds an FCA complaint alleging that the defendant committed several violations of Medicare marketing regulations.[80] The district court noted that CMS often imposed a range of intermediate sanctions for violating those same regulations, none of which included recouping payments or refusing to pay claims. Accordingly, the district court concluded that the alleged regulatory violations were not material to CMS's decision to pay the defendant's claims.

In contrast, some district courts found materiality satisfied where the government took action besides denying the claims to address the alleged violations. In ***U.S. ex rel. Byrd v. Acadia Healthcare Co.***, the relator alleged that the defendant hospitals violated the FCA by submitting claims for services performed by an advanced practice registered nurse who worked without a valid practice agreement or supervision.[81] The defendants argued that the complaint should be dismissed on materiality grounds because the relator failed to allege instances where the government had denied other claims for similar violations. The district court disagreed, finding materiality was pleaded adequately, in part, because the defendants previously had entered into a settlement agreement related to the same allegations with the state of Louisiana. This "one instance of a Government enforcement action," the district court reasoned, was sufficient for this factor to weigh in the relator's favor.

Likewise, in ***U.S. ex rel. Medina v. Stryker Orthopaedics***, the relator alleged that the defendant medical device manufacturer falsely certified compliance with country-of-origin (COO) requirements that all products be purchased from countries with trade agreements with the United States.[82] Even though the relator did not allege past government denials related to these violations, the district court denied the defendant's motion to dismiss as to materiality because the defendant obtained an exception from the government to the COO regulations after the lawsuit was filed. In the district court's view, the government's willingness to grant an exception to the COO requirements showed that the government believed the claims would not have been payable without one.

Materiality in Medicare Advantage Cases

There were several notable FCA decisions involving Medicare Advantage (MA) providers. For example, in ***U.S. ex rel. Osinek v. Permanente Med. Grp., Inc.***, an intervened case, the United States alleged that the defendants were liable under the FCA for failing to comply with International Classification of Diseases (ICD) Guidelines by adding diagnosis codes that were unrelated to the patient visit.[83] The defendants sought to dismiss the government's claims on the grounds that compliance with ICD Guidelines was immaterial, yet the district court reasoned that compliance with ICD Guidelines was material because the diagnosis codes submitted by MA providers determine CMS's payments. As support for this conclusion, the district court noted that the defendants' internal documents stressed the necessity of complying with ICD Guidelines.

Materiality of Misrepresentations to the FDA

In several cases involving drug and device manufacturers, courts clarified that false representations made to the FDA in connection with the FDA approval process are not necessarily material to government healthcare programs' payment decisions, even assuming the misrepresentations were material to the FDA.

In several cases involving drug and device manufacturers, courts clarified that false representations made to the FDA in connection with the FDA approval process are not necessarily material to government healthcare programs' payment decisions, even assuming the misrepresentations were material to the FDA.

79 *See also U.S. ex rel. DiLello v. Hackensack Meridian Health*, 2022 WL 1284734 (D.N.J. Apr. 29, 2022) (no materiality where the relator failed to allege that "CMS consistently refuses to pay claims" based on noncompliance with the regulatory provision at issue and where CMS was alleged to have repeatedly paid the defendant's claims despite its knowledge of the alleged noncompliance).

80 2022 WL 3587358 (W.D. Mo. Aug. 22, 2022).

81 2022 WL 879492 (M.D. La. Mar. 23, 2022).

82 2022 WL 522788 (D.N.J. Feb. 22, 2022).

83 2022 WL 16925963 (N.D. Cal. Nov. 14, 2022).

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

In ***U.S. ex rel. Yu v. Grifols USA, LLC***, the Second Circuit affirmed the dismissal of an FCA complaint where the relator alleged that a pharmaceutical manufacturer made false representations to the FDA to receive approval both for its drugs and to build a new manufacturing plant.[84] The Second Circuit held that the relator's complaint failed to state a viable FCA claim because none of the alleged misrepresentations and regulatory violations were material to payment. In reaching that conclusion, the Second Circuit determined that the relator failed to plead that any of the manufacturer's contracts conditioned payment on compliance with specific Current Good Manufacturing Practices (cGMPs) that were alleged to have been violated. And, to the extent that the contracts merely incorporated by reference all cGMPs by requiring that drugs not be considered adulterated, the Second Circuit rejected this argument as sufficient to show materiality. It also found that the misrepresentations and regulatory violations did not go to the essence of the bargain because the relator "allege[d] only that the various violations 'may' or 'could' cause negative consequences" and had not identified any specific adverse impacts.

In ***U.S. ex rel. Crocano v. Trividia Health, Inc.***, the district court considered allegations that a manufacturer of glucose test strips caused the submission of false claims to federal healthcare programs by placing its allegedly "misbranded" products into the market.[85] As part of this liability theory, the relator alleged that the manufacturer had failed to submit required "adverse event" reports to the FDA. The district court dismissed the claims for failure to plead materiality, reasoning that even if the manufacturer had an obligation to make the reports to the FDA, the relator had not alleged that compliance with the FDA's regulations was material to payment by the relevant government healthcare programs. The district court observed that the FDA could use its own regulatory enforcement powers to ensure compliance and the court was thus not "convinced that the False Claims Act [was] the proper avenue for holding [the defendant] accountable."

84 2022 WL 7785044 (2d Cir. Oct. 14, 2022).
85 2022 WL 2800380 (S.D. Fla. July 18, 2022).

The district court rejected a similar theory in ***U.S. ex rel. Bennett v. Bayer Corp***.[86] There, a relator alleged that two drug manufacturers had violated the FCA by causing physicians to prescribe allegedly misbranded drugs. In support of this claim, the relator cited purported false statements the manufacturers made to the FDA to win approval for the drugs. Rejecting the assertion that the misrepresentations were material, the district court held that the relator had not adequately alleged that the misrepresentations mattered even to the FDA, much less with respect to federal healthcare programs' subsequent payment decisions.

DEVELOPMENTS IN PLEADING STANDARDS

Supreme Court Declines to Weigh in on Pleading Standards

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

Many believed that the Supreme Court might resolve this disagreement after certiorari petitions had been filed in cases from the Sixth, Seventh, and Eleventh Circuits asking the Supreme Court to weigh in on whether an FCA complaint must include an example of a false claim or if the complaint need only provide reliable indicia that such claims likely have been submitted. The petitions argued that there was a growing split among the circuits with some, like the Sixth and Eleventh Circuits, requiring representative examples of claims submitted, and others, like the Seventh Circuit, accepting allegations that would lead to a strong inference that claims were submitted.

Although the Supreme Court had twice previously declined to take up this issue, many speculated that the Supreme Court might grant certiorari after it sought input from the Solicitor General regarding the United States' view of two of the petitions. As in prior instances, however, the Solicitor General discouraged the Supreme Court from granting certiorari, arguing that there was no true circuit split and that the different outcomes from

All courts agree that to survive a motion to dismiss under Rule 9(b), FCA complaints must first identify the particular details — including the "who, what, when, where, and how" — of the alleged fraudulent scheme.

86 2022 WL 970219 (D.N.J. Mar. 31, 2022).

lower courts have stemmed primarily from the "fact-intensive nature" of the cases. In October 2022, the Supreme Court denied all three petitions, leaving in place the various approaches applied by the lower courts.

Pleading the Details of a Fraudulent Scheme

All courts agree that to survive a motion to dismiss under Rule 9(b), FCA complaints must first identify the particular details — including the "who, what, when, where, and how" — of the alleged fraudulent scheme. This does not mean that the relator is required to prove its case in the complaint: but Rule 9(b) does require some level of factual specificity.

As the Fourth Circuit explained in ***U.S. ex rel. Nicholson v. MedCom Carolinas, Inc.***, this requirement is intended to prevent frivolous lawsuits, stop fishing expeditions, and protect defendants' reputations.[87] In that case, an employee of a company selling skin grafts alleged that the company violated the AKS by paying commissions to independent contractors based on their sales to VA hospitals. The relator did not describe how the commissions were paid out, to whom or even by whom. In describing the factual holes in the complaint, the Fourth Circuit noted that the allegations "sound[] like a neighbor's conversation only half overheard through the walls" and issued a warning before affirming dismissal of the relator's complaint with prejudice: "For future relators, it may be wise to err on the side of saying too much to avoid a kick from Rule 12(b)(6)."

Similarly, in ***U.S. ex rel. Enloe v. Heritage Operations Group, LLC***, the relator alleged that an operator of long-term care facilities and a pharmacy violated the FCA because nurses at the facilities dispensed Schedule II controlled substances without valid prescriptions.[88] The district court dismissed the relator's complaint, finding the mere allegation that the defendant failed to comply with regulatory requirements of the CSA fell short of the relator's burden to allege fraud with particularity. The complaint "hover[ed] at the highest level of generality," providing no details regarding *when* the defendant submitted false claims, *who* submitted false claims, *how many* claims were submitted, *how much* money the defendant received as a result, or the identities of any persons who provided invalid prescriptions. The complaint likewise failed to identify any representative examples of false claims or explain why facts were inaccessible to the relator so as to justify "information and belief" pleading to satisfy Rule 9(b).

In contrast, in ***U.S. ex rel. Siegel v. Novo Nordisk, Inc.***, the district court found that the relator adequately alleged an off-label promotion scheme by providing detailed allegations of how the defendant promoted a drug for uses not approved by the FDA, including incentivizing sales representatives for off-label use sales, disseminating posters promoting off-label uses, publicizing studies touting off-label uses, and paying physicians to give lectures in favor of off-label uses.[89] The district court also found that the relator adequately pleaded a kickback scheme due to detailed allegations of the defendant paying kickbacks to physicians for participating in studies, writing manuscripts, serving on advisory boards, speaking at patient events, and otherwise promoting off-label uses. Finally, the district court found that the relator adequately alleged the submission of an actual false claim by providing specific detail of the defendant's promotion of an off-label use to a particular patient and payment of kickbacks to induce him to use the drug.

Some circuits have continued to take a rigid approach, requiring the relators to plead specific details of false claims submitted. Others have taken a more flexible approach that would allow the submission of false claims to be inferred from the circumstances.

In ***U.S. ex rel. Chihi v. Catholic Health Initiatives***, the district court likewise concluded that the relator adequately alleged violations of the AKS.[90] The relator alleged that the defendant health system provided kickbacks in the form of international patient referrals, complimentary interpreters, and other administrative support to high-referring defendant providers in exchange for referrals of Medicare and Medicaid patients to the health system's hospital. The district court held that the relator had adequately pleaded a scheme with regard to these alleged kickbacks by providing multiple specific examples. The relator also pleaded that the defendant providers referred Medicare and Medicaid beneficiaries to the health system instead of other hospitals and identified one example referral. The relator pleaded that the health system's managers directed staff to provide more free support services to the defendant providers who referred government business to the hospital, and less to those who did not. Notably, the district court explained that the relator was only required to allege that one purpose of the remuneration was to induce referrals, even if there were also lawful purposes.

Pleading the Submission of False Claims

As previously noted, courts continued to take divergent approaches as to what Rule 9(b) requires to connect an alleged fraud scheme to specific false claims. Some circuits have continued to take a rigid approach, requiring the relators to plead specific details of false claims submitted. Others have taken a more flexible approach that would allow the submission of false claims to be inferred from the circumstances.

The Ninth Circuit, for example, continued to hold that specific invoices for reimbursement are not required when the particular allegations of a scheme to submit false claims are paired with "reliable indicia" that lead to a strong inference that claims were actually submitted. In ***UPPI LLC v. Cardinal Health, Inc.***, the relator alleged a "rent-a-vet" scheme through which Cardinal and a service-disabled veteran-owned small business (SDVOSB) misled the government into awarding the SDVOSB a contract to provide radiopharmaceutical products to VA hospitals, when Cardinal performed the vast majority of the work and kept the majority

87 42 F.4th 185 (4th Cir. 2022).
88 2022 WL 3543228 (N.D. Ill. Aug. 18, 2022).
89 2022 WL 16716299 (W.D. Okla. Nov. 4, 2022).
90 2022 WL 2657131 (S.D. Tex. Mar. 31, 2022), memorandum and recommendation adopted, 2022 WL 2652135 (S.D. Tex. July 8, 2022).

of the revenue.[91] The Ninth Circuit reversed the district court's dismissal of the relator's first amended complaint, finding the relator adequately alleged the *who* (defendants), *what* (eight SDVOSB contracts), *where* (the locations identified in the contracts), *when* (at the time the contracts were bid on and executed), and *how* (by falsely promising the SDVOSB would perform the work) to meet the requirements of Rule 9(b). While the relator did not identify specific invoices that were submitted by the SDVOSB for work actually performed by Cardinal, the Ninth Circuit concluded it was enough that the relator identified the contracts at issue, set forth the details of the scheme, and alleged that fraudulent invoices were submitted by the defendants and paid by the government.

Following a similar approach, late in 2021, the Seventh Circuit issued an opinion in ***U.S. ex rel. Mamalakis v. Anesthetix Mgmt. LLC***, which was a case brought by an anesthesiologist alleging that his former employer was billing for claims as "medically directed" when they qualified only for the lower "medically supervised" payment rate.[92] The Seventh Circuit agreed with the district court that allegations regarding the defendants' allegedly fraudulent billing practices were not enough on their own to satisfy Rule 9(b). The Seventh Circuit, however, reversed the district court's dismissal because, in filing his amended complaint, the relator included specific examples identifying the type and date of procedures in question, the anesthesiologists involved, and the specific way in which they did not perform the services required to bill at the "medically directed" rates. The relator alleged that these anesthesiologists nonetheless coded at the "medically directed" rate per the defendants' policies and confirmed that each patient was insured by Medicare based on personal knowledge. The Seventh Circuit held that, although these allegations did not include invoices showing that false claims were actually submitted to Medicare, they were nonetheless enough to qualify as "representative examples" by providing a particularized basis from which to "plausibly infer that at least on these occasions, [defendants] presented false claims to the government."

Early in 2022, the Seventh Circuit considered another case that had been dismissed under Rule 9(b) in ***U.S. ex rel. Sibley v. University of Chicago Medical Center***.[93] There, former employees of a debt collection agency alleged that their employer caused its clients to submit false cost reports seeking reimbursement from CMS for bad debts without first performing "reasonable collection efforts." The relators named two debt collection agencies and one hospital as the defendants. The district court dismissed the claims against all three with prejudice because the relators failed to provide "specific representative examples" of any bad debts that were included on a cost report without reasonable collections efforts having been undertaken.

On appeal, the Seventh Circuit affirmed dismissal of the hospital and one debt collection agency because the relators failed to plead enough details about the agency's "day-to-day" activities or the hospital's independent collection efforts. The Seventh Circuit noted that, while the relators alleged that the collection agency charged the hospital for nine employees when only two were performing the work, they failed to include details about the number of debts referred to the agency or how long it would take an average employee to complete reasonable collection efforts. The Seventh Circuit concluded that the relators' allegations required multiple inferential leaps to get from the alleged fact that only two employees were attempting to collect debts to the conclusion that specific Medicare bad debt was included on the hospital's cost reports for which neither the hospital nor the collection agency undertook reasonable collection efforts. In contrast, the relators alleged three specific examples where the second debt collection agency improperly declared debts as Medicare bad debts before the required 120-day period for reasonable collection efforts had expired, and that these debts were inappropriately written off as bad debt by another hospital that sought reimbursement for them from the government. Because the relators alleged the mechanics of how these representative examples were improperly declared as bed debt and included on a cost report, the Seventh Circuit reversed the dismissal as to that agency.

The reach of the less stringent "reliable indicia" standard that some courts have applied is not without limits. For example, in ***Kunin v. St. Luke's Health Sys., Inc.***, the district court granted the defendant's motion to dismiss claims related to alleged Stark Law violations.[94] The district court held that the relator did not allege reliable indicia leading to a strong inference that claims were actually submitted, as required by Eighth Circuit precedent, because he did not allege any firsthand knowledge of the defendant's billing practices. It was also not enough that the relator alleged that every claim submitted during the relevant period was false.

In ***U.S. ex rel. Fitzer v. Allergan, Inc.***, the district court dismissed a bariatric surgeon's kickback claims arising from the defendant's allegedly promoting physicians to implant its gastric banding device only if the physicians performed a minimum number of procedures with the product.[95] Applying the Fourth Circuit's pleading standard, which requires a relator

> Some courts allow a relator to satisfy Rule 9(b) without providing specific examples, only in certain circumstances, as an exception to the ordinary rule requiring representative claims.

91 2022 WL 3594081 (9th Cir. Aug. 23, 2022).
92 20 F.4th 295 (7th Cir. 2021).
93 44 F.4th 646 (7th Cir. 2022).
94 2022 WL 1213591 (W.D. Mo. Apr. 25, 2022); *see also U.S. ex rel. Crocano v. Trividia Health, Inc.*, 2022 WL 2800380 (S.D. Fla. July 18, 2022) (dismissing claims brought against a glucose test strip manufacturer because the complaint was bereft of particulars about the submission of false claims and explaining that it was not enough to rely on allegations that the defendant's product composed a substantial portion of Medicare claims for diabetes test strips and thus likely resulted in false claims); *Conte v. Kingston NH Ops. LLC*, 585 F. Supp. 3d 218 (N.D.N.Y. 2022) (granting motion to dismiss and rejecting the relator's inference that because most of the defendant nursing home's residents were eligible for Medicare or Medicaid, there was "no doubt" that the defendant submitted impliedly false claims based on noncompliance with COVID-19 safety mandates).
95 2022 WL 846211 (D. Md. Mar. 22, 2022).

to allege that the defendant engaged in conduct that would necessarily have led to the submission of false claims, the district court held that the relator's allegations of billing with a Medicare code that is applicable to multiple companies' devices merely described a scheme that *could* have led to the presentment of false claims but did not *necessarily* do so, and the court was unwilling to make the inferential leap.

Some courts allow a relator to satisfy Rule 9(b) without providing specific examples, only in certain circumstances, as an exception to the ordinary rule requiring representative claims. For example, in ***U.S. ex rel. NPT Assocs. v. Laboratory Corp. of Am. Holdings***, the district court granted a laboratory company's motion to dismiss the relator's allegations that the company carried out a fraudulent scheme with private insurance companies to increase its government program business.[96] The relator included conclusory allegations that network physicians were pressured to use the lab company for government claims, but the district court concluded it failed to provide sufficient detail describing how doctors were pressured or what was said to them. The district court also noted that the relator failed to identify examples of actual claims, despite alleging that the company submitted hundreds of thousands of claims to the government. Because the relator did not allege that particular claim details were exclusively held by the lab company and thus inaccessible to the relator, the relator was not entitled to the more relaxed standard that would have required it only to set forth plausible allegations that lead to a strong inference that specific claims were submitted.

Likewise, in ***U.S. ex rel. Dunn v. Procarent, Inc.***, the district court followed the Sixth Circuit's stricter pleading standard and granted an ambulance company's motion to dismiss claims relating to medically unnecessary transports.[97] First, the district court rejected the relator's argument that certain documentation counted as representative example claims because nothing on the face of the documents reflected billing a government healthcare program as opposed to private insurance. Second, the district court held that the relators did not qualify for a relaxed pleading standard because they did not specifically describe personal involvement in the billing process.

Even in circuits requiring specific allegations of representative claims, relators may not have to plead that a false claim was submitted at every location over the entire duration of the alleged scheme. For example, in ***U.S. ex rel. Anderson v. Curo Health Servs. Holdings, Inc.***, the government alleged defendant hospice providers falsely certified that patients' illnesses had reached a terminal stage warranting hospice care.[98] The defendant filed a motion to dismiss, asking the district court to narrow the government's claims to the time period and locations for which specific representative examples of the fraudulent scheme had been alleged. The district court declined to do so, noting that Rule 9(b) did not require the plaintiff to allege examples for each of the defendant's multiple locations or examples spanning the entire timeframe of the conduct at issue. Instead, it was enough for the government to allege exemplary claims with particularity, which the district court found it had done.

96 2022 WL 3718265 (S.D.N.Y. Aug. 29, 2022).
97 2022 WL 2834685 (W.D. Ky. July 20, 2022).
98 2022 WL 842937 (M.D. Tenn. Mar. 21, 2022).

DEVELOPMENTS REGARDING FALSITY

In 2022, both appellate and district courts issued numerous notable holdings concerning the issue of establishing falsity in FCA litigation.

Objective Falsity

We have previously covered the divide among federal appellate courts about whether a disagreement of medical opinion can establish that a physician's clinical judgment about patient treatment and any attendant certifications were "false" under the FCA. Specifically, the Third Circuit in ***U.S. ex rel. Druding v. Care Alternatives***[99] and the Ninth Circuit in ***U.S. ex rel. Winter v. Gardens Regional Hospital***[100] found that unreasonably held medical opinions or subjectively dishonest certifications could give rise to FCA liability. In contrast, the Eleventh Circuit in ***United States v. AseraCare***,[101] previously held that a mere subjective difference of clinical opinion could not render a physician's clinical judgment false. Faced with petitions for certiorari on this issue in prior years, the Supreme Court has declined to weigh in on this issue. As a result, lower courts have continued to grapple with the issue of objective falsity.

In ***U.S. ex rel. Anderson v. Curo Health Servs. Holdings, Inc.***, the defendant sought dismissal of the government's allegations that claims for hospice services were false because the patients were not terminally ill.[102] Relying on the Eleventh Circuit's opinion in ***AseraCare***, the defendant characterized the government's claims as seeking to impose FCA liability based on disagreements with the certifying physician's clinical judgments. The district court disagreed, noting that the government did not allege a mere clinical disagreement; but rather, "they allege fraud, in the simplest and most straightforward sense." Citing the Sixth Circuit's opinion in ***United States v. Paulus***, the district court concluded that "it is well settled that opinions are not, and have never been, completely insulated from scrutiny for fraud."[103]

Likewise, in ***Livingston v. Digirad Corp.***, the defendant urged the district court to grant summary judgment regarding the relator's allegations that reimbursement sought for nuclear stress tests violated Medicare regulations and resulted in FCA violations because of the relator's failure to present evidence on the question of falsity.[104] Citing ***AseraCare***, the defendant argued that the relator failed to identify an objective falsity because the claims for nuclear stress testing were dependent on "whether the billing physicians reasonably believed that they were qualified to and supervised the procedures that they billed for." The district court determined that a jury question as to falsity existed if the regulations at issue were subject to multiple interpretations but only one possible interpretation could be deemed to be correct. Because the relator had presented sufficient evidence to allow a reasonable jury to find that the billing physicians were not as involved in the nuclear stress tests as necessary to bill for the procedures, the district court rejected the defendant's arguments on the issue of falsity.

99 952 F.3d 89 (3d Cir. 2020).
100 953 F.3d 1108 (9th Cir. 2020).
101 938 F.3d 1278 (11th Cir. 2019).
102 2022 WL 842937 (M.D. Tenn. Mar. 21, 2022).
103 894 F.3d 267 (6th Cir. 2018).
104 2022 WL 4110897 (N.D. Ala. Sept. 8, 2022).

False Certification

In addition to liability for submitting "factually false" claims, defendants also can be held liable under the FCA for submitting "legally false" claims that either expressly or impliedly certify compliance with requisite statutes, regulations, or contractual provisions. As for implied false certification, the Supreme Court in *Escobar* held that defendants can be liable if: (1) "the claim does not merely request payment, but also makes specific representations about the goods or services provided;" and (2) "the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths."[105] During the past year, both appellate and trial courts continued to analyze the bounds of false certification liability.

In ***McElligott v. McKesson Corp.***, the relators alleged that McKesson failed to implement adequate security protocols for its controlled substance supply chain, which caused it to falsely certify compliance with "all applicable" laws and regulations, including various supply chain requirements.[106] The Ninth Circuit upheld the district court's dismissal of the lawsuit, holding that McKesson's failure to disclose that supplies were delivered through a noncompliant supply chain did not render the representation that the supplies were delivered misleading. The Ninth Circuit noted that McKesson's claims for payment did not make any "specific representations" about the medical supplies it provided that were rendered misleading half-truths by failure to disclose alleged supply chain issues.

In ***UPPI LLC v. Cardinal Health, Inc.***, the relator alleged that the defendant misled the government into awarding contracts to SDVOSBs for distribution of products to VA hospitals where Cardinal did the vast majority of the work and kept the majority of the revenue while the SDVOSBs took only a small cut for doing nominal work.[107] The district court dismissed this lawsuit, holding that the relator failed to plead falsity under either a fraud in the inducement or implied certification theory. The Ninth Circuit reversed the dismissal as to both theories of falsity. With respect to implied false certification, the Ninth Circuit held that due to Cardinal's failure to disclose the extent of its involvement and the extremely limited role intended by the SDVOSBs, the relator adequately stated a claim.

In ***United States v. Planned Parenthood Fed'n of Am. Inc.***, the relator conducted an undercover journalistic investigation alleging that the defendants provided fetal tissue collected from abortions to researchers and tissue procurement companies.[108] That investigation led the states of Louisiana and Texas to terminate the defendants from their state Medicaid programs. In response, the defendants filed lawsuits challenging the termination decisions, which resulted in preliminary injunctions granted in the defendants' favor. While the injunctions were in place, the defendants continued to submit claims to Medicaid. The Fifth Circuit later vacated the injunctions, prompting the relator to file a *qui tam* lawsuit alleging that the defendants failed to return known overpayments which arose from services billed while the injunctions were in place. The state of Texas intervened and the defendants moved to dismiss. The district court held that the state of Texas plausibly alleged that the defendants had falsely certified compliance with statutory and regulatory requirements to participate in Medicaid and that the states' termination of the defendants from Medicaid participation demonstrated that compliance with those requirements was a condition of payment.

In ***U.S. ex rel. Jehl v. GGNSC Southaven, LLC***, the relator alleged that the defendants' employment of a director of nursing, who lacked a valid state license to practice in Mississippi, rendered false the defendants' certification of compliance with applicable licensure laws in their requests for payment.[109] At summary judgment, the defendants argued that a nurse's license would be considered invalid only after a state governing board determined it to be invalid in a final adverse action from which there was no appeal. The relator argued that a license becomes invalid once any conduct inconsistent with the license occurs, even before the state governing board determines whether the conduct violates its rules. The district court ruled that CMS "unequivocally" took the defendants' interpretation and granted summary judgment to the defendants, ruling that the certifications were carried out in compliance with Medicare and Medicaid laws and were "demonstrably true and accurate."

In ***U.S. ex rel. Khoury v. Intermountain Healthcare, Inc.***, a vascular surgeon alleged that anesthesiologists and a hospital submitted false claims because the anesthesiologists allegedly were distracted by use of their personal electronic devices (PEDs) during surgeries.[110] The relator argued that use of PEDs during surgery caused the defendants to falsely certify they had provided "reasonable and necessary" services and alleged that the conduct resulted in false claims because it violated the applicable anesthesia payment regulations. The district court dismissed the relator's theory of falsity based on the actual anesthesia payment regulations, holding that those regulations required only presence by the anesthesiologist and that any alleged PED use did not violate those regulations. But, noting that the Tenth Circuit had adopted a "broad" definition of falsity under Medicare's reasonable and necessary standard, the district court held that the relator had adequately alleged false certification claims against the anesthesiologists for certifying that the services were reasonable and necessary.

Finally, in ***U.S. ex rel. Medina v. Stryker Orthopaedics***, the relator alleged that the defendant implant distributor falsely certified that it was buying products from countries which were compliant with the Trade Agreements Act (TAA), even though the defendant knew the products were actually manufactured in China and Malaysia.[111] The district court

> To establish an FCA violation, an FCA plaintiff must prove that the defendant acted with the requisite scienter, which the statute defines as actual knowledge, deliberate ignorance, or reckless disregard.

105 579 U.S. at 180.
106 2022 WL 728903 (9th Cir. Mar. 10, 2022).
107 2022 WL 3594081 (9th Cir. Aug. 23, 2022).
108 2022 WL 1290907 (N.D. Tex. Apr. 29, 2022).
109 2022 WL 983644 (N.D. Miss. Mar. 30, 2022).
110 2022 WL 271760 (D. Utah Jan. 28, 2022).
111 2022 WL 522788 (D.N.J. Feb. 22, 2022).

Applying the ***Safeco*** standard to the FCA is significant because it means that when the government or relators predicate their theory of falsity on an ambiguous statute or regulation, even if a court later finds that the defendant violated that statute or regulation, the defendant cannot be held liable under the FCA if its interpretation of the statute or regulation was objectively reasonable, and it had not been sufficiently warned away from that interpretation.

rejected the defendant's argument that the relator failed to allege any violation of the TAA, holding that, viewing the facts in the light most favorable to the relator, the complaint sufficiently alleged that the defendant falsely certified compliance with the TAA, which would constitute a basis for liability under the FCA.

DEVELOPMENTS REGARDING KNOWLEDGE AND SCIENTER

To establish an FCA violation, an FCA plaintiff must prove that the defendant acted with the requisite scienter, which the statute defines as actual knowledge, deliberate ignorance, or reckless disregard. Last year, we reported that a key development regarding the scienter element was the application to the FCA of the objective scienter standard from the Supreme Court's opinion in ***Safeco Ins. Co. v. Burr***, a case involving the Fair Credit Reporting Act. Under the standard articulated in ***Safeco***, a defendant cannot be found to have acted "knowingly" if: (1) its interpretation of the relevant statute or regulation was "objectively reasonable" (even if ultimately mistaken); and (2) no "authoritative guidance" warned the defendant away from that interpretation.[112] Applying the ***Safeco*** standard to the FCA is significant because it means that when the government or relators predicate their theory of falsity on an ambiguous statute or regulation, even if a court later finds that the defendant violated that statute or regulation, the defendant cannot be held liable under the FCA if its interpretation of the statute or regulation was objectively reasonable, and it had not been sufficiently warned away from that interpretation.

The most important case to address this issue has been ***U.S. ex rel. Schutte v. SuperValu, Inc.***, where a divided Seventh Circuit panel held that ***Safeco's*** objective reasonableness standard did apply to the FCA.[113] Following that decision, the Seventh Circuit again considered the same issue in ***U.S. ex rel. Proctor v. Safeway, Inc.***[114] There, the relator alleged that Safeway's pharmacy submitted false claims to the government by reporting its "retail" price for certain drugs as its "usual and customary (U&C)" price, even though many customers allegedly paid less than the retail price. Following its decision in ***Schutte***, the Seventh Circuit held on summary judgment that the relator could not establish scienter because it was objectively reasonable for Safeway to submit its retail price as its U&C price and no authoritative guidance had warned Safeway off that interpretation. Adding to the analysis, the Seventh Circuit held that authoritative guidance must come from "binding precedent from the courts of appeals or appropriate guidance from the relevant agency." The Seventh Circuit then held that a footnote in the CMS Manual did not constitute authoritative guidance where the manual was not binding on CMS and could be revised at any time. It also was not in a section of the manual directed at the disputed pharmacy programs and was removed from the manual by CMS during the relevant time without explanation.

The Eleventh Circuit followed a similar approach in ***Olhausen v. Arriva Medical, LLC***.[115] The defendant in that case sold mail-order diabetic testing supplies and other medical products, and was alleged to have violated Medicare rules requiring the defendant to obtain signatures from patients on assignment of benefit forms before billing the government. Relying on ***Safeco***, the Eleventh Circuit held that the relator failed to plead scienter because the defendant's interpretation of the Medicare rules was "objectively reasonable."

The Fourth Circuit also addressed the ***Safeco*** standard in 2022. In ***U.S. ex rel. Sheldon v. Allergan Sales, LLC***, a divided Fourth Circuit panel held that ***Safeco's*** objective reasonableness standard applies to the FCA, affirming the district court's grant of the defendant's motion to dismiss.[116] Subsequently, however, the full Fourth Circuit agreed to rehear the case en banc and vacated the panel's opinion. Following rehearing en banc, the Fourth Circuit was evenly divided on the outcome and so entered a per curiam order upholding the judgment of the district court without issuing a substantive opinion.[117] Because the Fourth Circuit considered issues about both the falsity and scienter elements during rehearing en banc, it is unclear what signal to take from the full Fourth Circuit evenly dividing on the case.[118]

112 551 U.S. 47, 69-70 & n.20 (2007).

113 9 F.4th 455 (7th Cir. 2021).

114 30 F.4th 649 (7th Cir. 2022).

115 2022 WL 1203023 (Apr. 22, 2022).

116 24 F.4th 340 (4th Cir. 2022).

117 49 F.4th 873 (4th Cir. 2022).

118 Another Fourth Circuit panel relied on *Sheldon* (before it was vacated) in finding that the relator could not establish scienter where the allegedly violated billing requirement was "ambiguous" and the defendant's "interpretation of the policy and agency guidance is reasonable." *U.S. ex rel. Gugenheim v. Meridian Senior Living, LLC*, 36 F.4th 173 (4th Cir. 2022). There, the Fourth Circuit also noted that there was no evidence that the defendant subjectively knew or even suspected that its interpretation of the billing requirement was incorrect.

In response to these developments, the relators petitioned the Supreme Court for writs of certiorari in ***Schutte***, ***Proctor***, ***Sheldon*** and ***Olhausen***.[119] In ***Schutte***, the Supreme Court invited the U.S. Solicitor General to file a brief expressing the views of the government, and in December, the Solicitor General filed a brief recommending that the Court grant the certiorari petition and reverse the Seventh Circuit's ruling. On January 13, 2023, the Supreme Court granted the certiorari petitions in ***Schutte*** and ***Proctor***, signaling that it will address the FCA's scienter requirement and the ***Safeco*** standard's bearing on it. The Court should issue an opinion in the cases near the end of its term in June 2023.

Other notable cases from this past year addressed scienter issues beyond the reach of ***Safeco's*** standard, which only applies in certain circumstances. In ***U.S. ex rel. Hart v. McKesson Corp.***, the district court confronted how a relator must establish scienter in an FCA case based on violations of the AKS.[120] The relator alleged that the defendant pharmaceutical wholesaler violated the FCA by engaging in a scheme to submit claims tainted by AKS violations—specifically, by providing business management tools to oncology practices that purchased drugs from the defendant. The district court reasoned that in an FCA case predicated on AKS violations, the relator has to satisfy both statutes' scienter requirements. It further held that to satisfy the AKS's requirement that the defendant acted "willfully," the relator must prove that the defendant knew its conduct was unlawful. The district court found the relator failed to make this showing where, among other things, the defendant openly publicized the disputed programs.

In two other cases, district courts found the FCA's scienter element satisfied where the defendant ignored red flags. In ***U.S. ex rel. Wallace v. Exactech, Inc.***, the relator alleged that a medical device manufacturer violated the FCA by conspiring to submit claims to government healthcare programs for knee replacement devices the defendant knew to be defective.[121] Among other evidence the district court considered in denying the defendant's motion for summary judgment, it held that a reasonable juror could find scienter established because the defendant disregarded red flags about high error rates among its devices. Another district court applied a similar analysis in ***U.S. ex rel. Permenter v. eClinicalWorks, LLC***, holding that the relator adequately pleaded scienter as to a healthcare technology company because the flaws in its software were so obvious that the defendant must have known its certifications of compliance with applicable EMR performance requirements were false.[122]

While at the pleading stage allegations of scienter need not meet the heightened requirement of Rule 9(b), they still must satisfy Rule 8(a)'s plausibility standard. Thus, conclusory allegations of knowledge alone are insufficient, as emphasized in ***U.S. ex rel. Taylor v. Boyko***.[123] The relator there alleged that the defendant hospital billed the government for physician-level services provided by mid-level practitioners, with bare allegations that the defendant "knowingly" made false records. The Fourth Circuit dismissed the *qui tam* complaint for failure to plead scienter, holding that such threadbare allegations fall short of meeting Rule 8(a)'s requirement.

Analysis of the FCA's reverse false claim provision often focuses on that provision's relationship to traditional FCA violations.

REVERSE FALSE CLAIMS

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

Analysis of the FCA's reverse false claim provision often focuses on that provision's relationship to traditional FCA violations. Courts continue to require that some additional allegations or evidence be presented to support reverse false claim liability beyond a defendant's alleged "direct" violations of §§ 3729(a)(1)(A) or (a)(1)(B) of the FCA.[124]

Courts also have focused on the scienter of defendants when evaluating reverse false claims issues. In ***U.S. ex rel. Sibley v. University of Chicago Medical Center***, the Seventh Circuit affirmed dismissal of the relators' reverse false claims allegations because the defendant did not have a duty to repay the government nor did it act knowingly in avoiding any such duty.[125] The Seventh Circuit first determined that the relators had not sufficiently pleaded that there was an obligation to repay the government where the allegations stated only generally that an entity engaged to collect bad debt did so with limited staffing and in violation of Medicare rules, but did not include "specific representative examples" of the conduct.[126] Following the Sixth and Tenth Circuits, the Second Circuit also endorsed the "double knowledge" standard for reverse false claims, insisting that a defendant must have known that it: (1) had an obligation to the United States; and (2) was avoiding that obligation. Finding that the complaint included too many inferential leaps to impute knowledge to the

119 *Schutte*, No. 21-1326 (U.S.); *Proctor*, No. 22-111 (U.S.); *Olhausen*, No. 22-374 (U.S.); *Sheldon*, No. 22-593 (U.S.).
120 2022 WL 1423476 (S.D.N.Y. May 5, 2022).
121 2022 WL 2919349 (N.D. Ala. July 25, 2022).
122 2022 WL 17478238 (M.D. Ga Dec. 6, 2022).
123 39 F.4th 177 (4th Cir. 2022).
124 *See U.S. ex rel. DiLello v. Hackensack Meridian Health*, 2022 WL 1284734 (D.N.J. Apr. 29, 2022) (rejecting reverse false claims liability where they merely recast the affirmative claims that the defendant billed CMS when they should not have); *U.S. ex rel. Chihi v. Catholic Health Initiatives*, 2022 WL 2657131 (S.D. Tex. Mar. 31, 2022), adopted sub nom., 2022 WL 2652135 (S.D. Tex. July 8, 2022) (same).
125 44 F.4th 646 (7th Cir. 2022).
126 *See also United States v. Carranza*, 2022 WL 3226191 (E.D. Va. July 1, 2022) (dismissing reverse false claims count where the relator failed to allege any specific obligation owed by the defendant).

A relator's claim can survive the public disclosure bar however if the relator qualifies as an "original source" of the FCA allegations.

defendant, the Seventh Circuit affirmed dismissal. Several district courts have dismissed claims on similar grounds, requiring that relators plead that a defendant was "on notice" of the requirement to repay an obligation.[127]

By contrast, lengthy retention of overpayments remains actionable, particularly where the government itself put the defendant on notice of the overpayment. In ***United States v. Walgreen Co.***, the district court held that the government adequately pleaded an actionable violation of the FCA's reverse false claim provision.[128] The government alleged that the defendant failed to return overpayments associated with fraudulent claims allegedly submitted by a former employee who had pleaded guilty to healthcare fraud. The district court first held that Walgreens could be held vicariously liable under the FCA. It then held that the government adequately pleaded that Walgreens: (1) received money it was not entitled to; (2) had knowledge that it retained fraudulently obtained payments from the government; and (3) failed to act on that knowledge for over five years. It reached this conclusion despite industry objections that such precedent could create potential fraud liability for entities that are negotiating in good faith over differences of opinion on overpayments.

PUBLIC DISCLOSURE BAR

The public disclosure bar is a statutory mechanism designed to deter opportunistic relators from filing parasitic lawsuits based on information substantially similar to information previously disclosed to the public. A relator's claim can survive the public disclosure bar however if the relator qualifies as an "original source" of the FCA allegations.[129]

The public disclosure bar provides a strong defense for a defendant facing allegations of fraud that are duplicative of publicly disclosed information. Once a defendant has asserted the public disclosure bar, the district court must determine: (1) whether a public disclosure previously occurred; (2) whether that disclosure was substantially similar to the relator's allegations; and, if so, (3) whether the relator is nevertheless an "original source" of the FCA allegations.

127 *See U.S. ex rel. DiLello v. Hackensack Meridian Health*, 2022 WL 1284734 (D.N.J. Apr. 29, 2022); *U.S. ex rel. Ginger v. Ensign Grp., Inc.*, 2022 WL 4110166 (C.D. Cal. Mar. 10, 2022) (dismissing reverse false claims where the relator failed to plead that the defendant knew of any false claim or overpayment received).
128 2022 WL 791562 (E.D. Tenn. Mar. 14, 2022).
129 31 U.S.C. § 3730(e)(4).

Jurisdictional vs. Non-Jurisdictional Public Disclosure Bar

Enacted in 2010, the Affordable Care Act (ACA) effectuated numerous changes to the FCA. With respect to the public disclosure bar, the statute previously stated that "No court shall have *jurisdiction* over an action …."[130] Under the ACA, however, the language of the statute was changed to "[a] court *shall dismiss* an action, unless opposed by the government…."[131] Since that statutory modification, most courts have held that the public disclosure bar is no longer jurisdictional but now acts as an affirmative defense that the defendant must prove.

The jurisdictional nature of the public disclosure bar becomes particularly complicated when the alleged conduct occurred both before and after the change in the statutory language in 2010. In ***Foster v. PHH Mortgage***, the relator claimed that beginning in January 2010, the defendant's banks made oral promises to homeowners that they would put their loans in forbearance, only to later renege and put the loans in default.[132] Although some of the initial promises preceded the ACA's 2010 enactment, most of the short sales of the properties occurred months or even years after the change in the FCA. Noting that the Seventh Circuit has "repeatedly declined to decide" whether the public disclosure bar remains jurisdictional under the ACA, the district court ruled that because at least *some* of the alleged conduct occurred when the rule was jurisdictional, the court would interpret the rule as jurisdictional for the *entirety* of the relator's claims.

The district court in ***Mendez v. Drs. Hosp. at Renaissance, Ltd.***, declined to adopt such an across-the-board jurisdictional approach.[133] Although some of the alleged fraud occurred in early 2010 and continued after the enactment of the ACA later that year, the district court held that the public disclosure bar was jurisdictional only for the allegations or transactions that predated the ACA's enactment. The non-jurisdictional public disclosure bar applied to allegations or transactions occurring after the ACA.

What is Considered a Public Disclosure?

Channels of Disclosure

Under the public disclosure bar, courts will dismiss actions or claims that are "substantially the same" as allegations that were publicly disclosed: "(i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party; (ii) in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or (iii) from the news media."[134] Courts have continued to address whether certain specific disclosures fit into those established categories.

In ***U.S. ex rel. Silbersher v. Allergan***, the relator alleged that the defendant pharmaceutical company "fraudulently obtained patents on two drugs to combat Alzheimer's disease and, by virtue of these fraudulent patents, prevented generic drug competitors from entering the market."[135] To obtain the patents, the defendant participated in the *ex parte* administrative proceeding known as a patent prosecution. In a matter of first impression, the Ninth

130 31 U.S.C. § 3730(e)(4)(A) (2009) (emphasis supplied).
131 31 U.S.C. § 3730(e)(4)(A) (2010) (emphasis supplied).
132 2022 WL 17228768 (N.D. Ill. Sept. 30, 2022).
133 2022 WL 584268 (S.D. Tex. Feb. 25, 2022).
134 31 U.S.C. § 3730(e)(4)(A).
135 46 F.4th 991 (9th Cir. 2022).

The term "news media," which is not defined in the FCA, likely allows for a broader application of the public disclosure bar.

Circuit ruled that a patent prosecution constitutes an "other Federal . . . hearing" under the public disclosure bar. Even though the government was not "a party" to those *ex parte* hearings, the government need not be a party to "Federal reports, hearings, audits, and investigations," which are concerned with gaining information rather than conducting adversarial proceedings. Thus, the relator's claims based on information disclosed in the patent prosecution process were barred.

The term "news media," which is not defined in the FCA, likely allows for a broader application of the public disclosure bar. In ***U.S. ex rel. Jacobs v. JP Morgan Chase Bank, N.A.***, the relator alleged that the defendant used forged mortgage notes to defraud Fannie Mae and Freddie Mac.[136] Based on Eleventh Circuit precedent that the term "news media" should have a "broad sweep," the district court held that three publicly available blog articles constituted "news media" for purposes of the public disclosure bar because the blog articles were on a publicly available website designed to disseminate information. The Eleventh Circuit rejected the relator's argument that news media must have some kind of "editorial process," and ultimately dismissed the claims.

Even if the term "news media" can encompass websites, the mere existence of a website describing some actions related to the fraud does not necessarily trigger the public disclosure bar. In ***Mark ex rel. U.S. v. Shamir USA, Inc.***, the Ninth Circuit held that even if websites are considered "news media" under the statute, promotional articles in industry publications giving a generalized description of the defendant's business model did not constitute prior disclosure of fraud allegations.[137] The Ninth Circuit, therefore, reversed the district court's dismissal.

In ***U.S. ex rel. Crocano v. Trividia Health, Inc.***, the district court addressed the public aspect of a public disclosure.[138] The relator alleged that the maker of glucose test strips submitted claims for reimbursement to the government despite knowing that its products were defective and misbranded. Prior to the *qui tam* complaint, the defendant had published press releases concerning the product defects, the FDA issued notices to consumers, and the media reported the product recalls. The district court noted that although the product defects were publicly disclosed, and even if the government knew the defendant submitted claims for defective tests, there was no *public* disclosure that the defendant submitted false or fraudulent claims to the government. Since the "standard is not whether each element of the fraudulent transaction is in the government's possession but rather whether each element of the fraudulent transaction is in the public domain," the district court held that the public disclosure bar did not apply.

136 2022 WL 573663 (S.D. Fla. Feb. 25, 2022).
137 2022 WL 327475 (9th Cir. Feb. 3, 2022).
138 2022 WL 2800380 (S.D. Fla. July 18, 2022).

The district court in ***U.S. ex rel. Schnupp v. Blair Pharmacy, Inc.***, reached a similar conclusion, rejecting the defendant's argument that the allegations were barred by previous disclosures in search warrant records filed with the court, search warrants issued to third parties, and other records related to a criminal investigation.[139] The district court noted that the records were under seal and not publicly disclosed outside the government until after the relator filed his complaint and that the third parties were ordered by the court not to disclose the existence of the warrants or the court's orders except to receive legal advice. The district court also held that disclosures in a prior civil lawsuit did not constitute public disclosures because the post-ACA version of the statute applied, and the government was not a party to the previous lawsuit.

What is "Substantially Similar?"

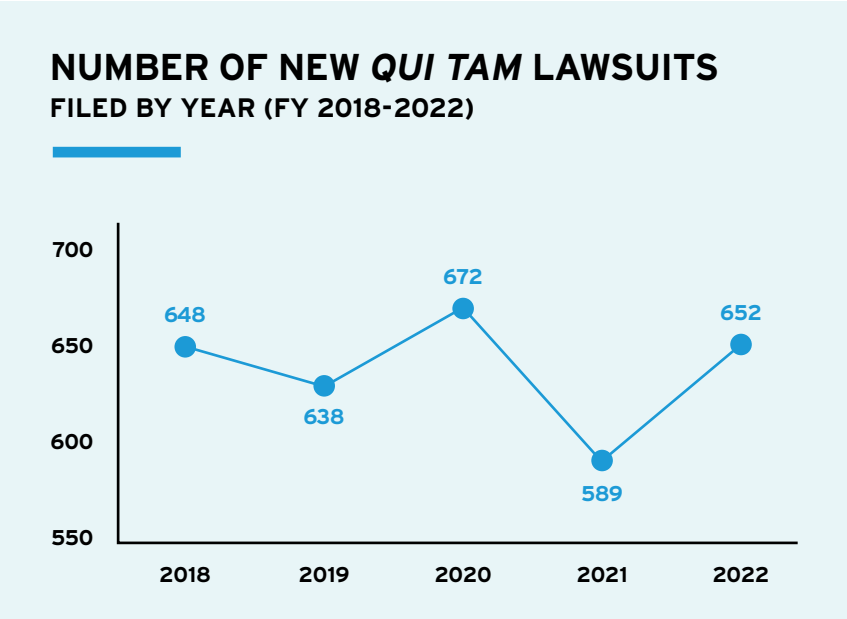
Even if a prior public disclosure occurred via one of the specified statutory channels, the public disclosure bar applies only if the allegations in the prior disclosure are "substantially the same" as the allegations in the present case.[140]

Although relators often argue that some of the facts alleged in their complaints were not publicly disclosed, courts generally have held that not all of the facts in the complaint need to have been disclosed previously for the bar to apply. As the district court held in ***Foster v. PHH Mortgage***, "the public disclosure bar does not require all elements to be in the public domain. Instead, allegations are publicly disclosed if the critical elements exposing the transaction as fraudulent are placed in the public domain."[141] Similarly, in ***Smith v. Athena Constr. Grp., Inc.***, the relator copied and pasted some allegations verbatim from a prior complaint filed by the same relator's counsel in a different district, including 10 additional examples of the defendant using a pass-through scheme to obtain government contracts.[142] The district court dismissed the claim under the public disclosure bar because the prior allegations "could have formed the basis for a governmental decision on prosecution," and adding additional examples therefore did not save the relator's allegations.[143]

However, information about the defendant's practices that do not expose the alleged fraud typically is not substantially similar. In ***U.S. ex rel. Taylor v. Boyko***, the Fourth Circuit held that previous disclosures through an investigation by the West Virginia Department of

Even if a prior public disclosure occurred via one of the specified statutory channels, the public disclosure bar applies only if the allegations in the prior disclosure are "substantially the same" as the allegations in the present case.

139 2022 WL 17584381 (D. Md. Dec. 9, 2022).
140 31 U.S.C. § 3730(e)(4)(A).
141 2022 WL 17228768 (N.D. Ill. Sept. 30, 2022).
142 2022 WL 888188 (D.D.C. Mar. 25, 2022), *cert. denied*, 2022 WL 2513500 (D.D.C. May 27, 2022).
143 *See also Peck v. CIT Bank, N.A.*, 2022 WL 17752388 (N.D. Ill. Dec. 19, 2022) (rejecting the relators' argument that their allegations were not substantially similar to disclosures where they added the allegation that the defendants acted knowingly because the government could "have made the same inference").



Health and Human Resources were not substantially similar to the current FCA allegations because "they focused entirely on asserted deficiencies in medical care" and "[n]othing in the report or investigation touched on billing or alleged fraud."[144]

The district court in ***United States v. Planned Parenthood Fed'n of Am. Inc.*** adopted a similar approach.[145] The defendants argued that the relator's false certification and reverse false claims theories were based on publicly available termination letters from the Texas and Louisiana Medicaid programs, a House Select Committee report, prior litigation, and investigation footage posted to YouTube. The district court noted that none of the public disclosures the defendants cited involved a *false certification* by the defendants. While the letters, reports, litigation, and footage provided information about why the defendants were terminated from the state Medicaid programs, the prior public disclosures did not mention the defendants' false certification of compliance or any obligation to repay ineligible payments. As such, the allegations of fraud in the complaint were not substantially similar to the information that was publicly disclosed.

144 39 F.4th 177 (4th Cir. 2022); *see also U.S. ex rel. Fahn v. GardaWorld Fed. Servs., LLC*, 2022 WL 2655777 (M.D. Ga. July 8, 2022) (holding that the public disclosure bar did not apply because the only prior allegations of fraudulent conduct were from anonymous website comments, while all other public disclosures made no mention of fraudulent falsification of records); *U.S. ex rel. Flanagan v. Fresenius Med. Care Holdings, Inc.*, 2022 WL 17417577 (D. Mass. Dec. 5, 2022) (holding that allegations related to medical director compensation were not barred because the prior disclosures lacked any allegation of fraud or misrepresentation but dismissing allegations related to joint venture agreements based on disclosures in previous *qui tam* litigation).

145 2022 WL 1290907 (N.D. Tex. Apr. 29, 2022).

When Is a Relator an Original Source?

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

In ***U.S. ex rel. CKD Project, LLC v. Fresenius Med. Care Holdings, Inc.***, the Second Circuit analyzed whether the relator qualified as an original source under either the pre-ACA or post-ACA version of the FCA because the relator alleged claims arising both before and after the amendment.[146] The Second Circuit held that the relator did not have "direct and independent knowledge of the information on which the allegations are based" because the relator was an entity formed solely for that litigation. The entity acquired its information from a third party and therefore did not possess direct knowledge. The relator did not have independent knowledge that materially added to the public disclosures under the post-ACA version because the relator provided additional details that, even if independent of the disclosures, did not materially add to them. The Second Circuit noted that providing "detail or color to previously disclosed elements of an alleged scheme" is not a material addition.

One court addressed which party bears the burden of establishing whether a relator is an original source. In ***Smith v. Athena Constr. Grp., Inc.***, the district court noted that when the public disclosure bar was considered jurisdictional, the relator bore the burden of proving original source status but that no court had directly addressed whether the burden shifted after the ACA's enactment.[147] The district court held that since the amended statute states that a court should dismiss an action that has been publicly disclosed "*unless* . . . the person bringing the action is an original source of the information," the original source rule should be treated as an exception to the public disclosure defense. Thus, the district court held that the burden for proving original source status should remain on the relator. Moreover, the district court determined that although the relator had independent knowledge that materially added to any publicly disclosed allegations, he failed to share that information with the government before filing and could not be an original source under either prong.

In contrast, the district court in ***United States v. Planned Parenthood Fed'n of Am. Inc.***, held that the relator squarely met the definition of an original source under both prongs.[148] The relator launched his own "undercover journalistic investigation to determine whether Planned Parenthood and its affiliates were providing fetal tissue collected from abortions to researchers and tissue procurement companies." After conducting his investigation and prior to publicly releasing the investigation footage, the relator shared his information with the Attorney General of Texas, which prompted investigations by the U.S. House of Representatives, DOJ, Federal Bureau of Investigation (FBI), and the states of Texas and Louisiana. The district court held the relator was an original source of the information under

146 2022 WL 17818587 (2d Cir. Dec. 20, 2022).

147 2022 WL 888188 (D.D.C. Mar. 25, 2022), *cert. denied*, 2022 WL 2513500 (D.D.C. May 27, 2022).

148 2022 WL 1290907 (N.D. Tex. Apr. 29, 2022).

The FCA's first-to-file bar prohibits any person or entity other than the government from "interven[ing] or bring[ing] a related action based on the facts underlying the pending action." The rule is designed both to encourage relators to bring allegations of fraud to light swiftly and to prohibit parasitic claims based on existing litigation.

either prong because he informed the Attorney General's office before publicly releasing the footage, and all later public disseminations of information and investigations conducted by the government resulted from the relator's initial disclosure.

Most courts agree that simply adding additional details regarding an alleged scheme do not make a relator an original source. In ***Roe v. Stanford Health Care***, the relator relied almost entirely on Medicare data released through a Freedom of Information Act request to allege that the defendant engaged in fraudulent billing.[149] After determining that this information constituted a public disclosure, the Ninth Circuit affirmed the district court's determination that the original source exception did not apply to the relator. The Ninth Circuit ruled that despite the fact that the relator had "specialized expertise" and had personally observed at least some of the allegedly fraudulent billing, nothing that the relator shared materially added to the information previously made public in the Medicare data. Similarly, in ***U.S. ex rel. Jacobs v. JP Morgan Chase Bank, N.A.***, the district court held that the relator's additional allegations regarding the defendant's attempts to cover up the previously disclosed fraud did not materially add to the core fraud allegations.[150] In both cases, the additional information supplied by the relators was insufficient to invoke the original source exception.

FIRST-TO-FILE BAR

The FCA's first-to-file bar prohibits any person or entity other than the government from "interven[ing] or bring[ing] a related action based on the facts underlying the pending action."[151] The rule is designed both to encourage relators to bring allegations of fraud to light swiftly and to prohibit parasitic claims based on existing litigation.

Jurisdictional vs. Non-Jurisdictional

In ***McClinton on behalf of United States v. SouthernCare, Inc.***, the district court acknowledged a current circuit split about whether the first-to-file bar is jurisdictional.[152] The district court noted that prior to 2015, all circuits to have addressed the first-to-file bar agreed that it was jurisdictional. In light of the Supreme Court's push to limit the "profligate" use of the term "jurisdiction," however, the Court has established a "bright-line rule" that unless Congress clearly stated that a rule is jurisdictional, it should be treated as non-jurisdictional.[153] The district court also noted that although the Supreme Court has not directly ruled on whether the first-to-file bar is jurisdictional, the order in which the Supreme Court addressed arguments in ***Kellogg Brown & Root Servs., Inc. v. U.S. ex rel. Carter***,[154] potentially indicated that the Supreme Court views the first-to-file bar as non-jurisdictional. The district court also noted that as a result of ***Carter***, the D.C., First and Second Circuits have all ruled that the first-to-file bar is non-jurisdictional. However, because the Fifth Circuit had not directly addressed the issue, the district court joined other district courts in the Fifth Circuit in holding that the first-to-file bar remains jurisdictional.

The district court in ***U.S. ex rel. Osinek v. Permanente Med. Grp., Inc.***, agreed with the holding in ***McClinton***.[155] In noting that the Fourth, Fifth, Sixth, Ninth, and Tenth Circuits have held that the first-to-file bar is jurisdictional, while the D.C., First, Second, and Third Circuits have held it is not jurisdictional, the district court relied on Ninth Circuit precedent to hold that the bar is jurisdictional, despite potentially contrary suggestions by the Supreme Court.

What is Another "Pending Action"?

To invoke the first-to-file bar, a related action already must be pending. Although consolidating separate actions involving the same underlying facts under Federal Rule of Civil Procedure 42 may be preferred in other cases, the FCA must balance two primary purposes that may be contrary to consolidation: (1) to incentivize prompt reporting of fraud; and (2) to prevent parasitic lawsuits.

In ***U.S. ex rel. Byers v. Amedisys SC LLC***, the district court weighed these considerations in the context of four separate *qui tam* complaints.[156] The first relator filed her lawsuit in the District of South Carolina in 2015, alleging that the defendants submitted or caused the submission of false or fraudulent claims to Medicare for ineligible hospice patients. A year later, three different relators filed separate but substantially related lawsuits in the Southern District of West Virginia and the Eastern District of New York. In consultation with the government, all of the relators agreed to consolidate the cases in the District of Massachusetts. The defendants moved to dismiss the three subsequent relators' complaints under the first-to-file bar. The district court granted that dismissal and held that "consolidation cannot be used to circumvent the first-to-file rule."

In ***United States v. Allstate Ins. Co.***, the district court reached a different result when a relator added a co-relator to an existing complaint by amendment.[157] The relator filed a *qui tam* FCA complaint alleging the defendant failed to make required reports to the government of their primary payor status and denied known obligations to pay. The relator's second amended complaint attempted to add a co-relator under Federal Rule of Civil Procedure 15. The district court noted that the Sixth Circuit has not addressed whether adding a

149 2022 WL 796798 (9th Cir. Mar. 15, 2022).
150 2022 WL 573663 (S.D. Fla. Feb. 25, 2022).
151 31 U.S.C. § 3730(b)(5).
152 2022 WL 1233212 (S.D. Miss. Apr. 26, 2022).
153 *Sebelius v. Auburn Reg'l Med. Ctr.*, 568 U.S. 145, 153 (2013).
154 575 U.S. 650 at 656, 662 (2015).
155 2022 WL 1422944 (N.D. Cal. May 5, 2022).
156 2022 WL 4237076 (D.S.C. Sept. 14, 2022).
157 2022 WL 3213529 (E.D. Mich. Aug. 9, 2022).

The first-to-file bar prohibits bringing subsequent "related action[s]" under the FCA. It is not always clear, however, how "related" claims must be to invoke the first-to-file bar. Since a subsequent claim rarely duplicates a prior action, courts must compare the claims extensively to determine if they include the same essential elements of fraud.

co-relator by amendment violates the first-to-file rule, but the Third and Fifth Circuits had permitted such an addition. The district court agreed with those Circuits and ruled that while the first-to-file bar prohibited interventions in existing suits or separate, but related suits, it said nothing about voluntarily adding co-relators to the same suit. The district court distinguished "intervention" by a non-party under Federal Rule of Civil Procedure 24 from the voluntary inclusion of a non-party by an existing party via Federal Rule of Civil Procedure 15. In these circumstances, the district court determined that the first-to-file bar did not apply.[158]

Even if a prior action exists, the first-to-file bar only applies if the prior action is "pending" at the time of the subsequent action, which can lead to complicated questions when prior and subsequent actions are filed, settled, and amended. For example, in ***McClinton***, the initial action was filed in 2013, but was settled and dismissed in 2018.[159] That action unquestionably was still "pending" when a subsequent action was filed in 2016. However, the relator in the subsequent action filed an amended complaint in 2021. The district court noted that the Supreme Court has stated that because "pending" means "undecided," the first-to-file bar no longer applies once the "pending" action is dismissed. Circuit courts are split about whether the jurisdictional defect can be cured by a subsequent amendment. Siding with the Second and D.C. Circuits, the district court held that the first-to-file bar applies as long as the subsequent claim is related to another claim that was pending at the time of the original filing. To allow relators to cure their first-to-file deficiencies by later amendment would undermine the first-to-file bar's purpose of encouraging prompt reporting of fraud.

158 Although the district court did not dismiss the claims under the first-to-file bar, it did dismiss the claims under the public disclosure bar based on prior disclosures in news articles and legal actions.
159 2022 WL 1233212 (S.D. Miss. Apr. 26, 2022).

How Similar Must the Claims Be?

The first-to-file bar prohibits bringing subsequent "related action[s]" under the FCA. It is not always clear, however, how "related" claims must be to invoke the first-to-file bar. Since a subsequent claim rarely duplicates a prior action, courts must compare the claims extensively to determine if they include the same essential elements of fraud.

The district court conducted this detailed analysis in ***U.S. ex rel. Jahr v. Tetra Tech EC, Inc.***[160] A series of relators filed four different *qui tam* actions related to work by government contractors to remediate radiation contamination at a former naval shipyard. When the defendants moved to dismiss the three subsequent complaints under the first-to-file bar, the district court compared in detail the allegations identified in the initial complaint with those included in the subsequent complaints. Stating that its analysis turned on whether the previous allegations provided the government with notice of the material facts of the fraud alleged in the subsequent complaints, the district court dismissed portions of the third and fourth complaints and dismissed the second one in its entirety.

In ***Cho on behalf of States v. Surgery Partners, Inc.***, the relator alleged that the defendants, a medical provider and private equity firm, submitted false claims to government payors through operating surgery and pain management centers and diagnostic testing labs.[161] The district court had dismissed the relator's claims under the first-to-file bar because an action by a different relator for similar claims was still pending against some of the defendants when the present claim was filed. As in ***McClinton,*** the Eleventh Circuit held that it is the relator's original complaint, not any subsequent amendments, that should be used to compare to any related pending actions. As a matter of first impression, the Eleventh Circuit also ruled that courts should apply the "same essential elements" test to determine whether subsequent actions are sufficiently "related" to be dismissed under the first-to-file bar. Under this test, actions are "related" if they "incorporate the same material elements of fraud." Despite the fact that the subsequent action added another defendant

The FCA's statute of limitations can significantly limit or require dismissal of an FCA claim. Under 31 U.S.C. § 3731(b), an action asserting FCA claims must be brought within the later of: (1) six years after the FCA violation occurred; or (2) three years after the United States official charged with responsibility to act knew or should have known the material facts, up to 10 years after the violation.

160 2022 WL 2317268 (N.D. Cal. June 28, 2022).
161 30 F.4th 1035 (11th Cir. 2022).

and a conspiracy claim, the Eleventh Circuit ruled that the pending action focused on the same fraudulent scheme as the original complaint of the subsequent action, and the court affirmed the district court's dismissal.

The district court conducted a similar analysis in ***U.S. ex rel. Osinek v. Permanente Med. Grp., Inc.***, holding that courts analyzing the first-to-file bar should compare the original version of the subsequent complaint to the version of the prior complaint that was operative at the time of the subsequent filing.[162] Citing ***Cho***, the district court noted that adding additional defendants "does not necessarily allow a later-filed action to evade the first-to-file bar," and that the analysis may depend on the scope of the fraud alleged. If the original complaint alleges a small-scale or localized fraud, the addition of new defendants may be permitted, but if the original complaint includes allegations of a nationwide or corporate-wide problem, the inclusion of additional affiliated defendants likely will not overcome the first-to-file bar. Because the initial complaint was limited to claims only in California, the second relator's complaint alleging a corporate-wide fraudulent scheme was not barred.

STATUTE OF LIMITATIONS

The FCA's statute of limitations can significantly limit or require dismissal of an FCA claim. Under 31 U.S.C. § 3731(b), an action asserting FCA claims must be brought within the later of: (1) six years after the FCA violation occurred; or (2) three years after the United States official charged with responsibility to act knew or should have known the material facts, up to 10 years after the violation. In the 2019 decision ***Cochise Consultancy, Inc. v. U.S. ex rel. Hunt***, the Supreme Court held that both limitation periods apply to a declined *qui tam* action.[163] That is, a relator may proceed with a declined *qui tam* action filed more than six years after the FCA violation occurs if it is filed within three years of when the relevant government official—and not the relator—should have known the material facts.

While such issues have resulted in high-profile opinions in prior years, there have been only a smattering of recent FCA district court cases implicating statute of limitations issues. In ***Osinek***, Kaiser-affiliated entities faced allegations from the government in its complaint in intervention that those entities violated the FCA by unlawfully obtaining payments from Medicare Part C by altering patient medical records to add diagnoses that did not exist or that were unrelated to the patient visits with Kaiser physicians.[164] The defendants asserted that such claims should be dismissed as time-barred with § 3731(b) acting as both a statute of limitations and repose to the extent the government's claims were based on conduct occurring more than 10 years prior to the filing of the government's complaint. In response, the government asserted that relation back should toll the repose period in light of prior lawsuits filed against Kaiser in 2013 and 2014, which would allow the government to wrap

Following *Escobar*, discovery disputes regarding requests from the government concerning its agencies' prior and current payment and enforcement practices continue to be litigated in both intervened and declined cases.

in conduct occurring six years prior to those lawsuits. The district court ultimately agreed with the government's position, concluding that relation back should keep the repose period intact as relation back pinpointed when the claim arose.[165]

In ***U.S. ex rel. Frey v. Health Mgmt. Sys., Inc.***, the district court considered a motion to dismiss a relator's claims that a state Medicaid contractor impaired certain states' obligation to remit money to the federal government in connection with regulations related to the recovery of funds from third-party insurers.[166] The defendant asserted that the relator's claims were time-barred as a result of an HHS-OIG report that largely presented the same allegations in the relator's complaint. While the district court acknowledged that the HHS-OIG report "cover[ed] much of what Relator alleges in the [Second Amended Complaint]," no evidence existed about "the dissemination of the HHS-OIG report or specifically, whether the Report was ever sent to DOJ." As a result, the district court would not apply the FCA's statute of limitations to bar the relator's claims because it was "unable to find that the DOJ 'knew or reasonably should have known' of the facts underlying Relator's FCA claims."

DISCOVERY DEVELOPMENTS

Following *Escobar*, discovery disputes regarding requests from the government concerning its agencies' prior and current payment and enforcement practices continue to be litigated in both intervened and declined cases. Other issues including the proper temporal scope and extent of discovery requests in FCA cases likewise continue to be considered by courts.

Government Related Discovery Requests

In ***U.S. ex rel. Silver v. Omnicare, Inc.***, the defendant sought documents and testimony from CMS in a declined *qui tam* involving allegations the defendant engaged in a scheme to offer nursing homes below market prices for prescription drugs to patients insured by

162 2022 WL 1422944 (N.D. Cal. May 5, 2022).
163 139 S. Ct. 1507 (2019).
164 2022 WL 16925963 (N.D. Cal. Nov. 14, 2022).

165 Courts also have considered the impact of relation back the FCA's limitations period. In *U.S. ex rel. Gray v. Mitias Orthopaedics, PLLC*, the district court considered whether § 3731(c)'s relation back provision applied to new defendants added to a lawsuit and how that consideration might intersect with Federal Rule of Civil Procedure 15(c)(1)(C)'s notice and knowledge factors. 2022 WL 1123796 (N.D. Miss. Apr. 14, 2022). The district court did not decide the issue but indicated an inclination to reject the defendant's assertion that the date of the filing of the government's complaint should be controlling for purposes of the FCA's statute of limitations and to accept the government's position that the cause of action under the FCA arose when the relator filed the initial *qui tam* complaint. Likewise, in *U.S. ex rel. Dunn v. Procarent, Inc.*, the district court considered relation back under Federal Rule of Civil Procedure 15(1)(B) in regards to an amended complaint and the assertion of a new theory of liability asserted by the relator. 2022 WL 2834685 (W.D. Ky. July 20, 2022). The district court dismissed the claim on other grounds and it was not necessary to reach the question of the application of the FCA's statute of limitations.
166 2022 WL 976161 (N.D. Tex. Mar. 31, 2022).

Medicare Part A to secure referrals of prescription drugs for patients insured by Medicare Part D and Medicaid.[167] CMS denied the requests but agreed to continue negotiating the scope of requested documents and testimony, eventually identifying a potential witness for deposition who had availability only after the fact discovery deadline. The relator moved to quash the subpoena to depose CMS outside of the court-ordered period for fact discovery. The magistrate judge found lack of good cause to modify the discovery schedule to allow the deposition and the district court affirmed, finding "the record demonstrates [defendant] was not diligent in pursuing the CMS deposition," waiting until the end of each impending, twice-extended fact discovery deadline to pursue the requested information and testimony. The district court rejected the defendant's argument that CMS had reneged on its promise to produce a witness in a timely manner, noting that CMS had merely *identified* a potential witness, not agreed to produce a witness for deposition, and CMS and the defendant had never reached agreement on the scope of the deposition. Further, the district court found the defendant had not "provided a basis as to why the discovery deadline could not have been reasonably met if [defendant] had pursued the deposition issue prior to mere days before the discovery end date."

Similarly, in ***U.S. v. Teva Pharms. USA, Inc.***, a case involving allegations that the defendant submitted false claims tainted by kickbacks the defendant paid in the form of illegal co-pay subsidies for one of its multiple sclerosis drugs, Copaxone, the defendant moved to compel the production of various categories of subpoenaed information regarding Medicare patients, including pharmacy claims data, medical claims data, and coverage and other eligibility data.[168] The magistrate judge issued a report and recommendation denying the motion on relevance grounds, finding the requested data was irrelevant to various key issues, including the defendant's intent to induce purchases of Copaxone by Medicare patients and any potential penalties or the calculation of damages. The defendant filed an objection, arguing the magistrate judge's ruling was clearly erroneous because: (1) the order framed the denial on relevance grounds, rather than addressing the proportionality factors in Federal Rule of Civil Procedure 26(b); and (2) in denying the requests for information related to the government's true out-of-pocket losses under a "benefit-of-the-bargain" approach to damages, the magistrate judge had prematurely decided that the measure of damages in the case would be the full amount of any kickback-tainted claims, which the defendant argued was contrary to law.

The district court adopted the magistrate judge's ruling over the defendant's objection and denied the motion to compel, finding the proportionality arguments were addressed in both written and oral arguments and considered on the whole. The district court also agreed with the magistrate judge's conclusions about the irrelevance of the requested discovery. Finally, the district court noted that while the First Circuit had not adopted the Seventh Circuit's holding in ***U.S. v. Rogan*** regarding the appropriate measure of damages in AKS-based FCA cases, the magistrate judge's citation to ***Rogan*** was not contrary to law because the defendants did not present any "'apposite authority' to ***Rogan*** to support its 'benefit of the bargain' damages position."

When the requesting party is the government itself, courts appear to be more deferential regarding the scope of discovery. In ***Matter of Admin. Subpoenas Duces Tecum Served Upon Missouri Baptist Med. Ctr.***, the government issued two separate administrative subpoenas to Missouri Baptist Medical Center and Missouri Baptist Hospital-Sullivan.[169] The subpoenas related to a criminal investigation of a single physician and his medical group for potential false claims relating to medically unnecessary, upcoded, or non-rendered services. The subpoenas sought seven categories of information from the hospitals. The parties negotiated the scope of the requests and the government agreed to: (1) strike the portion of the instructions requesting information from not only the hospitals but "any and all related entities" and employees; (2) clarify it did not seek any documents covered by the attorney-client privilege; and (3) marginally narrow the request for meeting minutes at which the physician was a topic of discussion, specifying meetings of certain hospital bodies and types of discussions. The defendant hospitals jointly moved to quash or modify and for entry of a protective order, objecting that the requests were overbroad and unduly burdensome even as modified.

After finding the standards for enforcing the administrative subpoena were met, the district court upheld the requests, noting the disclosures were not unreasonable or oppressive. The district court rejected the defendants' arguments to the contrary, finding the hospitals "fail[ed] to indicate exactly why or how compliance…will be an undue burden," and noting that the requests "seek a limited universe of records related to a single provider during a reasonably restricted time frame." Despite some of the requests seeking information for periods that would potentially be time-barred by the applicable statute of limitations, the district court upheld the requests, noting that the limitations period "does not foreclose discovery…because an act beyond the period of limitations may constitute relevant background evidence in a proceeding in which a current practice is at issue." The district court likewise rejected other cited bases for quashing, refusing to recognize the applicability of the peer review or insurer-insured privilege in the context of the federal criminal investigation and rejecting the defendants' "mistaken" argument that DOJ was not a health oversight agency under relevant regulations to whom the hospitals could disclose de-identified patient information. The district court also rejected the defendants' request for a protective order, noting they were permitted to disclose de-identified information to DOJ, and DOJ had already agreed to return original documents following the completion of its investigation and any post-conviction proceedings.

Government's Investigation Documents

In ***U.S. ex rel. Odom v. SouthEast Eye Specialists, PLLC.***, the district court granted in part and denied in part the defendant's motion to unseal documents filed in pleadings by the government during its investigation and following the intervention deadline.[170] The government initially declined intervention following more than two years of investigation but then moved to intervene six months later, claiming the emergence of "new evidence" resulting from its continued investigation and filing an affidavit of a federal agent to support its position. The district court held two hearings and ultimately denied the government's

167 2022 WL 4354321 (D.N.J. Sept. 20, 2022).
168 2022 WL 6820648 (D. Mass. Oct. 11, 2022).
169 2022 WL 1802809 (E.D. Mo. June 2, 2022).
170 586 F. Supp. 3d 787 (M.D. Tenn. Feb. 26, 2022).

motion, finding lack of good cause for late intervention. The government appealed, at which point the defendant moved to unseal all documents remaining under seal. The government then voluntarily dismissed its appeal.

Against this backdrop, the district court granted the defendant's request to unseal the government's affidavit. Although the district court found the affidavit was covered by the investigative and deliberate process privileges, it noted the government waived these qualified privileges by relying on the very content they sought to keep redacted during oral argument in the public hearing on the government's motion for intervention. Conversely, the district court denied the defendant's request to unseal the government's memoranda seeking seal extensions. The district court found these were covered by the investigative or law enforcement privilege and that the defendant had not rebutted the presumption against lifting the privilege given the district court's denial of the government's bid to intervene. The redacted information in the memoranda "include[d] information about the techniques and procedures the Government had, or intended, to employ, and suggest potential sources." Finally, the district court found no compelling reason to replace the transcript from its final hearing on the government's motion for intervention with a redacted version of the same. The district court noted the transcript was available for purchase by the public and filed on the public docket for two months prior to the government's request for it to be redacted and the "bell cannot now be unrung."

In ***Mason v. U.S. Dept. of Justice-Civil Div.***, after the government investigated *qui tam* allegations of improper hospital admissions from 2010 to 2017 and resolved those allegations through settlements in 2017 and 2018, the relator's retaliation claim was remanded to the district court.[171] The relator issued *Touhy* requests and accompanying subpoenas to DOJ's Civil and Criminal divisions seeking: (1) presentations made to DOJ; and (2) reports of witness interviews conducted by DOJ during investigation. Both DOJ divisions agreed in part to the requests, producing only the deposition transcript of one deceased deponent. After narrowing the requests and engaging in multiple meet-and-confers, the relator moved to compel one deposition and DOJ's interview summaries for 28 individuals that DOJ refused to provide.

The district court denied the relator's motion to compel, finding the relator had not shown substantial need or undue hardship under the applicable rules. First, the district court agreed that the relator failed to show that it could not obtain the substantial equivalent of the information sought by any other means without undue hardship. The district court noted "merely offering generalized statements that the witnesses will likely be unable to recall details about the alleged wrongdoing, while an entirely reasonable assumption, is insufficient to show undue hardship," and the time and expense with other methods of obtaining the information also did not suffice to show undue hardship. Second, the district court observed the relator failed to provide the required "individualized explanation of relevancy" regarding each document requested, and so, had failed to show particularized substantial need. Third, the district court held the passage of time alone was not enough to show substantial need, distinguishing other cases where this was found to be the case because in those cases, the government was an adversarial party. The district court acknowledged that "while…the period Plaintiffs were barred from taking discovery was unusually long, it is (unfortunately) hardly unique in the *qui tam* context."

171 2022 WL 737459 (W.D.N.C. Mar. 10, 2022).

Attempted Use of Discovery to Satisfy Rule 9(b)

In ***U.S. ex rel. Sedona Partners LLC v. Able Moving & Storage, Inc.***, the relators attempted to supplement their second amended complaint (SAC) with information obtained in discovery to satisfy Rule 9(b)'s heightened pleading standard.[172] The defendants moved to strike the information obtained in discovery and dismiss the SAC. The district court adopted the magistrate judge's report and recommendation to dismiss the SAC, strike the information obtained by the relators in discovery, and dismiss with prejudice. Citing ***Bingham v. HCA, Inc.***, the district court agreed that the relators may not use information obtained in discovery to satisfy Rule 9(b)'s pleading requirements in an amended complaint and it is proper to strike allegations based on materials obtained during discovery if striking would prevent the relators from circumventing the particularity requirement of Rule 9(b).[173] The relators' argument did not persuade the district court that the Eleventh Circuit's concerns in ***Bingham*** were not implicated because their discovery materials substantiated the claims in the first amended complaint, noting that if this were the standard, Rule 9(b) would be rendered a nullity. The district court also noted that dismissal with prejudice would be as to the relators only and the government could still pursue the claims if it chose to do so.

Staying Discovery Pending Dispositive Motion

In ***U.S. ex rel. Schroeder v. Medtronic, Inc.***, the defendants asked the district court to stay discovery or enter a protective order as to various categories of information requested by the relator pending the court's ruling on the defendants' partial motion to dismiss the relator's fourth amended complaint.[174] The defendants argued that the requests were aimed at discovering information about allegations the defendants had already settled with the government in a separate matter after the government's five-year investigation, and discovery would be overly burdensome and wasteful in light of their partial motion to dismiss the fourth amended complaint on public disclosure bar grounds.

After reciting the general rule that discovery is not stayed simply because a dispositive motion is pending, the district court granted the requested stay, agreeing "a partial stay is appropriate in this specific factual scenario because proceeding with the discovery would be unnecessary and burdensome." The defendants also argued that the delay of discovery would not unduly prejudice the relator as the pending motion to dismiss would necessarily be decided on the sufficiency of the fourth amended complaint, not evidence extrinsic to that pleading. In response, the relator claimed that they would be prejudiced because the public disclosure affirmative defense at issue in the motion to dismiss had been waived when the defendants did not raise it in response to earlier complaints. The district court

172 2022 WL 4115255 (S.D. Fla. Sept. 9, 2022).
173 783 F. App'x 868 (11th Cir. 2019).
174 2022 WL 4365703 (D. Kan. Sept. 21, 2022).

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

rejected this argument, noting the earlier complaints did not cover the same breadth of allegations or number of employees that could render the prior settled allegations relevant and potentially trigger the public disclosure bar.

ISSUES INVOLVING RELATORS

Retaliation

The FCA protects whistleblowers from adverse employment actions related to their efforts to stop violations of the statute.[175] To establish a prima facie FCA retaliation claim, plaintiffs must show that: (1) they engaged in protected activity; (2) their employer knew that they engaged in protected activity; and (3) their employer took an adverse employment action against them as a result. If a plaintiff makes this showing, the burden shifts to the employer to give a legitimate, non-retaliatory reason for the adverse action, which the plaintiff can rebut by demonstrating it was pre-textual.

Protected Activity and the Underlying Fraud. The starting point in any analysis of an FCA retaliation claim is determining whether the plaintiff-employee engaged in protected activity that was either "in furtherance" of an FCA action or part of any "other effort[] to stop 1 or more [FCA] violations." While an activity in furtherance of an FCA action (such as filing a *qui tam* lawsuit) can be intuitively a protected activity, what constitutes an "other effort" is often the subject of dispute. As courts have continued to analyze when a plaintiff efforts to stop an FCA violation, they typically look to whether a plaintiff-employee had an objectively reasonable belief that fraud on the government was occurring.

Issues considered in ***U.S. ex rel. Sibley v. Univ. of Chicago Medical Center*** highlighted how an employee's role within a company and the procedural posture of a case can impact a court's assessment of whether an employee's belief is objectively reasonable.[176] There, the Seventh Circuit reversed in part a district court's order dismissing FCA retaliation claims of three employees who allegedly were terminated after complaining their employer was violating Medicare debt collection regulations. As an initial matter, the Seventh Circuit found error in the district court's overreliance on cases decided at the summary judgment stage—where courts weighed the parties' showing of evidence—in dismissing the plaintiffs' complaint. The Seventh Circuit explained the plaintiffs need only allege facts that, "when viewed in their favor, support the inference that it was objectively reasonable for them to believe their employers were committing fraud against the government."

Assessing the allegations, the Seventh Circuit concluded that two of the plaintiff-employees adequately pleaded that they engaged in protected activity because they held managerial roles with the defendant-employer (a director supervising 12 employees and a manager in the bad debt collections and legal departments) and had first-hand, personal knowledge of the alleged conduct and how it allegedly violated Medicare regulations. As for the third employee, the Seventh Circuit found that she lacked a reasonable basis to believe that her employer was causing the submission of false claims and thus failed to plead she engaged in protected activity. In reaching this conclusion, the Seventh Circuit noted that this plaintiff was a lower-level customer service representative who complained about double billing but could not explain why the alleged practice was illegal or how any of her concerns related to claims submitted to the government.

In ***Simon ex rel. Fla. Rehab. Assocs., PLLC v. HealthSouth of Sarasota Ltd. P'ship***, the Eleventh Circuit measured the reasonableness of the plaintiff's belief that false claims were submitted against substantive FCA law on the issue of falsity.[177] The plaintiff, a physiatrist, was terminated after making verbal complaints that her employer was pressuring physiatrists to bill for a diagnosis (disuse myopathy) that she believed was fabricated. In affirming summary judgment in favor of the defendant-employer, the Eleventh Circuit explained that the plaintiff failed to show she had an objectively reasonable belief that her employer was submitting false claims to the government because she did not "establish that disuse myopathy is not a valid condition such that it is a false claim to submit billing based on it for government reimbursement." The Eleventh Circuit observed that the plaintiff herself had diagnosed patients with disuse myopathy and offered no evidence showing other doctors diagnosed patients with disuse myopathy to fraudulently obtain money from the government.

Relying on its opinion in ***United States v. AseraCare***, the Eleventh Circuit further noted that a reasonable difference in opinion or medical judgment amongst physicians is not sufficient to render those judgments false under the FCA, even if another physician later contends they were wrong. Rejecting the plaintiff's argument that ***AseraCare's*** standard concerns the requisite proof for falsity as to FCA *qui tam* claims and has no bearing on the FCA's anti-retaliation provision, the Eleventh Circuit reasoned that objective reasonableness

175 31 U.S.C. § 3730(h).

176 44 F.4th 646 (7th Cir. 2022).
177 2022 WL 3910607 (11th Cir. Aug. 31, 2022).

While the parameters of protected activity can vary from court to district court, at a minimum, a plaintiff's complaints about alleged wrongdoing must have some connection to the FCA.

must be viewed against existing substantive law. Because the plaintiff offered nothing more than her own medical opinion, the Eleventh Circuit concluded the plaintiff could not establish an objectively reasonable belief.

Similarly, in ***Corson v. JAMHI Health and Wellness, Inc.***, the district court granted summary judgment, holding that the plaintiff failed to demonstrate that he engaged in protected activity where he complained that his employer was violating Medicaid regulations by using procedures to restrict client rights, but "offer[ed] nothing in the way of evidence" other than his own, subjective belief that the alleged violations "might be a condition of Medicaid or Medicare funding."[178] The district court reached the opposite conclusion as to other conduct that the plaintiff alleged (complaints that his employer was amending certain billable service hours), explaining that "a reasonable jury could conclude that plaintiff was engaged in protected activity when he raised concerns about editing the service notes." The district court noted that whether the edits were substantive or technical in nature was a material fact question that precluded summary judgment on this issue.

Finally, while the parameters of protected activity can vary from court to district court, at a minimum, a plaintiff's complaints about alleged wrongdoing must have some connection to the FCA. The district court's opinion in ***Ling v. Pharmacy Alternatives, LLC***, underscored this baseline requirement. There, the district court granted an employer's motion to dismiss because the employee did not link any of her complaints about state law violations to possible FCA violations, even though the plaintiff repeatedly raised concerns to company executives that the company was violating state licensing laws.[179] As the district court further explained, the fact that the plaintiff had "found a way to link her complaints" to a possible FCA violation *after* her termination had no bearing on whether she engaged in protected conduct, or notified her employer of the same, *before* her termination.

District courts also have wrestled with how a plaintiff's responsibilities and obligations can affect what a plaintiff may be required to show to satisfy the FCA's notice element.

Employer Notice. Even if a plaintiff can demonstrate engaging in conduct protected by the FCA, the plaintiff also must show that his or her employer knew about that conduct to have a viable retaliation claim. Often plaintiff-employees satisfy this element by reporting fraud or unlawful activity to a supervisor, but the crux of this element is simply whether the employer was on notice that the plaintiff-employee tried to stop a potential FCA violation before taking any adverse action.

Not all plaintiffs are treated equally, however. For instance, many courts require compliance officers (and other employees with compliance-related responsibilities) to go above and beyond their daily duties to give an employer sufficient notice of protected activity. The Third Circuit explored what exactly a compliance officer must do to satisfy the notice element in ***U.S. ex rel. Ascolese v. Shoemaker Construction Co.***[180] There, a compliance officer raised several complaints that his employer falsely certified compliance with safety standards to obtain federal funds, first by emailing management and subsequently by alerting the entity that hired his employer. In reversing the district court's order granting the employer's motion to dismiss, the Third Circuit found that the compliance officer sufficiently pleaded his employer had notice of the officer's protected activity by alleging he had gone outside of his normal chain of command and beyond his normal job responsibilities to tell management his employer was receiving fraudulent government funds. As further support, the Third Circuit cited the compliance officer's allegations that he made several external reports about his concerns and continued to do so, even after management expressly told him to "keep his concerns to himself and not relay them [externally]."

District courts also have wrestled with how a plaintiff's responsibilities and obligations can affect what a plaintiff may be required to show to satisfy the FCA's notice element. The district court in ***Tener v. Mercy Health Services-Iowa, Corp.***, granted a motion to dismiss an FCA retaliation claim where the plaintiff (a nurse serving as director of a cardiovascular service line) failed to allege that her hospital-employer had sufficient notice of her complaints about illegal activity and fraud.[181] In reaching this decision, the district court emphasized that state regulations created an ethical legal obligation for nurses to report certain conduct, yet the plaintiff did not allege making reports "in such a manner to provide notice she was acting beyond the responsibilities and obligations entailed by her position and occupation." Even though the nurse repeatedly complained about potential medical malpractice, she only alleged one instance of reporting concerns about fraud, which the district court found insufficient to plead notice, "particularly given her managerial and occupational role."

178 2022 WL 356773 (D. Alaska Feb. 7, 2022).

179 2022 WL 36404 (D. Kan. Jan. 4, 2022).
180 55 F.4th 188 (3d Cir. 2022).
181 2022 WL 2972219 (N.D. Iowa July 27, 2022).

The notion that certain employees have a higher burden for retaliation, though, is not universally accepted. In ***Lord v. Univ. of Miami***, the district court observed that, because the FCA's anti-retaliation provision specifically protects "[a]ny employee," it would contradict the statutory test to place a higher burden on some employees than others, regardless of their official responsibilities.[182] There, a high-ranking university executive allegedly informed the university president, based on preliminary reports from an external audit the executive initiated, that the university was potentially facing $10 million in liability for overbilling. Additionally, during the audit, the university received a letter from OIG alleging similar overbilling claims, which the executive forwarded to the university board of trustees with the university president copied. In denying summary judgment, the district court found that the factual record "would easily permit a jury to conclude" that the university knew of plaintiff's protected activity, even under a heightened standard for compliance officers.

Causation and Pretext. Courts have continued to parse how plaintiffs must plead and prove a causal connection between an adverse employment action and their protected activity under the FCA. In ***Crosbie v. Highmark, Inc.***, the Third Circuit upheld the district court's grant of summary judgment for the defendants where the plaintiff had not demonstrated the employer's stated rationale for his firing was pretextual.[183] Specifically, the former employee argued that he was fired for reporting fraud a year earlier, while the defendants responded that they had fired him after an internal investigation confirmed he had mistreated a colleague. The Third Circuit's rejection of the plaintiff's retaliation claim shows courts may defer to the findings of an independent, while imperfect, internal investigation into a potential whistleblower's misconduct. As the Third Circuit succinctly put it: "[w]histleblowing does not insulate an employee from being fired for misconduct."

Some courts have found that a very close temporal proximity between the employee's protected activity and the employer's action can permit an inference of retaliatory motive, as occurred in ***Allgood v. Baptist Memorial Medical Group, Inc.***[184] In that case, the employee was suspended less than 48 hours after she reported suspected billing fraud. The district court ruled that a jury could find she had established a prima facie case of retaliation because the temporal proximity of the two events raised an inference that the plaintiff was suspended, at least in part, because of her protected activity.

The district court in ***Kane v. Quorum Health Resources, LLC***, highlighted that, to demonstrate a causal link to the employee's protected activity, the entity that took adverse action against the employee must have retaliatory animus.[185] The district court granted the defendants' motions for summary judgment because the former chief financial officer's (CFO's) termination was recommended by an independent consultant hired to evaluate the entire leadership team. The district court found there was insufficient evidence to indicate anyone with a retaliatory animus against the plaintiff influenced the independent evaluation. Thus, there was no genuine issue of material fact as to whether the CFO's protected activity was the "but-for" cause of her termination.

182 2022 WL 4767772 (S.D. Fla. Aug. 8, 2022).
183 47 F.4th 140 (3d Cir. 2022).
184 2022 WL 1306747 (W.D. Tenn. May 2, 2022).
185 2022 WL 4010668 (D. Colo. Aug. 4, 2022).

Although *qui tam* complaints initially are filed under seal and thus conceal the relator's identity during the seal period, courts have addressed whether the relator's identity should remain concealed when a *qui tam* matter does not proceed to litigation.

Most courts have concluded, like ***Kane***, that the standard to establish causation requires a plaintiff to prove the adverse action was a "but-for" cause of the protected activity, though some courts still apply a less stringent "motivating factor" test. The Eighth Circuit, meanwhile, has adopted a "sole basis" test for causation, which may be even more demanding than "but-for" causation. In ***Tener***, the district court applied that standard in requiring the plaintiff to demonstrate her discharge was motivated only by retaliatory animus connected to her protected activity.[186] The district court granted the motion to dismiss because the plaintiff's other employment history, including complaints about public safety and malpractice, and the defendants' alleged beliefs the plaintiff was urging others to file complaints and creating a toxic work environment, made it improbable her protected activity was the *sole* basis for her termination.

Relator's Role after Government Intervention

Courts have applied differing analyses in the past about whether a relator can continue to pursue claims separate from the government's claims after the government intervenes in an FCA action. In ***U.S. ex rel. Jahr v. Tetra Tech EC, Inc.***, a series of relators filed four different *qui tam* actions related to work by government contractors to remediate radiation contamination at a former naval shipyard.[187] The government intervened in three of the cases, and the relators attempted to pursue their own claims in each of those cases. The district court rejected the defendants' argument that the relators could not separately prosecute an FCA claim in an intervened case. The district court noted that language granting the government "primary responsibility for prosecuting the action" did not grant it "exclusive responsibility." In addition, other language in the statute contemplates the relators' continued participation. The district court concluded the plain language of the FCA does not "automatically bar relators from the litigation after the government intervenes."

Relator's Identity

Although *qui tam* complaints initially are filed under seal and thus conceal the relator's identity during the seal period, courts have addressed whether the relator's identity should remain concealed when a *qui tam* matter does not proceed to litigation.

186 2022 WL 2972219 (N.D. Iowa July 27, 2022).
187 2022 WL 2317268 (N.D. Cal. June 28, 2022).

The FCA allows a court to reduce a relator's share of the proceeds if the court finds that the relator planned and initiated the FCA violation and requires the court to dismiss a relator who is convicted of criminal conduct arising from his or her role in the FCA violation.

In ***Roe v. Stanford Health Care***, the Ninth Circuit reversed the district court's order requiring the relator to disclose her identity after her complaint was dismissed with prejudice.[188] The Ninth Circuit stated that a court must balance five factors to determine whether to allow anonymity: (1) severity of the threatened harm; (2) reasonableness of the anonymous party's fears; (3) the anonymous party's vulnerability to retaliation; (4) prejudice to the opposing party; and (5) public interest. Although the district court held that the fourth and fifth factors outweighed the first three, the Ninth Circuit reversed, noting the defendant already knew the relator's identity, and the public interest in litigation already dismissed is not as strong as that for ongoing litigation.

In ***U.S. ex rel. Dunn v. Merck & Co., Inc.***, the relators filed a motion to maintain the sealing order or to unseal only a redacted complaint after they voluntarily dismissed their complaint.[189] The district court affirmed the magistrate judge's rejection of the relators' arguments that maintaining the seal would allow them to investigate the defendants' wrongdoing further, the defendants would not be prejudiced because they were unaware of the action, and unsealing the matter would harm the public by providing a roadmap to commit similar wrongdoing. The district court noted the government's opposition to the relators' motion "all but seals the deal" because even the government noted that any interest the relators identified was outweighed by the "strong public interest in access to the judicial record," particularly where the case had remained under seal for more than nine years.

The district court in ***U.S. ex rel. Powell v. AeroCare Holdings, Inc.***, reached a similar result.[190] The relator moved to maintain the seal for two years after she dismissed her complaint because she feared retaliation at her new job and harm to her reputation in the healthcare industry, and because revealing her identity could have a chilling effect on future whistleblowers. The district court rejected those arguments, reasoning that the primary purpose of the FCA's seal requirement is to permit the government sufficient time to investigate and make an intervention decision, and otherwise a "strong presumption" exists in favor of keeping court records open to the public. The district court cited an extensive line of cases holding a generalized fear of retaliation or harm to reputation without any specific basis are not sufficient to keep a complaint under seal, noting the FCA contains an anti-retaliation provision, and the relator knew or should have known that her identity would be revealed when she filed her complaint.

Even if a relator were to provide a specific basis for fear of retaliation, courts may require factual support to maintain the seal. In ***United States v. Amador***, the relator moved to maintain the seal after she dismissed her complaint because she previously was married to one of the individual defendants who had a history of abuse and stalking, and the relator feared further abuse from him if he learned of her participation in the case.[191] The district court held those concerns did not overcome the strong presumption in favor of public access to court records, in part because they were "stated only upon information and belief and unsupported by an affidavit or other material evidence."

Relator's Share and Status Relative to Allegations

The FCA allows a court to reduce a relator's share of the proceeds if the court finds that the relator planned and initiated the FCA violation and requires the court to dismiss a relator who is convicted of criminal conduct arising from his or her role in the FCA violation.[192]

In ***U.S. ex rel. Dunn v. Procarent, Inc.***, the defendant moved to dismiss one of the relators because the original complaint alleged that another employee reported irregularities in physician certification statements to the relator, and the relator then "found" the missing forms and advised other employees not to email anyone else about the billing issues.[193] The district court denied the motion for numerous reasons. First, the defendant relied on allegations in the relators' original complaint, which had been superseded by two subsequent amended complaints. Second, the district court could not make a factual finding that the relator "planned and initiated" the alleged violations based on unproven allegations contained in a complaint. Third, the defendant did not argue that the relator had been convicted of any crime arising from the FCA violations, and the statutory remedy for the relator planning and initiating the violations was a reduction of the relator's share, not dismissal from the case. The district court noted, however, that if the relators succeeded in the case, the defendant could move to reduce the relator's share, if the evidence warranted such a motion.

While relators typically receive a share of any recovery from a *qui tam* lawsuit, the FCA's alternate-remedy provision also authorizes relators to receive a portion of the government's recovery from separate but related legal actions, even where the government declined to intervene in the *qui tam* complaint.[194] The remedy is most commonly available when the government recoups funds from a defendant through an administrative proceeding, although it can occur in other situations.

In order to share in an alternate-remedy, however, district courts often require relators to show that their *qui tam* allegations are the same or related to the theory behind the government's recovery. For instance, in ***U.S. ex rel. Kuriyan v. HCSC Insurance Services Co.***, the district court explained that, for a relator to share in the government's recoupment

188 2022 WL 796798 (9th Cir. 2022).
189 2022 WL 890037 (D.N.J. Mar. 24, 2022).
190 2022 WL 829497 (W.D. Ky. Mar. 18, 2022).
191 2022 WL 594548 (D. Nev. Feb. 25, 2022).
192 31 U.S.C. § 3730(d)(3).
193 2022 WL 2834685 (W.D. Ky. July 20, 2022).
194 31 U.S.C. § 3730(c)(5).

from an administrative proceeding, a relator must have brought information to prompt the government to act and the government must have relied on the relator's information when recouping payments.[195] On the other hand, the district court observed that a relator could not receive a share in the government's recovery if the government's recoupment process had already begun or if his actions made no impact on the process.

Share disputes can also arise where the government pursues criminal prosecutions, although whether the FCA's alternate-remedy provisions applies in the criminal context remains an open question. Where courts do allow a relator to seek a share of the government's recovery in a criminal case (whether it be in the form of forfeitures or restitution), courts still often require relators to establish that the criminal allegations stem from the same scheme as the one alleged in the *qui tam* complaint.

For example, in ***U.S. ex rel. Estate of Turner v. The Gardens Pharmacy, LLC***, the district court, after expressing skepticism that the alternate-remedy provision applied to criminal recoveries, denied a motion to recognize the relator's share because the *qui tam* allegations and the criminal proceedings involved distinct parties and distinct conduct. There, the *qui tam* complaint focused on illegal commissions for the sale of drug formulations (leading to AKS and Stark Law violations), while the criminal proceedings focused on whether the drug formulations were medically necessary and involved different individuals over an earlier timeframe.[196] While the district court recognized that the relator's alleged scheme loosely related to the government's criminal prosecutions in that the same drug formulations were involved in both, this minimal overlap did not entitle the relator to a share of the government's recovery.

195 2022 WL 704130 (D.N.M. Mar. 9, 2022).
196 2022 WL 2079718 (S.D. Miss. June 9, 2022).

STARK LAW/ ANTI-KICKBACK STATUTE

A consistent tool in government enforcement activity is the use of the AKS and Stark Law to establish FCA violations across healthcare industry sectors. As a result, courts have continued to issue significant decisions tackling causation under the AKS and exploring other Stark and AKS issues.

MORE FCA CIRCUIT SPLITS FOR CAUSATION UNDER THE AKS

Courts continued to wrestle with the appropriate causation standard in FCA cases premised on AKS violations under 42 U.S.C. § 1320a-7b(g), which provides that claims "resulting from" an AKS violation are "false or fraudulent" for FCA purposes. In ***U.S. ex rel. Cairns v. D.S. Medical LLC***, the Eighth Circuit became the first to hold that "resulting from" requires "but-for" causation between the AKS violation and the alleged false claim.[197] This created a

Courts continued to wrestle with the appropriate causation standard in FCA cases premised on AKS violations under 42 U.S.C. § 1320a-7b(g), which provides that claims "resulting from" an AKS violation are "false or fraudulent" for FCA purposes.

split with the Third Circuit, which held in ***U.S. ex rel. Greenfield v. Medco Health Solutions, Inc.***, that a direct causal link between the prohibited kickback and the subsequent claim for reimbursement is not required.[198]

In ***Cairns***, the relators alleged that a neurosurgeon and his fiancée engaged in a prohibited kickback scheme whereby the neurosurgeon ordered spinal implants from his fiancée's medical device distributor company, generating substantial sales commissions and lucrative stock options from the device manufacturer. According to the relators, these financial gains led the neurosurgeon to order even more implants. In reversing the district court's judgment following a jury verdict in favor of the government, the Eighth Circuit disagreed with the government's argument that claims "tainted" by illegal kickbacks were false and with the district court's instruction that mere failure to disclose an AKS violation could establish falsity. The Eighth Circuit held FCA claims premised on AKS violations require showing that "a defendant would not have included particular 'items or services' but for the illegal kickbacks."

In contrast, in ***U.S. ex rel. Fitzer v. Allergan, Inc.***, the district court explicitly declined to adopt the ***Cairns*** "but-for" causation standard. Instead, it opted to maintain adherence to ***Greenfield's*** "middle of the road approach" to causation.[199] In a fourth amended complaint, the relator alleged that two medical device companies used a physician locator on their website to conduct a kickback scheme whereby the defendants provided surgeons with free web-based advertisement to induce them to recommend the companies' LAP-BAND brand. The defendants allegedly implemented a quota of LAP-BAND surgeries for a physician to perform annually for inclusion on the physician locator. After the relator's third amended complaint was dismissed for, among other reasons, failure to show the defendants' "referral 'actually sat in the causal chain' between the alleged AKS violation and the allegedly false claim," the relator added several new allegations to its fourth complaint to remedy various pleading deficiencies, including establishing the requisite causal link. The district court subsequently denied the defendants' motion to dismiss the FCA claims. The district court explained that the relator's new allegations sufficiently linked the alleged AKS violation to the alleged false claims because they demonstrated at least two surgeons, who were aware of their inclusion on the locator, submitted claims for LAP-BAND surgeries performed while listed on the locator.

197 42 F.4th 828 (8th Cir. 2022).

198 880 F.3d 89 (3d Cir. 2018).

199 2022 WL 3599139 (D. Md. Aug. 23, 2022); *U.S. ex rel. Fitzer v. Allergan, Inc.*, 2022 WL 846211 (D. Md. Mar. 22, 2022) (dismissing the relator's third amended complaint based on the same facts described above for, among other reasons, failure to state an FCA claim premised upon an AKS violation), amended on denial of reconsideration, 2022 WL 1567645 (D. Md. May 18, 2022).

The government and relators continue to pursue FCA cases arising out of allegations that improper inducements to referring providers by hospitals, health systems and their executives violated the AKS, including sham contracts, free services and perks, improper investment opportunities, and above FMV business transactions.

HOSPITAL/PHYSICIAN KICKBACK SCHEMES

The government and relators continue to pursue FCA cases arising out of allegations that improper inducements to referring providers by hospitals, health systems and their executives violated the AKS, including sham contracts, free services and perks, improper investment opportunities, and above FMV business transactions. These cases met with mixed results when courts considered the sufficiency of the pleadings bringing these allegations.

United States v. Holland is the last in a series of criminal prosecutions against former Tenet hospital executives arising from alleged "sham" contracts used to disguise a kickback scheme in which Tenet hospitals made payments to a prenatal clinic for referrals of obstetric patients.[200] The district court concluded that the government's evidence did not prove that the defendants acted "willfully" as the application of the one-purpose rule was "unsettled and unclear." As such, establishing one of the purposes of the contracts was to induce referrals would be insufficient to show the defendants acted willfully in violation of the AKS. The district court determined instead that "the government must show that the individuals in question must have known they were breaking the law beyond knowing that one purpose of the deal was to induce referrals." Without evidence the contracts were not performed, the payments exceeded FMV or other "nefarious conduct," the district court could not conclude that the defendants had reason to believe they were violating the law.

In another case considering an alleged kickback scheme, the district court in ***U.S. ex rel. Chihi v. Catholic Health Initiatives*** denied the defendants' motion to dismiss a complaint alleging various healthcare providers referred their federal healthcare program patients to a hospital in exchange for kickbacks.[201] These alleged kickbacks took the form of international patient referrals, complimentary interpreters, free administrative assistance, and international travel perks to top referral sources in exchange for referrals to the hospital.[202] Evidence of the scheme included a roster of physicians that provided return referrals, emails expressing a preference for referring patients to certain defendants, and statements from a manager that referrals needed to be made to a particular physician to "keep him happy."[203]

Providing preferential treatment for investment opportunities continues to be an area of focus, as demonstrated in two district court decisions this past year. The relator in ***U.S. ex rel. Hockaday v. Athens Orthopedic Clinic*** raised FCA claims against Athens Orthopedic Clinic (AOC) and related surgery centers.[204] Among these claims, the relator alleged remuneration in the form of investment opportunities and compensation offered to physicians in exchange for referrals to AOC-affiliated surgery centers and for ancillary services. The district court granted summary judgment to the defendants on the majority of these claims. However, the district court allowed one claim to survive summary judgment where meeting minutes revealed two physicians would be allowed to become members of a surgery center with no buy-in in exchange for bringing 50% to 75% of their outpatient surgical cases to the AOC-affiliated surgery center and for being prohibited to participate in any outside surgery center. According to the district court, this arrangement "fits within the straightforward quid pro quo category that is clearly forbidden by the Anti-Kickback Statute." The district court also denied summary judgment to the defendants on claims alleging that bonuses were based on the employees' total receipts, including receipts for ancillary services referred by the respective employee.

The relator in ***Kuzma v. Northern Ariz. Healthcare Corp.*** alleged that the defendants' purchase of a physician-owned medical center exceeded FMV to reward the physician owners for past business and to induce future business in violation of the AKS.[205] The district court found a genuine issue of material fact as to whether the defendants paid FMV. The district court pointed to the relator's expert opinion, which highlighted various flaws in the defendants' valuation, allegedly inflating the amount by around $10 million. The defendants argued that there was no direct or circumstantial evidence that they acted knowingly and willfully, insisting "that the AKS does not criminalize entering into a business transaction with the hope or expectation of increased referrals, only paying for referrals."

The district court found evidence, however, that the defendants acted with actual knowledge or deliberate ignorance of the overpayment. For example, the defendants knew that the valuation did not incorporate updated and available data and omitted known costs, and the defendants failed to verify the valuation internally or by another qualified source. The district court also determined that the defendants acted with the intent to violate the law as illustrated by multiple references to referrals resulting from the transaction stricken from the original version of the defendants' internal PowerPoint presentation related to the transaction. Lastly, the district court found that there was a causal link between the alleged overpayment and the claims submitted. This link was supported by a non-compete clause

200 Criminal Action No. 1:17-CR-0234-AT (Nov. 15, 2022).
201 2022 WL 2657131 (S.D. Tex. Mar. 31, 2022).
202 The court found allegations that certain defendants rewarded with lavish international trips were conclusory, and therefore, insufficient to survive a motion to dismiss.
203 *See also* Press Release, Catholic Medical Center Agrees to Pay $3.8 Million to Resolve Kickback-Related False Claims Act Allegations, www.justice.gov/usao-nh/pr/catholic-medical-center-agrees-pay-38-million-resolve-kickback-related-false-claims-act.
204 2022 WL 2820103 (M.D. Ga. July 19, 2022).
205 2022 WL 2159027 (D. Ariz. June 15, 2022).

in the asset purchase agreement that restricted the physician owners' dealings with other facilities. Despite the defendants' argument that the non-compete did not limit where the physicians could perform surgeries, the district court reasoned that this argument actually strengthened the causal link because the physicians could have performed surgeries anywhere but chose to perform them at the defendants' facilities.

A relator made similar allegations in ***U.S. ex rel. CKD Project, LLC v. Fresenius Med. Care Holdings, Inc.***, where the relator alleged that Fresenius paid nephrologists for patient referrals in violation of the AKS.[206] The relator accused Fresenius of acquiring controlling interests in dialysis clinics by paying physicians in excess of FMV, with nearly 90 percent of the purchase price allocated to intangible assets like "goodwill" and requiring physicians to sign non-compete agreements. Fresenius successfully obtained dismissal under the public disclosure bar arguing that its securities filings previously disclosed material elements of these joint venture acquisitions.

Allegations that payments were outside of FMV or took into account the volume or value of physician referrals in violation of the Stark Law and AKS also resulted in settlements paid by hospital systems. For example, Weirton Medical Center, located in West Virginia, paid $1.5 million to resolve allegations that it violated the Stark Law by paying referring physicians compensation above FMV or that took into account the volume or value of the physicians' referrals to the hospital.[207] Similarly, Steward Health Care System agreed to pay $4.7 million to settle allegations that it charged less than FMV rent to referring physicians in space leases and paid referral sources under agreements for services not rendered.[208]

DME ENFORCEMENT UNDER AKS AND THE STARK LAW

Cases also highlighted the possibility of scrutiny faced by suppliers of DME. In ***U.S. ex rel. O'Bier v. TidalHealth Nanticoke, Inc.***, the Third Circuit affirmed a district court's decision to dismiss an FCA case involving allegations of an unlawful DME referral scheme, finding the relator's allegations were merely conclusory and not plausible.[209] The relator, a DME supply company owner, alleged that a hospital owner, two prescribers, and competitor DME suppliers were engaged in a scheme in which the prescribers "almost exclusively" referred patients to the relator's competitors and discouraged patients from using the relator's company. The Third Circuit affirmed the district court's dismissal of the relator's Stark Law claims, finding that the relator failed to allege a direct or indirect compensation arrangement between the prescribers and the DME competitors or that the prescribers' compensation varied with the volume or value of their DME referrals to the DME competitors. The Third Circuit further determined that the realtor failed to plausibly allege remuneration in violation of the AKS through conclusory claims of a kickback scheme.

206 2022 WL 17818587 (2d Cir. Dec. 20, 2022).
207 https://www.justice.gov/opa/pr/west-virginia-hospital-pay-15-million-settle-allegations-concerning-impermissible-financial.
208 https://www.justice.gov/usao-ma/pr/steward-health-care-system-agrees-pay-47-million-resolve-allegations-false-claims-act; *see also* https://www.justice.gov/usao-wdok/pr/oklahoma-city-home-health-company-and-two-former-corporate-officers-agree-pay-229 ($22.948 million settlement by home health company to resolve allegations of paying physicians to induce referrals of home health patients under the guise of medical directorships).
209 2022 WL 264554 (3d Cir. Jan. 28, 2022).

A district court reached the opposite result in ***U.S. ex rel. Everest Principals, LLC v. Abbott Labs., Inc.*** In that case, the district court denied a motion to dismiss the relator's federal FCA claims and granted the motion regarding the relator's state FCA claims with leave to amend.[210] The relator, a former Abbott employee, alleged that Abbott paid kickbacks in the form of, among other things, lavish meals, free marketing, and patient practice-building support to healthcare providers, with the specific intent of inducing the healthcare providers to perform cardiac procedures using Abbott's patented MitraClip. In denying the defendant's motion to dismiss, the district court cited the median age for the cardiac procedure is 76, indicating a majority of the patients were covered by Medicare. It also noted the relator's description of an alleged scheme over a one-year period where the relator hosted at least 10 meals for a specific physician and the physician's referring physicians with the goal of growing the physician's practice in the locations where the meals were held. The relator also arranged a lunch for the physician with a cardiology medical group for Abbott to target referrals to the physician. The district court noted that the physician in question implanted Abbott's device 25 times during the same one-year period, and received approximately $179,000 in Medicare payments for the cardiac procedure. Assuming the truth of these allegations, the district court found that the relator had sufficiently pleaded enough reliable indicia "that lead to a strong inference that false claims were actually submitted" to the federal government. The relator filed an amended complaint adding new allegations to the state FCA claims, including allegations related to free marketing events and practice support provided by Abbott to specific physicians in each state. Abbott moved to dismiss based on the relator's failure to provide particularized facts for the claims submitted to each state. The district court denied Abbott's motion to dismiss the state FCA claims for four states based upon specific allegations related to conduct in those states. However, the district court dismissed with prejudice the state FCA claims in 22 other states, stating the claims for those states contained only generalized blanket allegations.[211]

PHARMACEUTICAL MARKETING PRACTICES

Pharmaceutical companies' speaker programs and physician interactions continued to receive scrutiny for potential AKS violations.

Also included in our discussion of ***Pharmaceutical and Medical Device Developments*** later, in ***U.S. ex rel. Travis v. Gilead Sciences, Inc.***, the district court allowed a relator's FCA claims regarding Gilead Sciences' speaker programs to proceed. The relator, a former Gilead sales representative, alleged that Gilead had established sham speaker programs to give meals, vacations, and cash payments to high-volume prescribers of its hepatitis C drugs.[212] The district court held that the operative complaint adequately alleged the programs' purpose was to induce prescriptions, and Gilead willfully induced prescriptions by increasing the number of speaker events throughout a period of "systemically low attendance." The complaint also adequately alleged Gilead made payments to a third-party patient assistance program to encourage patients to obtain Gilead's drugs and submit corresponding claims to Medicare and Medicaid in violation of the FCA.

210 2022 WL 3567063 (S.D. Cal. Aug. 18, 2022).
211 2022 WL 17330838 (S.D. Cal. Nov. 29, 2022).
212 2022 WL 991382 (E.D. Pa. Apr. 1, 2022).

In contrast, the district court in ***United States v. Novartis Pharms. Corp.*** dismissed a declined *qui tam* action in which the relator alleged that the defendant improperly induced physicians to prescribe a multiple sclerosis drug through speaker events and other promotional and educational activities.[213] The relator argued the speaker programs were shams because they were: (1) constantly recycled and that simply repeated the drug package label information; (2) excessive in number and not informed by a needs assessment; and (3) poorly attended and regularly conducted at high-end restaurants. The relator further alleged that Novartis paid speakers for canceled events and selected physician speakers based on their prescribing potential. The district court granted the defendant's motion to dismiss for failure to plead the existence of a kickback scheme with sufficient particularity and declined to address the FCA claims premised on the AKS allegations. Although the district court was not bound by ***Travis***, it differentiated the relator's allegations by stating the ***Travis*** complaint included explanatory detail, such as the allegation a physician speaker was paid for sitting in a lunch area without ever giving a presentation, and the allegation that less well-known, unqualified speakers were involved in Gilead's speaker program. Such details were missing or not central to the claims against Novartis.

In one of the most significant settlements of 2022, Biogen agreed to pay $900 million to resolve FCA allegations in which the relator, a former Biogen sales manager, alleged Biogen had offered and paid kickbacks in the form of speaker honoraria, speaker training fees and consulting fees, and meals to physicians to induce them to prescribe Biogen's multiple sclerosis drugs. The relator argued this arrangement violated the AKS and caused the submission of false claims to Medicare and Medicaid.[214]

In one of the most significant settlements of 2022, Biogen agreed to pay $900 million to resolve FCA allegations in which the relator, a former Biogen sales manager, alleged Biogen had offered and paid kickbacks in the form of speaker honoraria, speaker training fees, and consulting fees and meals to physicians to induce them to prescribe Biogen's multiple sclerosis drugs.

A pharmaceutical wholesaler fared better by obtaining a dismissal of AKS allegations. In ***U.S. ex rel. Hart v. McKesson Corp.***, the district court dismissed a complaint that McKesson, a pharmaceutical wholesaler, provided drug pricing tools to specialty oncology practices in exchange for their participation in commitment programs requiring them to purchase a substantial proportion of their drugs from McKesson.[215] Although providing the tools to the physicians constituted remuneration under the AKS, the district court held that the complaint failed to allege McKesson knew its practices were unlawful as identification of a policy that violates the AKS and allegations a defendant had general awareness of laws regulating the pharmaceutical industry were insufficient to establish scienter.[216]

LABORATORY SETTLEMENTS AND EKRA

Laboratory and diagnostic service providers also entered into settlements to resolve alleged AKS violations, highlighting the fact that the government continues to scrutinize laboratory arrangements with providers who may refer or steer patients to certain laboratories for services. These settlements included allegations of lease payments made by laboratories to referring physicians in excess of FMV, investment opportunities and returns offered to physicians who referred laboratory services from certain hospitals and affiliated laboratories, and commission payments made to marketing contractors who in turn made payments to physicians who referred to certain hospitals and affiliated laboratories.[217]

BioReference Health, LLC, and OPKO Health, Inc., agreed to pay $9.85 million to resolve allegations that BioReference rented space above FMV from physician groups for its collection stations.[218] BioReference allegedly analyzed referrals generated from physicians when determining if it would rent space from or near the physicians, inaccurately calculated the amount of space to be leased, and conducted internal audits that identified that the rental payments to the physician-lessors exceeded FMV.

213 2022 WL 4217749 (S.D.N.Y. Sept. 13, 2022).

214 https://www.justice.gov/opa/pr/biogen-inc-agrees-pay-900-million-settle-allegations-related-improper-physician-payments.

215 2022 WL 1423476 (S.D.N.Y. May 5, 2022).

216 *See also* OIG Advisory Opinion No. 22-04 (favorable Advisory Opinion regarding a customer-funded program in which the requestor provided digital contingency management and related tools, including cash equivalents, to patients with substance use disorders, where, despite exceeding the patient engagement safe harbor cap, the cash equivalents have a relatively low value capped at $200 per month and $599 per year and the requestor does not bill any federal healthcare program for services furnished). *But see* https://www.justice.gov/usao-ma/pr/cardinal-health-agrees-pay-more-13-million-resolve-allegations-it-paid-kickbacks ($13.125 million FCA settlement by Ohio-based pharmaceutical distributor, Cardinal Health, Inc., to resolve allegations it violated the AKS by paying "upfront discounts" to its physician practice customers, but failed to attribute the upfront discounts to identifiable sales and provided purported rebates that customers had not actually earned).

217 For example, in *U.S. ex rel. Nicholson v. MedCom Carolinas, Inc.*, 42 F.4th 185 (4th Cir. 2022), the relator alleged a skin graft manufacturer used a company who paid its salespeople commissions based on the volume of sales made and reimbursement from federal healthcare programs in violation of the AKS, and, as a result, the sales were false claims. While acknowledging the facts could support a viable allegation, the Fourth Circuit affirmed the lower court's dismissal for failure to plead with particularity.

218 https://www.justice.gov/opa/pr/bioreference-laboratories-and-parent-company-agree-pay-985-million-resolve-false-claims-act.

Related to these cases and settlements, OIG also expressed its concern about questionable lab arrangements by issuing a negative advisory opinion explaining payments by a laboratory to a hospital for collecting, processing, and handling specimens that are paid on a per-patient-encounter basis would generate prohibited remuneration under the AKS.

In another notable settlement, Boston Heart Diagnostics Corporation along with 33 physicians and healthcare executives agreed to pay over $32 million to resolve FCA allegations for their involvement in a scheme to pay and receive illegal kickbacks in exchange for laboratory referrals. The civil settlements resolved allegations that the defendants violated the AKS by receiving thousands of dollars in remuneration from nine hospital affiliated, marketer-owned MSOs in exchange for ordering laboratory tests. The MSO payments to the physicians were supposedly investment returns, but the government alleged the payments were actually based on, and offered in exchange for, referrals.[219]

Related to these cases and settlements, OIG also expressed its concern about questionable lab arrangements by issuing a negative advisory opinion explaining payments by a laboratory to a hospital for collecting, processing, and handling specimens that are paid on a per-patient-encounter basis would generate prohibited remuneration under the AKS.[220]

Finally, district courts continued to interpret the Eliminating Kickbacks in Recovery Act (EKRA). In ***U.S. v. Schena***, a district court considered whether EKRA applies to situations where a marketer obtains a referral of patients by securing them indirectly from physicians rather than working directly with individual patients.[221] The defendant, the president of a publicly traded technology company, was charged with a scheme involving obtaining orders for allergy and COVID-19 testing by paying illegal kickbacks and bribes to marketers and purported marketing companies in exchange for blood samples collected from patients and orders for allergy testing from healthcare providers. The defendant argued that because the EKRA allegations were premised on the defendant's use of marketers to *indirectly* recruit patients, those charges should be dismissed. The district court found the defendant violated EKRA by paying marketers illegal kickbacks to influence physicians' referrals of patients to the defendant's company for laboratory tests. The district court stated that by its terms, EKRA applies to situations where someone "pays or offers any remuneration," to "induce" an individual into using laboratory or clinical services, and EKRA does not contain any requirement of direct interaction between the marketer and the individual. In doing so, the district court rejected a previous district court's interpretation of EKRA, which held if a marketer was overseeing physician client accounts rather than interacting directly with patients, the marketer's compensation was not paid to induce referrals because there was no referral by the marketer of an individual patient for laboratory services.[222]

CHALLENGING ADVISORY OPINIONS

At least one provider went on the offensive by pushing back on OIG's issuance of an unfavorable advisory opinion, which may pave the way for future challenges. As we discuss in more detail in ***Pharmaceutical and Medical Device Developments***, in ***Pfizer, Inc. v. U.S. Dep't of Health and Hum. Servs.***, the district court dismissed Pfizer's request for a declaratory judgment challenging an OIG advisory opinion finding that Pfizer's co-pay assistance program violated the AKS.[223] The district court ruled the AKS does not require a "corrupt" intent or quid pro quo, only "that payments are made with an intent to influence a decision about medical care or purchases." Pfizer appealed to the Second Circuit, which affirmed the district court ruling.[224]

219 https://www.justice.gov/usao-edtx/pr/21-charged-including-hospital-and-lab-ceos-connection-multistate-healthcare-kickback.

220 OIG Advisory Opinion, No. 22-09.

221 2022 WL 1720083 (N.D. Cal. May 28, 2022). EKRA prohibits kickbacks in connection with clinical treatment facilities, laboratories, and recovery homes. Unlike most other federal fraud and abuse laws, however, EKRA generally applies to all payors.

222 *S&G Labs Hawaii v. Graves*, 2021 WL 4847430 (D. Haw. Oct. 18, 2021).

223 2021 WL 4523676 (S.D.N.Y. Sept. 30, 2021).

224 42 F.4th 67 (2d Cir. 2022). Pfizer filed a petition for certiorari to the Supreme Court, which was denied on January 9, 2023.

MANAGED CARE/MEDICARE ADVANTAGE

MA enrollment has more than doubled in the last decade. In 2022, 28.4 million (or 48% of Medicare-eligible individuals) elected to enroll in a MA plan. Payments made by CMS to MA plans amount to over $427 billion annually (or 55% of total federal Medicare spending). In 2023, MA enrollment is projected to reach 52% of Medicare-eligible individuals and surpass traditional Medicare enrollment for the first time.

This marked growth has brought enhanced scrutiny through increased FCA litigation. Further, the future of the Overpayment Rule in the Part C context and Risk Adjustment Data Validation audit methodologies and recoveries and related litigation in coming years could have far-reaching implications for the industry.

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

Litigation focused on alleged efforts to defraud the government by inflating risk adjustment scores through improper diagnosis code submissions remains ongoing.

To calculate a beneficiary's risk score, CMS looks to medical records, which contain the risk-adjusting diagnoses submitted by MAOs. MAOs are required to "certify (based on best knowledge, information, and belief) that the data it submits" for risk adjustment are "accurate, complete, and truthful."[225] Much of the government's enforcement efforts concern allegations that risk-adjusting diagnosis codes (*i.e.*, those diagnosis codes that can impact the capitated payment amount) were either inaccurate or not properly supported in the underlying medical record.

PENDING LITIGATION RELATING TO MEDICARE ADVANTAGE AND RISK ADJUSTMENT

Litigation focused on alleged efforts to defraud the government by inflating risk adjustment scores through improper diagnosis code submissions remains ongoing.

We reported previously on the proceedings in ***U.S. ex rel. Osinek v. Permanente Med. Grp., Inc.***, in which the government intervened in six complaints alleging that members of the Kaiser Permanente consortium violated the FCA through improper use of addenda to medical records. The litigation includes allegations that between 2009 and 2018, Kaiser added approximately 500,000 diagnoses via addenda that were unsupported in the medical record, resulting in payments from CMS "in the range of $1 billion."

In November 2022, the district court granted in part and denied in part Kaiser's motion to dismiss the United States' complaint-in-intervention.[226] The motion to dismiss focused on whether the government sufficiently pleaded evidence of a Kaiser-driven, corporate-wide scheme of submitting false diagnosis codes via addenda, and whether the government could rely on a failure to follow sub-regulatory guidance as a predicate for FCA liability.

Kaiser prevailed on its argument that the government had not sufficiently pleaded evidence of a systematic scheme except with regard to one diagnosis (cachexia) holding that reference to three specific examples in the government's complaint was "not enough to make out a plausible case for such a systemic scheme" of submitting unsupported diagnosis codes. But, the district court rejected Kaiser's argument that FCA liability cannot be predicated on a failure to satisfy sub-regulatory guidelines, finding that reliance on the ICD-10 guidelines was appropriate in this context.

225 42 C.F.R. § 422.504.
226 2022 WL 16925963 (N.D. Cal. Nov. 14, 2022).

In December 2022, the United States filed an amended complaint in which it has attempted to bolster its allegations related to a corporate-wide scheme of clinically inaccurate diagnosis codes.[227]

In ***United States v. Anthem, Inc.***, the district court denied Anthem's motion to dismiss the government's lawsuit alleging that Anthem submitted inaccurate diagnosis data in conjunction with its MA plans that would have resulted in alleged overpayments in violation of the FCA.[228] In its motion to dismiss, Anthem asserted the government's complaint failed to meet the FCA's materiality requirement. Evaluating the motion under the framework set out in *Escobar*, the district court found that the alleged overpayments totaling over $100 million to be "substantial and not merely administrative." The district court explained that, while an absolute refusal from CMS to pay had it known of the alleged misrepresentation would certainly constitute materiality, something less than that could also satisfy the materiality standard.

In ***U.S. ex rel. Cutler v. Cigna Corp.***, the government intervened in a *qui tam* lawsuit alleging that Cigna-HealthSpring violated the FCA by submitting false and invalid diagnoses resulting from in-home assessments carried out by Cigna's vendor clinicians.[229] In-home assessments are programs where nurses or other clinicians visit beneficiaries at home to assess a beneficiary's health conditions. While these programs serve a legitimate role in supporting continuity of care, the government has long perceived these programs as high-risk for misuse and as a way to artificially inflate beneficiaries' risk scores. More specifically, when a condition is diagnosed solely through a home assessment and without follow-up or treatment, the government has raised concerns about the validity of the diagnosis, completeness of the data submitted, and whether appropriate treatment was provided. The government's intervention decision underscores its continued focus in this area. Cigna has moved to dismiss the government's complaint, which remains pending.

In ***U.S. ex rel. Fernandez v. Freedom Health, Inc.***, a relator filed a *qui tam* lawsuit alleging that the defendants, Freedom Health, Inc., Optimum Healthcare, Inc., and Physician Partners, LLC, intentionally submitted incorrect and/or unsubstantiated risk adjustment data as part of a scheme to increase payments from CMS. The relator alleged that, among other things, Physician Partners pressured patients to schedule medically unnecessary screenings and encouraged vendors to submit fraudulently inflated diagnosis codes.

The defendants each filed motions to dismiss the relator's amended complaint, which the district court granted without opining on the substance of the defendants' arguments because the relator failed to timely respond to those motions, as well as a motion for entry of final judgment.[230]

In ***U.S. ex rel. Zafirov v. Florida Med. Assocs. LLC***, a relator filed a lawsuit alleging that MA defendants Freedom Health, Inc. and Optimum Healthcare, Inc., as well as provider defendants Physician Partners, LLC, Florida Medical Associates LLC, and Anion Technologies, LLC, engaged in a coordinated scheme to submit unsupported risk adjustment data to increase their capitation payments. The relator alleged that the provider defendants engaged in inappropriate querying of providers through the use of a checklist that encouraged diagnosis of inactive conditions as active and steered providers towards more severe conditions than were supported by the medical record.

The defendants moved to dismiss the relator's amended complaint on the grounds that the relator failed to plead the FCA claims as a matter of law. In response, the United States filed a statement of interest asserting that if the allegations in the amended complaint were found to be true, those allegations could be material to its decision to pay. In denying the defendants' motions to dismiss, the district court held that the amended complaint did allege facts with particularity by adding nearly 100 pages of additional detail.[231] In particular, the district court found sufficient "indicia of reliability" to support the relator's allegations against the MA defendants based on multiple patient-specific examples and the relator's purported access to the MA defendants' online physician portal, which contained records of allegedly false diagnosis codes that were submitted to the government. Finally, the district court stated that the relator had adequately pleaded both materiality and causation by pleading sufficient facts to support the allegation that improper risk-adjustment diagnoses led to overpayments from the government, including allegations that the defendants routinely overrode physician judgments to submit false diagnosis codes and pressured physicians to increase the risk scores of their patients.

OVERPAYMENT RULE

CMS's Overpayment Rule requires the reporting and returning of "overpayments" within 60 days of identification.[232] This Rule applies to Medicare Parts A, B, C and D. With respect to Medicare Part C, a MA plan need not have "knowledge" of any overpayment for the rule to apply; rather, a MA plan has "identified" an overpayment (that must be returned to CMS) when it has determined or should have determined "through the exercise of reasonable diligence," that it has received an overpayment.[233]

The applicability of the Overpayment Rule to Part C was the subject of litigation in which UnitedHealth argued that the Rule violates Medicare's "actuarial equivalence" standard and the "same methodology requirements." In ***UnitedHealthcare Ins. Co. v. Azar***, the district court vacated the Medicare Part C Overpayment Rule, finding it was "arbitrary and capricious" and "violate[d] the statutory mandate of 'actuarial equivalence.'"[234] In that decision, the district court held that the "reasonable diligence" standard impermissibly created FCA liability for mere negligence. That victory was short lived, however, as the D.C. Circuit reversed this decision and held that the Overpayment Rule does not violate the Medicare statute's "actuarial equivalence" and "same methodology" requirements and is not arbitrary and capricious as an unexplained departure from CMS's fee-for-service adjuster policy.

227 No. 3:313-cv-03891, Dkt. No. 240 (N.D. Cal. Dec. 12, 2022).
228 2022 WL 4815978 (S.D.N.Y. Sept. 30, 2022).
229 No. 3:21-cv-00748, Dkt. No. 178 (M.D. Tenn. Oct. 14, 2022).
230 No. 8:18-cv-01959, Dkt. No. 125 (M.D. Fla. Aug. 15, 2022).
231 2022 WL 4134611 (M.D. Fla. Sept. 12, 2022).
232 42 U.S.C. §1320a-7k(d)(1)-(2)).
233 42 C.F.R. § 422.326(c).
234 330 F. Supp. 3d 173, 176 (D.D.C. 2018), rev'd and remanded sub nom. *UnitedHealthcare Ins. Co. v. Becerra*, 9 F.4th 868 (D.C. Cir. 2021), amended on denial of reh'g, No. 18-5326, 2021 WL 5045254 (D.C. Cir. Nov. 1, 2021), and superseded, 16 F.4th 867 (D.C. Cir. 2021), and rev'd and remanded sub nom. *UnitedHealthcare Ins. Co. v. Becerra*, 16 F.4th 867 (D.C. Cir. 2021).

On December 14, 2022, CMS proposed changes to the Overpayment Rule as part of a larger MA proposed rulemaking for the 2024 coverage year. In an apparent response to the D.C. Circuit's decision, the CMS proposed rule seeks to replace the "reasonable diligence" standard with the "knowledge" standard used by the FCA.[235] Under the proposed rule, a MA plan will be considered to have identified an overpayment based on actual knowledge of the existence of the overpayment or if the plan acts in reckless disregard or deliberate ignorance of the overpayment. The proposed removal of the "reasonable diligence" standard and adoption of the FCA "knowledge" standard for overpayments would apply to Medicare Parts A, B and D in addition to Part C.

On December 14, 2022, CMS proposed changes to the Overpayment Rule as part of a larger MA proposed rulemaking for the 2024 coverage year. In an apparent response to the D.C. Circuit's decision, the CMS proposed rule seeks to replace the "reasonable diligence" standard with the "knowledge" standard used by the FCA.

235 87 Fed. Reg. 79452, 79455 (Dec. 27, 2022).

PHARMACEUTICAL AND MEDICAL DEVICE DEVELOPMENTS

Regulatory and enforcement agencies continued to monitor the activities of pharmaceutical and medical device manufacturers with heightened scrutiny.

In ***U.S. ex rel. Travis v. Gilead Sciences, Inc.***, the relator alleged that Gilead violated the FCA and AKS when promoting its hepatitis C virus medications, Sovaldi and Harvoni, by: (1) conducting pre-approval and off-label marketing; (2) making misleading, inaccurate, and false marketing statements to prescribers; (3) colluding with a charitable organization to fund co-pays for patients prescribed the drugs; and (4) establishing sham "speaker programs" to provide meals, vacations, and cash payments to high-volume prescribers.[236]

The district court denied Gilead's motion to dismiss the claims related to the speaker programs and co-pay subsidies but granted the motion with respect to the relator's claims relating to pre-approval and off-label marketing. In dismissing the pre-approval and off-label marketing claims, the district court concluded that the FCA's materiality standard requires the relator to specifically allege patients were prescribed medications in medically unnecessary circumstances because of the alleged illegal or misleading marketing. However, the district court found the realtor's allegations that Gilead increased the number of speaker events despite low attendance and recruited little-known speakers who were high-volume prescribers to present at conferences in desirable locations were sufficient to allege violations of the AKS and FCA. The district court also found that the relator's allegations that Gilead worked directly with patients prescribed Gilead's drugs to secure co-pay assistance from the charitable organization were sufficient to state a claim.

In ***U.S. ex rel. Bennett v. Bayer Corp.***, the relator alleged that Bayer and various Johnson & Johnson (J&J) entities violated the FCA by misbranding the antibiotics Cipro and Levaquin because the drugs were more dangerous than described on their labels.[237] The relator asserted that the misbranding caused healthcare professionals to inappropriately prescribe the drugs and, in turn, to falsely certify to Medicare and Medicaid that the drugs were appropriately prescribed. The district court concluded that the relator's theory of implied false certification did not adequately plead facts to establish falsity or materiality.

As to falsity, the district court found that the complaint did not allege the false statements that Bayer and J&J made about the drugs, the specific information Bayer and J&J failed to disclose, or why Bayer and J&J were under a duty to disclose that information even though the FDA knew about the alleged dangers, but did not require them to update their labels in response to the pleaded concerns. As to materiality, the district court concluded that the relator did not plead that the defendants failed to comply with a material statutory, regulatory, or contractual requirement, which is required to show materiality under an implied false certification theory. Because the FDA knew about the alleged concerns and decided not to act, the relator could not subsequently bring an FCA claim alleging that the defendants induced providers to submit false claims based on the information the FDA decided not to include in the drugs' labeling requirements.

Pfizer challenged the manner in which the AKS would be interpreted in a series of cases. Pfizer first filed suit against HHS in 2020 in ***Pfizer, Inc. v. U.S. Dep't of Health and Hum. Servs.***, in which it sought a declaratory judgment that its proposal to directly subsidize co-payments for patients who had been prescribed its costly drug to treat a rare heart condition would not violate the AKS.[238] Before filing suit, Pfizer requested an advisory opinion from OIG with respect to its proposed co-payment assistance program. Pfizer filed suit after OIG informed Pfizer that the opinion would be unfavorable but before OIG issued the opinion, asserting that to violate the AKS the program must be administered with a corrupt intent that improperly skews the patient's decision-making. The district court rejected Pfizer's argument, concluding that nothing in the AKS's text requires a corrupt intent, and dismissed Pfizer's claims. Pfizer appealed the district court's decision to the Second Circuit, which rejected Pfizer's argument that the word "induce," as used in the AKS, requires or implies an element of corruption and affirmed summary judgment.[239]

236 596 F. Supp. 3d 522 (E.D. Pa. 2022).

237 2022 WL 970219 (D.N.J. Mar. 31, 2022).

238 *Pfizer, Inc. v. U.S. Dep't of Health and Hum. Servs.*, No. 1:20-cv-04920 (S.D.N.Y. June 26, 2020).

239 42 F.4th 67 (2d Cir. 2022). Pfizer filed a petition for certiorari with the Supreme Court, asking the Court to decide whether the AKS is violated only if the person offering "remuneration…to induce" the purchase of a federally reimbursable item *intends to corrupt* the recipient's medical decision making. In its petition, Pfizer argued that the lower courts' and OIG's interpretation of the AKS was overbroad and thus prohibits a wide swath of routine, beneficial conduct in connection with federally funded healthcare. The Supreme Court denied Pfizer's petition on January 9, 2023.

DOJ has continued its effort at cracking down on pharmaceutical companies offering consulting agreements, speaker programs, and meals to prescribers.

In ***Hinton v. Integra LifeSciences Holdings Corp.***, the district court held that a relator's "assertions" against a medical device manufacturer were supported by "particularized facts" that "adequately alleged an off-label marketing scheme to submit false claims."[240] In that case, Integra allegedly marketed and profited from the off-label use of Auragen, a device used for brain mapping. The FDA had previously approved Auragen for intraoperative use during surgery but not post-operative monitoring of patients. The relator alleged that Integra repeatedly made false and misleading statements in its training and marketing materials to healthcare providers about its post-operative use, causing the submission of false claims. To support these allegations, the relator used a variety of sources, including testimony from a physician who relied on these statements, patients injured as a result of post-operative use of Auragen, Integra's internal training site, and company documents discussing CPT codes for post-operative use of the device. In its motion to dismiss, Integra claimed that the relator's assertions were too broad, arguing that Auragen's off-label use did not pose a danger to patients in all cases or result in fraudulent claims because off-label uses require a medically necessary reason. The district court disagreed and found that the relator's complaint plausibly alleged particularized facts that Integra marketed Auragen for off-label use that was not medically necessary, resulting in the submission of false claims.

In ***U.S. ex rel. Streck v. Takeda Pharmaceuticals Americas, Inc.***, the district court denied one defendant's motion for summary judgment on scienter and falsity grounds, holding that the defendant's interpretation of the statute was "objectively unreasonable."[241] In that case, pharmaceutical company Eli Lilly participated in a Medicaid Drug Rebate Program and entered into fee-for-service agreements (FFS Agreements) with drug distributors that included a distribution fee for services and a price appreciation credit. The relator alleged that Eli Lilly only paid the distribution fee if a drug distributor's sales of its products exceeded any drugs remaining in the inventory, which would, in turn, determine the amount of the price appreciation credit. The relator alleged that Eli Lilly's FFS Agreements with drug distributors violated the FCA because it incorrectly interpreted the statutory text when calculating the rebate computations.

The district court agreed and rejected Eli Lilly's claim that the statute was unclear about its obligations in calculating the rebate. After an "objectively reasonable inquiry," the district court found that the statutory text explicitly explained the rebate calculations and, as a result, denied Eli Lilly's motion for summary judgment based on scienter. On the issue of falsity, the district court found that the clear statutory text foreclosed alternative interpretations of rebate calculations and therefore granted the relator's motion for summary judgment on falsity, holding that all of Eli Lilly's rebate calculations and related certifications were "factually and legally false."

DOJ has continued its effort at cracking down on pharmaceutical companies offering consulting agreements, speaker programs, and meals to prescribers. For instance, in ***Bawduniak v. Biogen Idec Inc.***, the relator alleged that Biogen targeted 1,200 of the top 6,000 neurologists responsible for writing sixty percent (60%) of all multiple sclerosis medications with multiple kickback schemes.[242] On September 26, 2022, Biogen agreed to a $900 million settlement to resolve allegations that it offered and paid remuneration to prescribers, including in the form of speaker honoraria, speaker training fees and consulting fees, and meals, to healthcare professionals who spoke at or attended Biogen's speaker programs, speaker training meetings, or consultant programs to induce them to prescribe Biogen's drugs.[243] The relator alleged that presentations were often given in empty rooms or at dinners at high-end restaurants and that Biogen reimbursed expenses for travel and lodging. Certain neurologists allegedly received thousands of dollars in "speaking fees," with an average fee of $2,500 per dinner.

240 2022 WL 1036777 (W.D. Mo. Apr. 6, 2022).
241 2022 WL 595308 (N.D. Ill. Feb. 28, 2022).

242 *U.S. ex rel. Bawduniak v. Biogen Idec Inc.*, No. 12-CV-10601-FDS (D. Mass. July 11, 2013).
243 https://www.justice.gov/opa/pr/biogen-inc-agrees-pay-900-million-settle-allegations-related-improper-physician-payments.

APPENDIX
2022 NOTABLE SETTLEMENTS

HOSPITALS AND HEALTH SYSTEMS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
1/11/2022	UC San Diego Health	Health system agreed to pay $2.98 million to resolve FCA allegations that it billed Medicare for medically unnecessary genetic tests.[1]	**$2.98 million**
2/9/2022	Catholic Medical Center	Hospital agreed to pay $3.8 million to resolve FCA allegations that it provided free call coverage services for a cardiologist in exchange for patient referrals, in violation of the AKS.[2]	**$3.8 million**
2/14/2022	NCH Healthcare System	Hospital operator agreed to pay $5.5 million to resolve allegations that it made improper, non-bona fide donations to local units of government, including in the form of free nursing and athletic training services to a local school board, to improperly fund the state's share of Medicaid payments to the health system.[3]	**$5.5 million**
4/6/2022	BayCare Health System Inc.	Health system and its operating entities agreed to pay $20 million to resolve allegations that the health system made improper, non-bona fide donations to a local unit of government to improperly fund the state's share of Medicaid payments to the health system.[4]	**$20 million**
4/12/2022	Providence Health & Services Washington	Health system agreed to pay more than $22 million to resolve FCA allegations that it submitted claims to federal healthcare programs for medically unnecessary procedures performed by two neurosurgeons. As part of the resolution, the health system entered into a five-year CIA with HHS-OIG.[5]	**$22.69 million**
5/16/2022	Oklahoma Heart Hospital South, LLC	Hospital agreed to pay $1.15 million to resolve self-disclosed FCA allegations that it submitted claims for intensive cardiac rehabilitation services for Medicare beneficiaries when the required physician-authorized treatment plan had not been completed or updated as required.[6]	**$1.15 million**
5/17/2022	University of Maryland Shore Regional Health	Health system agreed to pay $296,870 to resolve FCA allegations that it billed Medicare for radiation therapy and diagnostic services that were performed without the required physician supervision.[7]	**$296,870**

1 https://www.justice.gov/opa/pr/uc-san-diego-health-pays-298-million-resolve-allegations-ordering-unnecessary-genetic-testing.
2 https://www.justice.gov/usao-nh/pr/catholic-medical-center-agrees-pay-38-million-resolve-kickback-related-false-claims-act.
3 https://www.justice.gov/opa/pr/florida-s-nch-healthcare-system-agrees-pay-55-million-settle-common-law-allegations.
4 https://www.justice.gov/opa/pr/florida-s-baycare-health-system-and-hospital-affiliates-agree-pay-20-million-settle-false.
5 https://www.justice.gov/usao-edwa/pr/providence-health-services-agrees-pay-227-million-resolve-liability-medically.
6 https://www.justice.gov/usao-wdok/pr/oklahoma-city-hospital-pays-over-11-million-settle-allegations-submitting-false-claims.
7 https://www.justice.gov/usao-md/pr/university-maryland-shore-regional-health-agrees-pay-296870-settle-federal-false-claims.

HOSPITALS AND HEALTH SYSTEMS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
6/10/2022	Steward Health Care System LLC	Health system and related corporate entities agreed to pay $4.73 million to resolve FCA allegations that an affiliated medical center entered agreements with a urology clinic and separate physician practice to administer a prostate cancer center and made payments under the same, even though the center was never created and the practice never provided a physician to serve as the center's director, in violation of the AKS and Stark Law. The settlement also resolves self-disclosed FCA allegations that the medical center: (1) improperly paid a medical director for services it could not confirm were performed; and (2) had below FMV lease arrangements with other referring providers, in violation of the AKS and Stark Law. As part of the resolution, the health system entered into a five-year CIA with HHS-OIG.[8]	**$4.73 million**
7/7/2022	Weirton Medical Center	Hospital agreed to pay $1.5 million to resolve self-disclosed FCA allegations that it submitted claims to Medicare for services referred by physicians with whom it had improper compensation arrangements, in violation of the Stark Law. The settlement is expressly based on the hospital's financial condition.[9]	**$1.5 million**
8/18/2022	Ventura County Medi-Cal Managed Care Commission d/b/a Gold Coast Health Plan (Gold Coast); Ventura County	County agreed to pay $29 million and county-organized health system agreed to pay $17.2 million to resolve FCA allegations that they submitted or caused the submission of false claims for "additional services" to Adult Expansion Medi-Cal members that were: (1) contractually not allowed; (2) duplicative of other required services; and/or (3) did not reflect the FMV of the services provided. Gold Coast and Ventura County entered into a five-year CIA with HHS-OIG as part of the resolution.[10]	**$46.2 million**
8/18/2022	Dignity Health	Health system that operates two acute care hospitals in Ventura County, California, agreed to pay $12 million to resolve FCA allegations that it submitted claims for "additional services" to Adult Expansion Medi-Cal members that were: (1) contractually not allowed; (2) duplicative of other required services; and/or (3) did not reflect the FMV of the services provided.[11]	**$12 million**
8/18/2022	Clinicas del Camino Real, Inc.	Healthcare organization headquartered in Ventura County, California, agreed to pay $12.5 million to resolve FCA allegations that it submitted claims for "additional services" to Adult Expansion Medi-Cal members that were: (1) contractually not allowed; (2) duplicative of other required services; and/or (3) did not reflect the FMV of the services provided.[12]	**$12.5 million**

8 https://www.justice.gov/usao-ma/pr/steward-health-care-system-agrees-pay-47-million-resolve-allegations-false-claims-act.
9 https://www.justice.gov/usao-ndwv/pr/west-virginia-hospital-pay-15-million-settle-allegations-concerning-impermissible-0.
10 https://www.justice.gov/usao-cdca/pr/ventura-county-s-organized-health-system-and-3-medical-providers-agree-pay-707-million.
11 https://www.justice.gov/usao-cdca/pr/ventura-county-s-organized-health-system-and-3-medical-providers-agree-pay-707-million.
12 https://www.justice.gov/usao-cdca/pr/ventura-county-s-organized-health-system-and-3-medical-providers-agree-pay-707-million.

HOSPITALS AND HEALTH SYSTEMS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
9/14/2022	New York-Presbyterian/Queens Hospital	Hospital agreed to pay more than $2.5 million to resolve FCA allegations that it submitted claims related to medically unnecessary surgical procedures to replace the batteries of implanted medical devices performed by a physician formerly affiliated with the hospital.[13]	**$2.58 million**
9/27/2022	Parkview Health System	Hospital system agreed to pay $2.9 million to resolve FCA allegations that several of its hospitals submitted claims and retained overpayments related to improperly coded blood-clotting tests.[14]	**$2.9 million**
10/17/2022	Sutter Health; Sutter Bay Hospitals	Hospital system agreed to pay more than $13 million to resolve FCA allegations that it billed government healthcare programs for toxicology screening tests that were actually performed by third-party laboratories.[15]	**$13.09 million**
10/26/2022	Oswego Hospital	Hospital agreed to pay more than $98,000 to resolve FCA allegations that it billed Medicare and Medicaid for unsupervised or inadequately documented outpatient mental healthcare services provided by two social workers.[16]	**$98,694**
12/7/2022	Dignity Health	Health system that operates three hospitals and one clinic in Santa Barbara County and San Luis Obispo County, California, agreed to pay $15 million to resolve FCA allegations that it caused the submission of claims for "enhanced services" to Adult Expansion Medi-Cal members that were: (1) contractually not allowed; (2) duplicative of other required services; and/or (3) did not reflect the FMV of the services provided.[17]	**$15 million**
12/7/2022	Twin Cities Community Hospital; Sierra Vista Regional Medical Center	Two Tenet Healthcare-owned acute care hospitals operating in San Luis Obispo County, California, agreed to pay $7.5 million to resolve FCA allegations that they caused the submission of claims for "enhanced services" to Adult Expansion Medi-Cal members that were: (1) contractually not allowed; (2) duplicative of other required services; and/or (3) did not reflect the FMV of the services provided. As part of the resolution, the hospitals entered into a five-year CIA with HHS-OIG.[18]	**$7.5 million**

13 https://www.justice.gov/usao-edny/pr/new-york-presbyterianqueens-hospital-settles-allegations-federal-health-care-fraud-over.
14 https://events.in.gov/event/attorney_general_todd_rokita_and_team_achieve_29_million_settlement_in_medicaid_fraud_case.
15 https://www.justice.gov/usao-ndca/pr/sutter-health-agrees-pay-13-million-settle-false-claims-act-allegations-improper.
16 https://www.justice.gov/usao-ndny/pr/oswego-hospital-agrees-pay-9869436-improper-medicare-and-medicaid-billing.
17 https://www.justice.gov/opa/pr/three-health-care-providers-agree-pay-225-million-alleged-false-claims-california-s-medicaid.
18 https://www.justice.gov/opa/pr/three-health-care-providers-agree-pay-225-million-alleged-false-claims-california-s-medicaid.

HOSPICE AND HOME HEALTH

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
1/4/2022	Academy Health Care Services	Home health provider agreed to pay $500,000 to resolve FCA allegations that it billed Medicare for individual services when: (1) group services were actually provided; and/or (2) the provider did not spend the requisite time with the patient to receive reimbursement for individual services. The agency agreed to cease operations by June 2022 as part of the settlement.[19]	**$500,000**
1/6/2022	Home Care VNA; Constant Ogutt; Shakira Lubega	Home health provider and its owners agreed to pay $630,000 to resolve FCA allegations that they billed MassHealth for services that were not appropriately authorized by a physician as medically necessary. The settlement also resolves allegations that Home Care VNA became aware of home health payments to which it was not entitled but failed to disclose or refund the overpayments in a timely manner.[20]	**$630,000**
3/24/2022	Compassionate Homecare, Inc.	Home health provider agreed to pay, and the bankruptcy court has approved, $6.53 million to resolve FCA allegations that it billed MassHealth for services that were not appropriately certified by a physician as medically necessary. In September 2019, Compassionate and its former owner pleaded guilty to separate criminal healthcare fraud charges. In May 2020, Compassionate filed for bankruptcy. Under the settlement agreement, up to $375,000 will be prioritized for distribution to former employees for unpaid wages.[21]	**$6.53 million**
3/25/2022	All American Homecare Agency	Home health provider agreed to pay $4 million to resolve FCA allegations that it falsely claimed to have paid its home care aides the minimum wage required under New York State law, thereby receiving Medicaid reimbursement to which it was not entitled.[22]	**$4 million**
3/25/2022	Crown of Life Care NY LLC	Home health provider agreed to pay $1.4 million to resolve FCA allegations that it falsely claimed to have paid its home care aides the minimum wage required under New York State law, thereby receiving Medicaid reimbursement to which it was not entitled.[23]	**$1.4 million**
5/5/2022	SHC Home Health Services of Florida, LLC	Home health company operator agreed to pay $2.1 million to resolve FCA allegations that it submitted claims to Medicare for home health services provided to beneficiaries who: (1) were not homebound; (2) did not require the level of care provided; (3) did not have a valid or otherwise appropriate plan of care in place; and/or (4) were not appropriately certified for home health services.[24]	**$2.1 million**

19 https://www.justice.gov/usao-sdoh/pr/ohio-home-healthcare-provider-agrees-pay-500000-part-false-claims-act-settlement.
20 https://www.mass.gov/news/ag-healey-secures-630000-from-home-health-care-company-to-resolve-false-billing-allegations.
21 https://www.mass.gov/news/home-health-agency-agrees-to-pay-653-million-to-masshealth-to-resolve-allegations-of-fraud.
22 https://www.justice.gov/usao-edny/pr/home-healthcare-agencies-settle-fraud-claims-54-million-and-agree-pay-wages-and.
23 https://www.justice.gov/usao-edny/pr/home-healthcare-agencies-settle-fraud-claims-54-million-and-agree-pay-wages-and.
24 https://www.justice.gov/usao-wdky/pr/home-health-company-operating-florida-pays-21-million-resolve-false-claims-allegations.

HOSPICE AND HOME HEALTH

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
5/5/2022	Integrity Home Care Solutions, LLC; Joseph Kimani; Beatrix Fingfing	Home health provider and its owners agreed to pay $550,000 to resolve FCA allegations that they submitted claims to MassHealth for services that were not appropriately authorized by a physician. In order to continue to participate in MassHealth, Integrity is required to implement a three-year compliance program through an independent compliance monitor.[25]	**$550,000**
8/19/2022	Familia Healthcare Services Inc. d/b/a Del Cielo Hospice and Palliative Care	Hospice provider agreed to pay more than $990,000 to resolve FCA allegations that it submitted claims to Medicare for hospice services provided to patients who were not eligible or qualified to receive the hospice benefit.[26]	**$990,478**
10/5/2022	Allied Health Systems; Henry Azzun	Home health provider and its CEO agreed to pay $430,000 to resolve FCA allegations that they submitted claims to MassHealth for services that were not appropriately authorized by a physician. In order to continue to participate in MassHealth, Allied is required to implement a three-year compliance program through an independent compliance monitor.[27]	**$430,000**
10/18/2022	CHC Holdings, LLC d/b/a Carter Healthcare; Stanley Carter; Brad Carter	Home health provider, its former CEO, and its former COO agreed to pay more than $22 million to resolve FCA allegations that they paid physicians sham medical director payments to induce the referral of patients, in violation of the AKS. As part of the resolution, Carter Healthcare entered into a five-year CIA with HHS-OIG. The two former officers are excluded from participating in federal healthcare programs for five years.[28]	**$22.94 million**
10/18/2022	CHC Holdings, LLC d/b/a Carter Healthcare; Stanley Carter; Brad Carter	Home health provider agreed to pay $6.92 million, its former CEO agreed to pay $75,000, and its former COO agreed to pay $175,000 to resolve FCA allegations that the company billed Medicare for medically unnecessary and/or upcoded therapy services. As part of the resolution, Carter Healthcare entered into a five-year CIA with HHS-OIG. The two former officers are excluded from participating in federal healthcare programs for five years.[29]	**$7.17 million**
12/9/2022	White Glove Community Care, Inc.	Home health provider agreed to pay more than $1.26 million to resolve FCA allegations that it falsely claimed to have paid its home care aides the minimum wage required under New York State law, thereby receiving Medicaid reimbursement to which it was not entitled. White Glove has also agreed to pay its aides $2 million for past due wages under a separate agreement with the Labor Bureau of the New York State Attorney General's Office.[30]	**$1.26 million**

25 https://www.mass.gov/news/ag-healey-secures-550000-from-home-health-care-company-to-resolve-false-billing-allegations.
26 https://www.justice.gov/usao-sdtx/pr/hospice-agrees-pay-nearly-1m-settle-false-claims-liability.
27 https://www.mass.gov/news/ag-healey-secures-430000-from-springfield-home-health-agency-to-resolve-fraudulent-billing-allegations.
28 https://www.justice.gov/usao-wdok/pr/oklahoma-city-home-health-company-and-two-former-corporate-officers-agree-pay-229.
29 https://www.justice.gov/opa/pr/carter-healthcare-affiliates-and-two-senior-managers-pay-7175-million-resolve-false-claims.
30 https://www.justice.gov/usao-edny/pr/home-health-care-agency-settles-fraud-claims-126-million-and-agrees-pay-2-million-wages.

SKILLED NURSING FACILITIES AND NURSING HOMES

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
3/11/2022	England Associates, L.P. d/b/a New London Health Center	SNF provider agreed to pay $400,000 to resolve FCA allegations that it billed Medicare for therapy services that were not reasonable, necessary, and/or skilled. New London allegedly: (1) upcoded patients' Resource Utilization Group scores in order to receive higher Medicare reimbursement; (2) provided the minimum number of minutes required to bill a given reimbursement level while discouraging therapy beyond those minutes; (3) ramped up therapy during reimbursement determination periods solely to receive higher Medicare reimbursement; and (4) provided therapy services to patients who did not need or could not benefit from such services.[31]	**$400,000**
6/21/2022	RollinsNelson LTC Corp.; Vicki Rollins; Bill Nelson	SNF operator and two owners settled FCA allegations in a declined *qui tam* action involving allegations of medically unnecessary admissions of nursing home patients to a hospital.[32]	**Undisclosed**
6/29/2022	TCPRNC, LLC d/b/a Plaza Rehab and Nursing Center; Citadel Consulting Group LLC d/b/a Citadel Care Centers LLC	SNF provider and its management company agreed to pay $7.85 million to resolve allegations that Plaza, at the direction of Citadel, frequently changed residents' insurance coverage without their consent or knowledge, in an effort to increase Medicare reimbursements. As part of the resolution, Plaza and Citadel entered into a five-year CIA with HHS-OIG.[33]	**$7.85 million**
6/30/2022	MorseLife Health System Inc.	Nursing home operator agreed to pay $1.75 million to resolve FCA allegations that it misused funds from the Centers for Disease Control and Prevention Pharmacy Partnership for Long-Term Care Program to facilitate COVID-19 vaccines for hundreds of persons who were neither residents nor staff, including board members, donors, and staff family members.[34]	**$1.75 million**
7/29/2022	Old Man's Home of Philadelphia d/b/a Saunders House	SNF provider agreed to pay $819,640 to resolve FCA allegations that it submitted claims to Medicare for services that were not medically necessary and/or were provided to patients who did not need or could not benefit from such services.[35]	**$819,640**
8/2/2022	Elderwood Administrative Services, LLC	SNF operator and affiliated facilities agreed to pay $950,000 to resolve allegations that they submitted claims to Medicare and Medicaid for medically unnecessary physical, occupational, and speech therapy services.[36]	**$950,000**

31 https://www.justice.gov/usao-ndga/pr/england-associates-lp-dba-new-london-health-center-pays-40000000-resolve-false-claims.
32 *U.S. ex rel. Winter v. Gardens Regional Hospital, Inc., et al.*, No. 14-cv-08850 (C.D. Cal.), Dkt. No. 302.
33 https://www.justice.gov/usao-sdny/pr/us-attorney-announces-785-million-settlement-citadel-skilled-nursing-facility-bronx.
34 https://www.justice.gov/opa/pr/morselife-nursing-home-health-system-agrees-pay-175-million-settle-false-claims-act.
35 https://www.justice.gov/usao-edpa/pr/montgomery-county-skilled-nursing-facility-pay-more-819000-resolve-false-claims-act.
36 https://www.justice.gov/usao-wdny/pr/elderwood-agrees-pay-950000-resolve-allegations-senior-care-company-fraudulently-billed.

SKILLED NURSING FACILITIES AND NURSING HOMES

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
8/10/2022	American Senior Communities, L.L.C.	SNF operator agreed to pay more than $5.5 million to resolve FCA allegations that it billed Medicare for various therapy services provided to beneficiaries who had already been placed in hospice, resulting in double-billing for services already covered by patients' Medicare hospice benefit.[37]	**$5.59 million**
11/3/2022	Sea View Retreat, Inc.; Stephen Comley II	SNF provider and its owner agreed to pay $175,000 to resolve FCA allegations that they submitted claims to MassHealth despite knowledge that they were not implementing mandatory infection control and prevention procedures during the COVID-19 pandemic, which allegedly resulted in some residents contracting and at least one dying from COVID-19. As part of the resolution, the company and its owner agreed to no longer own, operate, or manage long-term care or assisted living facilities in Massachusetts.[38]	**$175,000**
11/29/2022	Tranquility Incorporated d/b/a San Miguel Villa	Nursing home operator agreed to pay $2.3 million to resolve allegations that it billed Medicare and Medi-Cal for grossly substandard nursing services that did not meet the minimum required standards for skilled nursing care.[39]	**$2.3 million**

37 https://www.justice.gov/usao-sdin/pr/us-attorney-s-office-recovers-over-55-million-civil-false-claims-settlement-american.
38 https://www.mass.gov/news/ag-healey-reaches-settlement-with-rowley-nursing-home-over-pandemic-response-failures.
39 https://www.justice.gov/usao-ndca/pr/concord-nursing-home-pay-23-million-settle-allegations-grossly-substandard-care.

PHARMACEUTICAL AND DEVICE

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
1/4/2022	Central Medical Systems, LLC; Alan Trent Harley; Joan Harley	Medical equipment supplier, its owner/president, and his wife agreed to pay $600,000 to resolve FCA allegations that the owner changed item quantities in the billing software, thereby inflating the company's Medicare reimbursements. In addition, after the United States intervened and Medicare suspended payments to the company, the government alleged that the owner and his wife conspired with another company to bypass the suspension and continue to receive Medicare payments. The owner pleaded guilty to related criminal charges in 2020 and was sentenced to 15 months in prison.[40]	**$600,000**
1/12/2022	Foot Care Store, Inc. d/b/a Dia-Foot; Robert Gaynor	Medical equipment supplier and its CEO agreed to pay more than $5.5 million to resolve claims that they provided diabetic patients with shoe inserts made from generic foot models when the customers ordered custom-made inserts. The company billed Medicare and Medicaid for custom inserts or sold the products to other companies who in turn billed the government for custom inserts. As part of the settlement, the company and its CEO entered into a three-year IA with HHS-OIG.[41]	**$5.53 million**
1/31/2022	Cardinal Health, Inc.	Pharmaceutical distributor agreed to pay more than $13 million to resolve FCA allegations that it provided upfront discounts to physician practices that were not tied to specific purchases, in violation of the AKS. As part of the resolution, the company's subsidiary at issue entered into a five-year CIA with HHS-OIG.[42]	**$13.12 million**
3/7/2022	Mallinckrodt ARD LLC	Pharmaceutical company agreed to pay, and the bankruptcy court has approved, $260 million to resolve allegations that it: (1) underpaid drug rebates to Medicaid by calculating rebates as if its drug, Acthar, was new in 2013, when it was actually approved in 1952; and (2) used a foundation as a conduit to pay co-pay subsidies, in violation of the AKS. As part of the settlement, the company entered into a five-year CIA with HHS-OIG.[43]	**$260 million**
4/29/2022	Eargo Inc.	Medical device distributor agreed to pay $34.37 million to resolve FCA and common law allegations that it submitted claims to the Federal Employees Health Benefit Program (FEHBP) for hearing aids using diagnosis codes that were not supported by a required hearing loss diagnosis. The government alleged that, after conducting an internal review of its coding and billing practices, the distributor continued to submit the unsupported claims and on bills that it knew FEHBP participants would use to obtain reimbursement.[44]	**$34.37 million**

40 https://www.justice.gov/usao-mdfl/pr/central-medical-systems-llc-alan-trent-harley-and-joan-harley-agree-pay-600k-settle.
41 https://www.justice.gov/usao-sdfl/pr/diabetic-shoe-company-agrees-pay-55-million-resolve-false-claims-act-allegations.
42 https://www.justice.gov/usao-ma/pr/cardinal-health-agrees-pay-more-13-million-resolve-allegations-it-paid-kickbacks.
43 https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-260-million-settle-lawsuits-alleging-underpayments-medicaid-drug.
44 https://www.justice.gov/opa/pr/hearing-aid-company-eargo-inc-agrees-pay-3437-million-settle-common-law-and-false-claims-act.

PHARMACEUTICAL AND DEVICE

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
6/10/2022	Tri-State Medical Supplies, LLC	Medical equipment supplier agreed to pay $363,116 to resolve allegations that it submitted claims to the Oklahoma Medicaid program for equipment and services using inflated pricing and shipping charges.[45]	**$363,116**
7/1/2022	Reliance Medical Systems LLC; Bret Berry; Adam Pike	Medical device distributor, its owners, and two physician-owned distributorships (PODs) agreed to pay $1 million to resolve allegations that they operated the PODs in order to provide compensation to physicians based on their use of the distributor's devices in surgeries, in violation of the AKS. The government alleged that the PODs paid physicians based on their referrals, terminated physicians who did not generate enough referrals, and provided false information to providers. Other PODs' owners previously settled their role in the alleged scheme for a total of more than $9 million.[46]	**$1 million**
7/22/2022	Biotronik Inc.	Medical device manufacturer agreed to pay $12.95 million to resolve allegations that it paid physicians for training events in excess of what was necessary, including events that did not occur or had little value, in exchange for the physicians' use of the manufacturer's products. The government also alleged that the company paid for parties, winery tours, meals, airfare, and speaking fees in exchange for making brief appearances at conferences, in violation of the AKS. As part of the settlement, the company entered into a five-year CIA with HHS-OIG.[47]	**$12.95 million**
8/23/2022	Essilor International; Essilor of America, Inc.; Essilor Laboratories of America, Inc.; Essilor Instruments USA	Medical device manufacturer and affiliated companies agreed to pay $16.4 million to resolve FCA allegations that they created programs to provide remuneration to eye care providers to induce purchases of their optical lenses, in violation of the AKS. In connection with the settlement, the companies entered into a five-year CIA with HHS-OIG.[48]	**$16.4 million**
8/25/2022	BSN Medical Inc.	Medical equipment manufacturer agreed to pay more than $785,000 to resolve FCA allegations that it marketed and promoted devices that were not approved for Medicare coverage or for which approval had expired.[49]	**$785,672**
8/30/2022	Vision Quest Industries, Incorporated	Medical device manufacturer agreed to pay $2.25 million to resolve FCA allegations that it paid commissions to an independent sales representative and his company for each knee brace ordered by a group of clinics for which they facilitated sales, in violation of the AKS. In connection with the settlement, the company entered into a five-year CIA with HHS-OIG.[50]	**$2.25 million**

45 https://www.oag.ok.gov/articles/attorney-general-o'connor-announces-settlement-tri-state-medical-supplies.
46 https://www.justice.gov/opa/pr/department-justice-settles-lawsuit-against-spine-device-distributor-and-its-owners-alleging.
47 https://www.justice.gov/opa/pr/medical-device-manufacturer-biotronik-inc-agrees-pay-1295-million-settle-allegations-improper.
48 https://www.justice.gov/usao-edpa/pr/essilor-agrees-pay-164-million-resolve-false-claims-act-liability-paying-kickbacks.
49 https://www.justice.gov/usao-wdnc/pr/charlotte-medical-device-and-equipment-manufacturer-agrees-pay-over-780000-resolve.
50 https://www.justice.gov/usao-mn/pr/vision-quest-industries-pay-2250000-resolve-false-claims-act-allegations.

PHARMACEUTICAL AND DEVICE

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
8/31/2022	Novo Nordisk Inc.	Pharmaceutical company agreed to pay $6.3 million to resolve FCA allegations that it sold needles manufactured in non-designated countries to United States government agencies, in violation of the Trade Agreements Act of 1979, which restricts the procurement of goods under certain government contracts to purchases from specific designated countries.[51]	**$6.3 million**
9/1/2022	Philips RS North America LLC f/k/a Respironics, Inc.	Medical device manufacturer agreed to pay $24.75 million to resolve FCA allegations that it provided physician prescribing data to suppliers to assist with the suppliers' marketing efforts in exchange for equipment orders from the suppliers, in violation of the AKS. The company entered into a five-year CIA with HHS-OIG as part of the resolution.[52]	**$24.75 million**
9/2/2022	Bayer Corp.; Bayer HealthCare Pharmaceuticals Inc.; Bayer HealthCare LLC; Bayer AG	Pharmaceutical manufacturer and related entities agreed to pay $40 million to resolve FCA allegations in a declined *qui tam* action that they paid kickbacks to physicians and hospitals in attempts to persuade them to use two drugs, in violation of the AKS, and also marketed the drugs for off-label uses that were not reasonable and necessary. In addition, the companies allegedly downplayed the risks of two of their drugs and misrepresented one of the drug's efficacy. As a result of those misrepresentations, the Defense Logistics Agency allegedly was induced to renew contracts for one of the drugs.[53]	**$40 million**
9/14/2022	Akorn Operating Company LLC	Pharmaceutical company agreed to pay $7.9 million to resolve allegations that it delayed seeking FDA approval to switch three medications from prescription-only status to generic, over-the-counter medications and continued to sell generic versions using prescription packaging, resulting in Medicare reimbursements being paid for generic medications in violation of Medicare regulations.[54]	**$7.9 million**
9/22/2022	Philips RS North America LLC f/k/a Respironics, Inc.	Medical device manufacturer agreed to pay more than $1.2 million to resolve FCA allegations that it helped a DME supplier procure a 12-month, interest-free loan by fully guaranteeing the loan itself, in violation of the AKS. As part of the resolution, the company entered into a five-year CIA with HHS-OIG.[55]	**$1.28 million**
9/26/2022	Biogen Inc.	Pharmaceutical company agreed to pay $900 million to resolve FCA allegations in a declined *qui tam* action that it provided speaker honoraria, training fees, consulting fees, and meals to physicians and other healthcare professionals in attempt to persuade them to prescribe specific drugs, in violation of the AKS.[56]	**$900 million**

51 https://www.justice.gov/usao-nj/pr/global-healthcare-company-pay-63-million-resolve-false-claims-act-allegations.
52 https://www.justice.gov/opa/pr/philips-subsidiary-pay-over-24-million-alleged-false-claims-caused-respironics-respiratory.
53 https://www.justice.gov/usao-nj/pr/bayer-corp-pay-40-million-resolve-alleged-use-kickbacks-and-false-statements-relating.
54 https://www.justice.gov/usao-ma/pr/pharmaceutical-company-akorn-operating-company-llc-agrees-pay-79-million-resolve.
55 https://www.justice.gov/usao-ndia/pr/sleep-and-respiratory-equipment-manufacturer-pay-12-million-resolve-allegations.
56 https://www.justice.gov/usao-ma/pr/biogen-inc-agrees-pay-900-million-settle-false-claims-act-allegations-related-improper.

PHARMACEUTICAL AND DEVICE

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
12/5/2022	Essilor Laboratories of America, Inc.	Medical device manufacturer and affiliated companies agreed to pay $23.8 million to resolve allegations that it submitted claims tainted by kickbacks in the form of up-front cash payments to eye care providers in exchange for the referral of certain volumes of business, in violation of the AKS and California's Insurance Frauds Prevention Act.[57]	**$23.8 million**
12/20/2022	Advanced Bionics LLC	Medical device manufacturer agreed to pay more than $12 million to resolve FCA allegations that it misrepresented the results of radio-frequency emissions tests for certain cochlear implant processors in pre-market approval applications to the FDA and billed federal healthcare programs for the defective devices. As part of the resolution, the company entered into a five-year CIA with HHS-OIG.[58]	**$12.6 million**
12/20/2022	BioTelemetry Inc.; CardioNet LLC	Medical device company and its subsidiary agreed to pay more than $44.8 million to resolve FCA allegations that they submitted claims for heart monitoring tests that were performed, in part, outside the United States, and in many cases by technicians who were not qualified to perform such tests. As part of the settlement, the companies entered into a five-year CIA with HHS-OIG.[59]	**$44.87 million**
12/23/2022	Zyno Medical LLC	Medical device manufacturer agreed to pay nearly $500,000 to resolve FCA allegations that it submitted claims to Medicare in connection with infusion medication administration sets that it knew were materially defective.[60]	**$493,140**

57 http://www.insurance.ca.gov/0400-news/0100-press-releases/2022/release084-2002.cfm.
58 https://www.justice.gov/opa/pr/advanced-bionics-llc-pay-over-12-million-alleged-false-claims-cochlear-implant-processors.
59 https://www.justice.gov/opa/pr/cardiac-monitoring-companies-pay-more-448-million-resolve-false-claims-act-liability-relating.
60 https://www.justice.gov/opa/pr/medical-device-company-zyno-medical-llc-agrees-pay-nearly-500000-resolve-false-claims-act.

PHARMACY SERVICES

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
1/28/2022	Hayat Pharmacy	Pharmacy agreed to pay more than $2 million to resolve FCA allegations that it billed Medicare and Medicaid for two prescription medications after switching beneficiaries to these medications from lower-cost options without any medical need and/or valid prescription.[61]	**$2.05 million**
5/2/2022	PillPack, LLC	Online pharmacy agreed to pay $5.79 million to resolve FCA allegations that it dispensed insulin pens to patients in higher quantities than needed according to their prescriptions and then under-reported the days-of-supply dispensed. As a result of the under-reporting, the pharmacy dispensed and submitted claims for refills prematurely.[62]	**$5.79 million**
6/29/2022	Habana Hospital Pharmacy, Inc.; Longevity Drugs, LLC; Forest Hill Pharmacy, LLC	Three pharmacies agreed to pay more than $830,000 to resolve FCA allegations that they used unlawful collaborative practice agreements to delegate prescribing authority from physicians to pharmacists, resulting in unlawful prescriptions. The pharmacies allegedly then wrote and filled prescriptions without physician involvement and submitted claims for the unlawful prescriptions to Medicare and Medicaid.[63]	**$830,707**
7/13/2022	Solera Specialty Pharmacy; Nicholas Saraniti	Pharmacy and its CEO agreed to pay $1.31 million to resolve FCA allegations that they: (1) dispensed a high-priced drug used to reverse opioid overdoses after completing the prior authorization forms required by insurers themselves instead of requiring prescribing physicians to complete them, resulting in the submission of prior authorization requests with false signatures and, in some instances, incorrect clinical information; and (2) waived co-pay requirements for Medicare beneficiaries without analyzing whether they had a financial hardship. As part of the resolution, the company and its CEO entered into a three-year IA with HHS-OIG. The company also entered into a deferred prosecution agreement in connection with a criminal information charging the pharmacy with healthcare fraud.[64]	**$1.31 million**
7/26/2022	DJ Drugs & Surgicals Inc.	Specialty pharmacy agreed to pay $115,000 to resolve FCA allegations that it altered patient medical records and submitted those altered records to Medicare in support of prior authorization requests.[65]	**$115,000**

61 https://www.justice.gov/usao-edwi/pr/milwaukee-pharmacy-chain-pay-over-2-million-resolve-allegations-it-violated-false.
62 https://www.justice.gov/usao-sdny/pr/us-attorney-announces-settlement-fraud-lawsuit-against-online-pharmacy-overdispensing.
63 https://www.justice.gov/usao-sdfl/pr/three-florida-pharmacies-agree-pay-830707-resolve-allegations-they-fraudulently-billed.
64 https://www.justice.gov/opa/pr/solera-specialty-pharmacy-agrees-enter-deferred-prosecution-agreement-company-and-ceo-pay-131.
65 https://www.justice.gov/usao-ma/pr/dj-drugs-surgicals-inc-agrees-pay-115000-resolve-allegations-prior-authorization-fraud.

PHARMACY SERVICES

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
8/11/2022	Spivack, Inc. f/k/a Verree Pharmacy; Mitchell Spivack	Pharmacy and its owner-pharmacist agreed to pay more than $4.1 million as part of a civil consent judgment. The judgment resolves FCA allegations that they dispensed controlled substances despite indications of abuse then made false statements in order to maintain a stock of the drugs. The judgment also resolves allegations that the pharmacy routinely billed federal healthcare programs for drugs that were not actually dispensed. The owner-pharmacist separately forfeited $500,000, and the parties will also be banned from prescribing, dispensing, or distributing controlled substances and will be excluded from participating in Medicare and Medicaid for 22 years.[66]	**$4.1 million**
10/12/2022	DermaTran Health Solutions, LLC; Pharmacy Insurance Administrators, LLC; MLDP of Texas, LP a/k/a Legends Pharmacy; TriadRx; Titan Medical Marketing, LLC; various owners	Several pharmacies and related entities and owners agreed to pay more than $6.8 million to resolve FCA allegations that they: (1) waived co-pays for compound pain creams based on unverified statements of financial need; (2) misrepresented to federal healthcare programs the price of pain creams charged to uninsured patients; and (3) after being terminated from various payor networks, engaged in pass-through billing to circumvent the terminations.[67]	**$6.87 million**
12/13/2022	PharmScript of KS, LLC	Long-term care pharmacy agreed to pay $3 million to resolve FCA allegations that it billed Medicare and Medicaid for controlled substances dispensed to nursing home and long-term care residents without valid prescriptions.[68]	**$3 million**

66 https://www.justice.gov/usao-edpa/pr/philadelphia-pharmacy-and-owner-who-pled-guilty-agree-resolve-civil-fraud-and.
67 https://www.justice.gov/usao-ndga/pr/dermatran-and-three-other-pharmacies-pay-over-68-million-settle-civil-claims.
68 https://www.justice.gov/usao-ks/pr/pharmscript-ks-llc-agrees-pay-3-million-resolve-allegations-it-improperly-dispensed.

LABORATORY, PATHOLOGY, RADIOLOGY, AND DIAGNOSTICS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
2/18/2022	American Health Associates, Inc.	Diagnostic testing company agreed to pay $142,718 to resolve FCA allegations that it billed Medicare for laboratory tests conducted during inpatient hospital stays when the tests were already covered under the inpatient admission.[69]	**$142,718**
3/7/2022	Redwood Toxicology Laboratory, Inc.	Toxicology laboratory agreed to pay more than $4.7 million to resolve FCA allegations that it billed Connecticut Medicaid for urine drug tests at higher rates than it billed other third parties, in violation of Connecticut's "Most Favored Nation" regulation.[70]	**$4.79 million**
3/31/2022	Radeas LLC	Clinical laboratory agreed to pay $11.6 million to resolve FCA allegations that it billed Medicare for both presumptive and confirmatory urine drug tests which were performed at the same time, resulting in reimbursements being paid for confirmatory tests which were not medically necessary. The government also alleged that the laboratory paid sales organizations based on the volume of drug test referrals those representatives made, in violation of the AKS. As part of the resolution, the company entered into a five-year CIA with HHS-OIG.[71]	**$11.6 million**
5/4/2022	Crescendo Bioscience, Inc.; Myriad Genetics, Inc.	Two laboratory testing companies paid $45.25 million to resolve FCA allegations in a declined *qui tam* action that the companies engaged in a kickback scheme by paying processing fees for physician offices, and waiving and capping patient co-pays and deductibles, to induce blood testing orders.[72]	**$45.25 million**
5/19/2022	VirtuOx, Inc.	Diagnostic testing facility operator agreed to pay $3.15 million to resolve FCA allegations that it submitted or caused the submission of claims to Medicare that falsely indicated that pulse oximetry tests were performed at a different location in order to receive a higher reimbursement rate. The settlement also resolves allegations that the company submitted claims for both overnight tests and spot checks on the same patients when only overnight tests were performed. As part of the settlement, the company entered into a five-year CIA with HHS-OIG.[73]	**$3.15 million**
6/1/2022	Caris Life Sciences, Inc.	Molecular testing company agreed to pay over $2.88 million to resolve FCA allegations that it violated Medicare's 14-Day Rule by submitting claims directly to Medicare for: (1) tests ordered within 14 days of inpatient discharge; (2) tests ordered within 14 days of inpatient or outpatient discharge instead of encouraging providers to wait until after the 14-day period to order tests; and (3) tests ordered within 14 days of outpatient procedures.[74]	**$2.88 million**

69 https://www.justice.gov/usao-sdoh/pr/diagnostic-testing-company-agrees-resolve-claims-improperly-billed-testing.
70 https://www.justice.gov/usao-ct/pr/national-laboratory-pays-nearly-48-million-settle-allegations-it-overcharged-connecticut.
71 https://www.justice.gov/usao-ma/pr/radeas-llc-agrees-pay-116-million-resolve-allegations-fraudulent-billing.
72 *U.S. ex rel. STF, LLC v. Crescendo Bioscience, Inc., et al.*, No. 16-cv-2043 (N.D. Cal.), Dkt. No. 143.
73 https://www.justice.gov/usao-sdfl/pr/miami-based-virtuox-inc-agrees-pay-315-million-resolve-allegations-it-fraudulently.
74 https://www.justice.gov/usao-edny/pr/caris-life-sciences-pays-over-28-million-settle-false-claims-act-allegations-delay.

LABORATORY, PATHOLOGY, RADIOLOGY, AND DIAGNOSTICS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
7/14/2022	BioReference Health LLC f/k/a BioReference Laboratories, Inc.; OPKO Health, Inc.	Clinical laboratory and its parent company agreed to pay $9.85 million to resolve allegations that the laboratory leased space from physicians and physician groups at above-market rental rates in exchange for the referral of patients, in violation of the AKS. As part of the resolution, BioReference also entered into a five-year CIA with HHS-OIG.[75]	**$9.85 million**
7/20/2022	Inform Diagnostics, Inc. f/k/a Miraca Life Sciences, Inc.	Clinical laboratory agreed to pay $16 million to resolve FCA allegations that it billed Medicare for additional testing of biopsy specimens that was conducted prior to a pathologist's review to determine if the further testing was medically necessary.[76]	**$16 million**
7/22/2022	Metric Lab Services LLC; Metric Management Services LLC; Spectrum Diagnostic Labs LLC; Sherman Kennerson; Jeffrey Madison	Two clinical laboratories and their owners agreed to pay $5.7 million to resolve FCA allegations that they: (1) entered into agreements with marketers to pay hourly rates for various services, but in reality paid those marketers a percentage of revenue, in violation of the AKS; and (2) billed for genetic tests that were conducted based on false assertions of medical necessity. The two owners each previously pleaded guilty to conspiracy to defraud the United States and are awaiting sentencing.[77]	**$5.7 million**
10/3/2022	Radeas LLC	Clinical laboratory agreed to pay more than $3.6 million to resolve FCA allegations that it billed North Carolina Medicaid for both presumptive and confirmatory urine drug tests which were performed at the same time, resulting in reimbursements being paid for confirmatory tests which were not medically necessary. In March 2022, the laboratory agreed to a five-year CIA with HHS-OIG in connection with a separate resolution related to Medicare billing.[78]	**$3.65 million**

75 https://www.justice.gov/opa/pr/bioreference-laboratories-and-parent-company-agree-pay-985-million-resolve-false-claims-act.
76 https://www.justice.gov/usao-ma/pr/inform-diagnostics-agrees-pay-16-million-resolve-false-claims-act-allegations-medically.
77 https://www.justice.gov/usao-nj/pr/two-clinical-labs-and-their-owners-agree-pay-57-million-resolve-false-claims-and-kickback.
78 https://ncdoj.gov/attorney-general-josh-stein-reaches-3-6-million-medicaid-settlement-with-radeas/.

BEHAVIORAL HEALTH AND SUBSTANCE ABUSE TREATMENT

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
1/21/2022	Lipshutz & Wills Medical Group, LLP d/b/a Monos Health	Addiction treatment provider agreed to pay more than $2 million to resolve FCA allegations that it: (1) performed definitive urine drug testing (UDT) on the same day as presumptive UDT without first reviewing the results of the presumptive test and assessing the individualized need for a definitive test; (2) unnecessarily tested at higher rates when testing at a lower rate associated with less reimbursement would have been sufficient; and (3) used standing orders for definitive UDT in violation of Medicaid and Medicare guidelines. As part of the resolution, the company entered into a three-year IA with HHS-OIG.[79]	**$2 million**
2/23/2022	Geriatric & Adult Psychiatry, LLC; Alan Siegal, M.D.	Psychiatric practice and its owner agreed to pay more than $300,000 to resolve allegations that they employed a physician as the practice's clinical director after he had been excluded from participating in federal healthcare programs as a result of his conviction of conspiracy to commit healthcare fraud. During the director's employment, the practice submitted claims to government healthcare programs in violation of HHS rules.[80]	**$310,874**
2/25/2022	A Brief Counseling Center a/k/a Healthy Counseling Center; Dr. Ray Smith	Mental health practice and its owner agreed to pay $138,984 to resolve FCA allegations that they billed Medicaid for services provided by unlicensed and unqualified therapists who were not contracted with the state or eligible to obtain Medicaid reimbursements for their services and for misrepresenting that services were provided by licensed and qualified therapists.[81]	**$138,984**
3/3/2022	The Pennsylvania State University	University agreed to pay nearly $900,000 to resolve a voluntary disclosure related to its behavioral health clinic submitting allegedly improper claims with respect to: (1) supervision of doctoral students; (2) "incident-to" billing requirements; (3) practitioner Medicare credentialing; and (4) evaluation & management (E&M) services that were not supported by documentation in the medical record.[82]	**$899,824**
3/31/2022	OGCC Behavioral Health Services, Inc.; Dionne Huffman	Behavioral health practice and its owner/executive director agreed to pay $750,000 to resolve FCA allegations that they: (1) falsified the identity and qualifications of healthcare providers to receive higher reimbursement; (2) inflated the amount of time spent with patients; (3) submitted claims for patient visits that never occurred; (4) misrepresented dates of service; and (5) fabricated documents in response to the government's investigation. As a part of the resolution, the practice and its owner entered into a three-year IA with HHS-OIG.[83]	**$750,000**

79 https://ag.nv.gov/News/PR/2022/Attorney_General_Ford_Announces_Medical_Group_to_Pay_Over_$2_Million_to_Settle_Allegations_Involving_Improper_Billing_of_Urine_Drug_Testing/.
80 https://www.justice.gov/usao-ct/pr/hamden-psychiatric-practice-and-its-owner-pay-310k-employing-excluded-individual.
81 https://www.justice.gov/usao-edwa/pr/spokane-mental-health-counselor-agrees-pay-more-135000-fraudulent-medicaid-billing.
82 https://www.justice.gov/usao-mdpa/pr/pennsylvania-state-university-agrees-pay-89982455-settle-voluntary-disclosure-related.
83 https://www.justice.gov/usao-ndga/pr/ogcc-behavioral-services-and-dionne-huffman-pay-75000000-settle-false-claims-act.

BEHAVIORAL HEALTH AND SUBSTANCE ABUSE TREATMENT

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
4/18/2022	Springbok Health Inc.; Mark Jankelow	Substance abuse treatment clinic and its owner/CEO agreed to pay a minimum of $125,000 and up to a maximum of $335,494 to resolve FCA allegations that they billed Medicare and Medicaid for high-complexity, more expensive E&M services when less expensive counseling services, or no services at all, were actually rendered. The ranged resolution is based on the parties' ability to pay.[84]	**$125,000 – $335,494**
5/9/2022	Prism Behavioral Solutions	A provider of behavioral therapy for autistic children agreed to pay $650,000 to resolve allegations that it billed Medi-Cal for services that were not provided, including billing for cancelled appointments.[85]	**$650,000**
6/1/2022	Healthkeeperz, Inc.	Behavioral healthcare provider agreed to pay $2.1 million to resolve allegations that it received reimbursements from North Carolina Medicaid for case management services that are not covered.[86]	**$2.1 million**
7/19/2022	Virginia Treatment Center, LLC d/b/a Roanoke Comprehensive Treatment Center	Opioid treatment center agreed to pay $348,934 to resolve allegations that it billed Virginia Medicaid for addiction treatment counseling provided by individuals without the required credentialing as if it had been provided by properly-credentialed professionals.[87]	**$348,934**
11/1/2022	Psychiatric Care Consultants LLC; Dr. Kishorchandra Gonsai	Psychiatric practice and its owner agreed to pay $532,830 to resolve allegations that they billed the Connecticut Medical Assistance Program for longer psychotherapy sessions than were actually provided. The investigation originated from a fraud referral from the state Department of Social Services.[88]	**$532,830**
12/5/2022	Camden Treatment Associates LLC	Opioid abuse treatment provider agreed to pay a total of $3.15 million to resolve: (1) civil FCA allegations that it billed Medicaid for methadone mixing services tainted by kickbacks in the form of profit-sharing to Camden by the mixing company, who was owned by the same entity; and (2) criminal penalties related to the kickback allegations and allegations that Camden obstructed a Medicaid audit by falsifying documents. The company also entered into a three-year deferred prosecution agreement in connection with the criminal information.[89]	**$1.65 million (civil)** **$1.5 million (criminal)**
12/16/2022	Pathway, Inc.; Pathway of Baldwin County, LLC	Youth rehabilitation center and its operator agreed to pay over $3.49 million to resolve allegations that it submitted claims to Alabama Medicaid for services provided to youth beneficiaries, when the services were not actually provided.[90]	**$3.49 million**

84 https://www.justice.gov/usao-co/pr/colorado-substance-abuse-treatment-clinic-and-owner-agree-settle-false-claims-act.
85 https://www.justice.gov/usao-sdca/pr/southern-california-center-autistic-children-pays-650000-resolve-allegations-fraudulent.
86 https://www.justice.gov/usao-wdnc/pr/healthkeeperz-inc-pay-21-million-resolve-false-claims-act-allegations.
87 https://www.justice.gov/usao-wdva/pr/roanoke-based-opioid-treatment-center-settles-civil-case-united-states.
88 https://portal.ct.gov/AG/Press-Releases/2022-Press-Releases/Attorney-General-Tong-Announces-False-Claims-Settlement-With-Psychiatric-Care-Consultants.
89 https://www.justice.gov/usao-nj/pr/opioid-abuse-treatment-facility-pay-315-million-kickback-violations-obstructing-federal.
90 https://www.justice.gov/usao-sdal/pr/youth-rehabilitation-center-agrees-pay-over-34-million-resolve-allegations-false-claims.

MANAGED CARE AND HEALTH PLANS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
1/4/2022	Empower Healthcare Solutions, LLC	Managed care company agreed to pay almost $8 million to resolve allegations that it violated the Arkansas Medicaid False Claims Act by improperly reporting expenses. The settlement comprised $1 million in civil penalties and costs and an adjustment to Empower's report of expenses that increased its year end reconciliation payment to the Medicaid Fraud program by $6,983,511.[91]	**$7.98 million**
Various	Centene Corporation	Pharmacy benefits manager entered into settlements with multiple states to resolve allegations related to its subsidiaries overcharging for pharmacy benefits management services and failing to pass on retail discounts to state Medicaid programs. Resolutions in 2022 include: • New Mexico: $13.8 million (6/13/2022)[92] • Washington: $32 million (8/24/2022)[93] • Texas: $165.6 million (9/19/2022)[94] • Massachusetts: $14 million (9/29/2022)[95] • Oregon: $17 million (12/6/2022)[96] • Iowa: $44.4 million (12/15/2022)[97]	**$286.8 million**
6/21/2022	Molina Healthcare, Inc.; Pathways of Massachusetts	Managed care company and its former mental health centers subsidiary agreed to pay over $4.62 million to resolve FCA allegations that they billed MassHelath for services provided by staff who were not properly licensed or properly supervised and for which supervision was not adequately documented.[98]	**$4.62 million**
7/1/2022	MCS Advantage, Inc.	Medicare Advantage plan operator agreed to pay $4.2 million to resolve FCA allegations that it gave gift cards to providers' administrative assistants to induce them to enroll Medicare beneficiaries in one of the company's plans, in violation of the AKS.[99]	**$4.2 million**

91 https://www.arkansasonline.com/news/2022/jan/05/empower-healthcare-agrees-to-pay-nearly-8m-to/.
92 https://www.santafenewmexican.com/news/local_news/attorney-general-settles-with-centene-over-lack-of-price-transparency/article_9c88c4ce-eb40-11ec-8636-e34bf8611ea2.html.
93 https://www.atg.wa.gov/news/news-releases/ag-ferguson-health-care-giant-centene-pay-washington-19-million-overcharging.
94 https://www.texasattorneygeneral.gov/news/releases/paxton-recovers-over-165-million-taxpayer-funds-protects-integrity-texas-medicaid-program.
95 https://www.mass.gov/news/ag-healey-secures-14-million-in-settlement-with-nations-largest-medicaid-managed-care-insurer.
96 https://www.doj.state.or.us/media-home/news-media-releases/oregon-announces-17-million-settlement-with-health-care-giant-centene.
97 https://www.thegazette.com/government-politics/iowa-medicaid-insurer-agrees-to-44m-settlement-in-fraud-case.
98 https://www.justice.gov/usao-ma/pr/molina-healthcare-agrees-pay-over-45-million-resolve-allegations-false-claims-act.
99 https://www.justice.gov/usao-pr/pr/mcs-advantage-agrees-pay-42-million-dollars-resolve-allegations-it-violated-false-claims.

SPECIALTY CARE AND OTHER PROVIDER ENTITIES

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
1/12/2022	New Jersey Interventional Pain Management Center, P.C.; Advanced Interventional Pain Management Center LLC; Global Anesthesia Group LLC; Park Avenue Surgery Center LLC; Springfield Surgery Center LLC; Endo Surgi Center of Old Bridge LLC; Dr. Amit Poonia	Various medical practices and surgery centers and one physician-owner agreed to pay more than $7.4 million to settle allegations that they billed federal healthcare programs for the use of surgically implanted neurostimulators when they actually used electro-acupuncture devices that are not implanted surgically and not eligible for reimbursement. As part of the resolution, the entities and owner entered into a three-year IA with HHS-OIG.[100]	**$7.44 million**
1/20/2022	Tri-State Specialists, L.L.P.	Physician group agreed to pay more than $612,000 to settle allegations that it knowingly submitted false claims for the following services performed by a plastic surgeon formerly with the group: (1) cosmetic procedures that were not reimbursable and billed as medically necessary; (2) insufficient services sufficient to support billing for certain high-value surgical procedures; and (3) high-value office visits and surgical procedures when the services provided were not sufficient to justify high-value claims.[101]	**$612,501**
2/2/2022	The Door – A Cent of Alternatives	Youth development center agreed to pay over $12.9 million to resolve allegations that it over-reported the number of visits to its facility in order to receive excessive funding from the federal and New York-funded Indigent Care Pool program that reimburses providers for healthcare services provided to low-income residents.[102]	**$12.9 million**
2/15/2022	Brockton Urology Clinic LLC	Urology practice agreed to pay $100,000 to resolve allegations that it received payments from a hospital purportedly pursuant to an agreement to administer a prostate cancer center, even though the center was never created and the practice never provided a physician to serve as the center's director.[103]	**$100,000**
3/8/2022	Comprehensive Health Services LLC	Global medical services provider agreed to pay $930,000 to resolve allegations that it stored patients' electronic medical records at government-run facilities in Iraq and Afghanistan in unsecured locations, in violation of its contract with the State Department to provide a secure system. The company also allegedly provided supplies, including controlled substances, that were not approved by the FDA or European Medicines Agency as contractually required.[104]	**$930,000**

100 https://www.justice.gov/usao-edny/pr/surgery-centers-and-medical-offices-brooklyn-and-new-jersey-settle-allegations-federal.
101 https://www.justice.gov/usao-ndia/pr/sioux-city-based-physician-group-tri-state-specialists-llp-agrees-pay-over-600000.
102 https://www.justice.gov/usao-sdny/pr/us-attorney-announces-129-million-settlement-door-submitting-fraudulent-cost-reports.
103 https://www.justice.gov/usao-ma/pr/brockton-urology-agrees-pay-100000-resolve-allegations-it-violated-false-claims-act.
104 https://www.justice.gov/opa/pr/medical-services-contractor-pays-930000-settle-false-claims-act-allegations-relating-medical.

SPECIALTY CARE AND OTHER PROVIDER ENTITIES

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
3/18/2022	Windham Eye Group, P.C.; Dana Woods, M.D.; William Kaufold, M.D.	Ophthalmology practice and its owners agreed to pay $192,699 to resolve allegations that they employed a practice administrator who was excluded from participation in federal healthcare programs due to a conviction for healthcare fraud. During the time of his employment, the practice received reimbursements from Medicare, Medicaid, and TRICARE, some of which were used to pay the administrator's compensation.[105]	**$192,699**
3/25/2022	Peninsula Internal Medicine, L.L.C.; Estate of Candy Burns	Medical practice and the estate of its former owner agreed to pay more than $286,000 to resolve allegations that it submitted false claims to Medicare for the following services: (1) blood draws that were actually performed by a laboratory company; (2) smoking cessation counseling that was not conducted; and (3) services performed by mid-level providers at a rate that covers services incidental to those provided by a physician when no physician was present, violating Medicare's "incident to" rule. In 2019, the former owner was indicted on related criminal charges, but died later that year.[106]	**$286,631**
3/29/2022	American Medical Response of Connecticut, Inc.	Ambulance company agreed to pay more than $600,000 to resolve allegations that it improperly billed Medicare and Medicaid for Advanced Life Support services when the company provided Basic Life Support services and in joint response situations with local fire departments because it lacked a written billing agreement with the departments. The company also entered into a consent agreement with the state of Connecticut to cease the prohibited conduct and pay a civil penalty.[107]	**$601,759**
4/11/2022	Skagit Family Health Clinic	Clinic agreed to pay $120,000 to resolve allegations that it billed the Washington State Medicaid program for birth control medications that were imported from outside the United States and not approved by the FDA.[108]	**$120,000**

105 https://www.justice.gov/usao-ct/pr/windham-eye-care-practice-and-its-owners-pay-192k-employing-excluded-individual.
106 https://www.justice.gov/usao-md/pr/salisbury-medical-practice-pays-united-states-over-286000-resolve-claims-it-billed.
107 https://www.justice.gov/usao-ct/pr/ambulance-company-pays-over-600k-settle-allegations-it-submitted-improper-claims.
108 https://www.justice.gov/usao-wdwa/pr/doj-and-skagit-county-health-clinic-resolve-false-claims-act-investigation-over-use.

SPECIALTY CARE AND OTHER PROVIDER ENTITIES

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
4/12/2022	Physician Partners of America LLC; Rodolfo Gari, M.D.; Abraham Rivera, M.D.; various affiliated entities	Pain management practice, its physician-founder and its former chief medical officer agreed to pay $24.5 million to resolve allegations that they violated the FCA by: (1) submitting claims for urine drug tests that were not medically necessary because they required physicians to order both initial and definitive testing at the same time; (2) compensating physicians a portion of the profits received from initial testing, violating the Stark Law; (3) submitting claims for genetic and psychological tests performed prior to physician visits with patients, without regard for medical necessity; and (4) requiring physicians to schedule evaluation and management appointments more frequently than the practice's normal monthly appointments and bill these visits using high-level procedure codes, after the state government suspended non-emergency medical procedures due to COVID-19. Simultaneously, the practice allegedly made false statements to obtain a PPP loan from the Small Business Administration by representing it was not engaged in unlawful activity. As part of the resolution, the company, its founder, and certain affiliated entities entered into a five-year CIA with HHS-OIG.[109]	**$24.5 million**
4/13/2022	Care Plus Management, LLC; Paul D. Weir; John R. Morgan, M.D.; various anesthesia entities	A company that owns and operates anesthesia practices, its founders, and 18 of its practices, agreed to pay $7.2 million to resolve allegations that they induced the physician owners of outpatient surgery centers to award them exclusive services agreements by: (1) allowing physician owners of the centers to be partial owners of the companies created to provide the exclusive services; and (2) subsidizing the costs of drugs, supplies, and equipment the centers used, all in violation of the AKS.[110]	**$7.2 million**
4/27/2022	Care Partners Medical Management, LLC; Josef Schenker, M.D., P.C.; Dr. Josef Schenker	Two urgent care clinics and their physician-owner agreed to pay more than $550,000 to resolve allegations that they billed Medicare for mid- and high-level evaluation and management office visits when the only service provided was a routine COVID-19 test or vaccine.[111]	**$564,217**
6/3/2022	Rodney L. Yentzer	The owner of a group of pain clinics agreed to pay $900,000 to resolve allegations that he caused claims for urine drug tests to be submitted to Medicare when the tests were not medically necessary and not used for diagnosis or treatment of the patients. The owner also agreed to be excluded from federal healthcare programs for 22 years. In March 2022, he pleaded guilty to related criminal charges.[112]	**$900,000**

109 https://www.justice.gov/opa/pr/physician-partners-america-pay-245-million-settle-allegations-unnecessary-testing-improper.
110 https://www.justice.gov/usao-ndga/pr/paul-d-weir-john-r-morgan-md-care-plus-management-llc-and-anesthesia-entities-pay-72.
111 https://www.justice.gov/usao-edny/pr/urgent-care-doctor-and-his-facilities-settle-allegations-federal-health-care-fraud.
112 https://www.justice.gov/usao-mdpa/pr/cumberland-county-man-pay-900000-violations-false-claims-act.

SPECIALTY CARE AND OTHER PROVIDER ENTITIES

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
6/6/2022	Snap Diagnostics LLC; Gil Raviv; Stephen Burton	Home sleep testing provider agreed to pay $3.5 million, and its founder and vice president agreed to pay $300,000 and $125,000, respectively, to resolve allegations that, at the founder's direction, the company billed federal healthcare programs for multiple nights of home sleep testing, when it knew that only one night was necessary and routinely tested and billed only one night for patients with private insurance. The government also alleged that the company multiplied co-pay amounts from Medicare beneficiaries and provided incentives to physicians and staff in exchange for the referral of home sleep testing services, in violation of the AKS. As part of the resolution, the company and its founder entered into a five-year CIA with HHS-OIG.[113]	**$3.92 million**
6/16/2022	PA Foot & Ankle Associates LLC; Adam Teichman, DPM; Thomas Rocchio, DPM; R T Equity Holdings LLC	Podiatrist clinic and its podiatrist co-owners agreed to pay more than $181,000 to resolve allegations that they billed Medicare for the application of an electric stimulation device (Sanexas) or vitamin injections used in conjunction with the device even though they were administered in a way that was not covered under a Medicare NCD and other LCDs.[114]	**$181,758**
7/26/2022	Dental Center, Inc.; Dental Center, P.C. d/b/a Cloudland Dental; Dr. Don Flanagan, D.D.S.	Two dental companies and their dentist owner agreed to pay $1.5 million to resolve allegations that they submitted claims to TennCare for dental services that falsely identified the rendering provider and that were actually furnished by uncredentialed dentists ineligible to bill TennCare. The government also settled with Cloudland Dental's business manager for her role in the alleged conduct.[115]	**$1.5 million**
7/26/2022	Piedmont Infusion Services; Jacob Patterson	Infusion center and its owner agreed to pay $310,000 to resolve allegations that they billed Medicare and Medicaid for high-level office visits that could not have occurred because the center did not employ the qualified medical professionals required to provide such services. In addition, the center allegedly billed Medicare Part B for medications already billed to Medicare Part D.[116]	**$310,000**
8/3/2022	North Country Neurology, P.C.	Neurology practice agreed to pay $850,000 to resolve allegations that it billed Medicare for services provided by a physician assistant as if they were provided or supervised by a physician, when no licensed physician was in the office at the time. The practice also allegedly billed Medicare for Botox in instances where the drug had already been paid for by private insurers.[117]	**$850,000**

113 https://www.justice.gov/usao-ndil/pr/suburban-chicago-home-sleep-testing-company-pay-35-million-settle-federal-health-care.
114 https://www.justice.gov/usao-edpa/pr/two-doctors-and-their-medical-practice-pay-more-181000-resolve-false-claims-act.
115 https://www.justice.gov/usao-edtn/pr/dental-provider-agrees-settle-allegations-improper-billing-tenncare.
116 https://www.justice.gov/usao-wdva/pr/piedmont-infusion-services-danville-and-its-owner-jacob-patterson-pay-false-claims-act.
117 https://www.justice.gov/usao-ndny/pr/watertown-medical-practice-pay-850000-resolve-false-claims-act-allegations.

SPECIALTY CARE AND OTHER PROVIDER ENTITIES

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
8/5/2022	Gonzaga Interventional Pain Management; Melvin Gonzaga, M.D.; Rommel Gonzaga	A pain management clinic, its anesthesiologist and pain management specialist owner, and the clinic's CEO agreed to pay $980,000 to resolve allegations that they billed government healthcare programs for medically unnecessary urine drug testing, using blanket orders for testing and ignoring test results when prescribing patients opioids and other controlled substances. As part of the settlement, the clinic and Dr. Gonzaga entered into a three-year IA with HHS-OIG.[118]	**$980,000**
8/23/2022	Cockerell Dermatopathology; Dr. Clay Cockerell	Dermatopathology clinic agreed to pay $3.75 million to resolve allegations that it allowed a laboratory management company to use the clinic's lab license to submit claims to federal healthcare programs for medically unnecessary tests in exchange for a percentage of the revenue from the tests. The clinic and its owner also allegedly knowingly avoided and concealed their obligation to repay the government for the monies received from the false claims. Under the agreement, the clinic's owner and principal physician will be liable for any part of the settlement amount the clinic fails to pay.[119]	**$3.75 million**
9/1/2022	Maranatha Human Services, Inc.	Nonprofit community service organization agreed to pay $850,000 to resolve allegations that it provided funds to for-profit entities owned by its founder, paid consulting fees and salaries to the founder's family members, and paid personal expenses for the founder, claiming many of these expenditures as allowable costs when reporting expenses to Medicaid. Maranatha's founder, Henry Alfonso Coley, previously agreed to pay $220,000 to resolve allegations related to his role and entered into a 15-year exclusion agreement with HHS-OIG in November 2021.[120]	**$850,000**
9/6/2022	Dynamic Physical Therapy, LLC; Emad Yassa	Physical therapy company and its owner agreed to pay $400,000 to resolve allegations that they billed Medicaid and Medicare for individual aquatic therapy sessions instead of the group sessions that were actually provided and for group sessions without accurate documentation of the patients' participation. They also allegedly billed TRICARE for physical therapy services that were provided by an unauthorized individual.[121]	**$400,000**
9/6/2022	Lifestyle Resumption Integrative Health; Klaude Kocan, D.C.	A chiropractic clinic and its owner agreed to pay $200,000 to resolve allegations that they improperly billed Medicare for the surgical implantation of neurostimulator devices when, in fact, the clinic's nurse practitioner applied non-covered electro-acupuncture devices to patients' ears with an adhesive.[122]	**$200,000**

118 https://www.justice.gov/usao-md/pr/western-maryland-physician-and-pain-management-practice-group-agree-pay-980000-settle.
119 https://www.justice.gov/usao-ndtx/pr/cockerell-dermatopathology-pay-375-million-resolve-healthcare-fraud-claims.
120 https://www.justice.gov/usao-sdny/pr/us-attorney-settles-fraud-lawsuit-against-non-profit-inflating-medicaid-reimbursements.
121 https://www.justice.gov/usao-co/pr/colorado-springs-company-and-owner-pay-400000-resolve-allegations-they-submitted-false.
122 https://www.justice.gov/usao-edky/pr/fort-mitchell-chiropractic-clinic-agrees-settle-allegations-improper-billing-electro.

SPECIALTY CARE AND OTHER PROVIDER ENTITIES

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
10/3/2022	Southeast Florida Hematology and Oncology Group	Hematology and oncology practice agreed to pay $130,000 to resolve allegations that it received upfront discounts from a pharmaceutical distributor that were not tied to specific purchases of the distributor's drugs, in violation of the AKS. The distributor entered into a separate settlement earlier in 2022 to resolve these and other related allegations.[123]	**$130,000**
10/5/2022	Physicians Group Services, P.A.	Physician practice agreed to pay $700,000 to resolve allegations that it billed Medicaid for quantitative urine drug tests that were not individualized to each patient's needs, rendering the tests medically unnecessary.[124]	**$700,000**
10/5/2022	Iredell Physician Network, LLC	Physician group agreed to pay $138,612 to resolve FCA allegations that it received overpayments for E&M services performed by one of its providers and knowingly retained such overpayments.[125]	**$138,612**
10/6/2022	HQRC Management Services LLC; Dr. Barry L. Jacobson; various pediatric dental practices	Pediatric dentist, his management company, and affiliated practices agreed to pay $753,457 to resolve allegations that they billed Medicaid for unnecessary therapeutic procedures on pediatric patients and provided incorrect provider information on claims submitted to Medicaid MCOs.[126]	**$753,457**
10/27/2022	Southeast Regional Pain Center; Kenneth Barngrover, M.D.	Pain medicine specialist and his practice agreed to pay $1 million to resolve allegations that the practice billed Medicare and TRICARE for medically unnecessary and upcoded evaluation and management services and for psychological testing services that were not appropriately administered. The settlement also resolved allegations that the physician did not comply with specific recordkeeping requirements of the CSA in conjunction with a worker's compensation pharmacy that he operated from the practice's offices. The physician and his practice also entered into a three-year Memorandum of Agreement with the DEA.[127]	**$1 million**

123 https://www.justice.gov/usao-ma/pr/florida-medical-practice-agrees-pay-130000-resolve-allegations-it-received-kickbacks.
124 https://www.justice.gov/usao-mdfl/pr/jacksonville-health-care-provider-physicians-group-services-agrees-pay-700000-resolve.
125 https://www.justice.gov/usao-wdnc/pr/iredell-health-system-subsidiary-agrees-pay-over-130000-resolve-allegations-it.
126 https://www.justice.gov/usao-nj/pr/pediatric-dentist-and-affiliated-practices-pay-over-750000-resolve-false-claims-act.
127 https://www.justice.gov/usao-mdga/pr/columbus-pain-medicine-practice-agrees-pay-1-million-resolve-violations-under.

SPECIALTY CARE AND OTHER PROVIDER ENTITIES

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
11/10/2022	Feel Well Health Center of Southington, P.C.; Kevin P. Greene, M.D.	Primary care practice and its principal member and owner agreed to pay more than $2.6 million to resolve allegations that they billed government healthcare programs for: (1) medical visits when fitness services were actually provided, with no legitimate medical component, at a gym the practice operated staffed by medically unlicensed personnel, and then created false medical records and diagnoses; (2) office visits provided by the physician that occurred when he was not actually present in the office; (3) telemedicine visits that did not meet the requirements for office location or the use of an interactive telecommunication system; and (4) medically unnecessary testing and procedures. The settlement also resolved allegations that they accepted payments – in the form of "processing and handling" fees and "speaker" fees above FMV – from a laboratory company in exchange for ordering services for Medicare patients from the company, in violation of the AKS. As part of the resolution, the practice and its owner entered into a three-year IA with HHS-OIG.[128]	**$2.65 million**
11/23/2022	HealthOne Critical Care Transport Service, Inc. d/b/a MedicOne Medical Response	Ambulance company agreed to pay more than $300,000 to resolve FCA allegations that it billed Medicare for transporting patients to and from dialysis treatment when the services were not medically necessary.[129]	**$302,124**

128 https://www.justice.gov/usao-ct/pr/physician-and-medical-office-pay-over-26-million-settle-false-claims-act-and-kickback.
129 https://www.justice.gov/usao-sdil/pr/ambulance-company-settles-allegations-billing-medicare-unnecessary-non-emergency.

INDIVIDUAL PROVIDERS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
1/14/2022	Dr. Vuthy Leng	Physician agreed to pay $228,000 to resolve allegations that he billed Medicare and Medicaid for urine drug tests that were never performed or were performed too late to be useful. For much of the time claims were submitted, the medical equipment for testing the urine samples was broken, resulting in some samples being frozen for testing at a later date and some samples never being tested.[130]	**$228,000**
1/20/2022	Jaspaul Bhangoo, M.D.; Robert Megna, D.O.; Baxter Montgomery, M.D.; Murtaza Mussaji, D.O.; David Sneed, D.O.; Kevin Lewis, D.O.; Angela Mosley-Nunnery, M.D.; B-Saz, P.A.; Richard DeFoore	Seven physicians and one of their professional associations agreed to pay more than $1.1 million in total to resolve allegations that they received illegal remuneration disguised as investment returns from eight MSOs in exchange for the physicians' referrals for laboratory tests from three laboratory companies, in violation of the AKS and Stark Law. In a related settlement, the former hospital CEO agreed to pay $50,000 to settle allegations that he worked with two of those laboratory companies to pay physicians for referrals to the laboratories through MSOs. The hospital allegedly billed commercial insurers for the referred tests, while the laboratories billed federal healthcare programs for the same tests. The former CEO will be excluded from participating in federal healthcare programs for three years. The physicians and former CEO agreed to cooperate with the government's ongoing investigations of and litigation against other involved parties. This settlement followed the government's separate settlements with a laboratory and other providers in 2019 and 2020 for their involvement in the alleged conduct.[131]	**$1.1 million**
2/15/2022	Dr. Mark Stephen Wilson	Orthopedic surgeon agreed to pay $342,750 to resolve allegations that he received illegal kickbacks disguised as medical director fees from a specialty pharmacy in exchange for prescribing and recommending pain creams the pharmacy compounded and produced to patients insured under the Federal Employees Compensation Act Program.[132]	**$342,750**
2/15/2022	Judith K. Caporiccio, N.D.	Naturopathic physician agreed to pay over $70,000 to resolve FCA and CSA allegations that she improperly prescribed controlled substances she was not authorized to prescribe. The physician voluntarily surrendered her DEA registration and was required to implement additional controls and procedures to prevent her conduct from recurring.[133]	**$70,096**

130 https://www.justice.gov/usao-wdwa/pr/doj-and-federal-way-washington-doctor-settle-false-claims-act-allegations-over-drug.
131 https://www.justice.gov/usao-edtx/pr/seven-texas-doctors-and-hospital-ceo-agree-pay-over-11-million-settle-kickback.
132 https://www.justice.gov/usao-ndok/pr/oklahoma-orthopedic-surgeon-agrees-pay-almost-343000-settle-false-claims-act.
133 https://www.justice.gov/usao-edwa/pr/richland-naturopath-agrees-pay-70096-improper-prescription-controlled-substances.

INDIVIDUAL PROVIDERS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
2/24/2022	Dr. Jose Escandon	Physician agreed to pay more than $500,000 to resolve FCA allegations that he billed Medicare for excessive ultrasounds that were medically unnecessary or unreasonable. The investigation arose out of a proactive review of claims showing the physician was a significant statistical outlier for ultrasound claims. The physician and his clinic entered into a three-year IA with HHS-OIG as part of the resolution.[134]	**$504,588**
3/22/2022	Tamar Brionez, M.D.; Gary Goff, M.D.; John Hierholzer, M.D.; Bruce Maniet, D.O.; Huy Chi Nguyen, M.D.; Dung Chi Nguyen, M.D.; Rakesh Patel, D.O.; Cuong Trinh, M.D.; Randall Walker, M.D.; Michael Whiteley, D.O.; Gary Goff, M.D., PA; DFW Primary Medical Alliance, LLC; Brett Markowitz	As a follow-up to a settlement involving parallel allegations in January 2022, 10 physicians and two of their affiliated entities agreed to pay a total of over $1.68 million to resolve allegations that they received illegal remuneration disguised as investment returns from eight MSOs in exchange for the physicians' referrals for laboratory tests from three laboratory companies, in violation of the AKS and Stark Law. In a related settlement, the founder and CEO of a medical practice operator agreed to pay $185,000 to resolve allegations that one of those laboratory companies paid referral fees to a company associated with the founder/CEO in exchange for patient referrals by the practices operated by his company, in violation of the AKS. The physicians and CEO agreed to cooperate with ongoing investigations of and litigation against other involved parties.[135]	**$1.68 million**
3/28/2022	Dr. Harry Doyle; Sonya Doyle	Psychiatrist and his office assistant agreed to pay $3 million to resolve FCA allegations that they billed the Department of Labor Office of Workers' Compensation Programs (OWCP) for services that were not provided, upcoded claims, and double-billed for claims to both patients and the OWCP. The Doyles agreed to voluntarily be excluded from federal healthcare programs for 25 years.[136]	**$3 million**
3/31/2022	Anuja Kurichh, M.D.	Physician agreed to pay $555,000 to resolve allegations that she billed federal healthcare programs for ultrasound studies that occurred on dates she was out of the country or that were not actually performed as billed.[137]	**$555,000**
4/6/2022	Dr. Ahmed Khan	Physician agreed to pay $40,800 to resolve FCA allegations that he received consultation fees from a third-party marketing company in exchange for ordering DME and topical pain creams for patients with whom he did not have an established provider-patient relationship, often having no interaction at all with the patients.[138]	**$40,800**

134 https://www.justice.gov/usao-sdtx/pr/physician-pays-over-half-million-settle-allegations-concerning-ultrasound-billing.
135 https://www.justice.gov/usao-edtx/pr/ten-texas-doctors-and-healthcare-executive-agree-pay-over-168-million-settle-kickback.
136 https://www.justice.gov/usao-edpa/pr/philadelphia-psychiatrist-pay-3-million-resolve-allegations-false-workers-compensation.
137 https://www.justice.gov/usao-md/pr/maryland-internal-medicine-physician-agrees-pay-more-500000-dollars-settle-federal-false.
138 https://www.justice.gov/usao-mdpa/pr/medical-doctor-pay-40800-resolve-civil-liability-alleged-violations-false-claims-act.

INDIVIDUAL PROVIDERS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
4/6/2022	Dr. Judith Rubin	Podiatrist agreed to pay $865,000 to resolve FCA allegations that she submitted claims to Medicare for the surgical implantation of neurostimulator electrodes when the procedures performed were actually non-surgical application of electro-acupuncture devices.[139]	**$865,000**
4/14/2022	Vinay K. Malviya, M.D.	Gynecologic oncologist agreed to pay $775,000 to resolve FCA allegations that he billed federal healthcare programs for medically unnecessary hysterectomies and chemotherapy services, as well as evaluation and management services that he did not perform or misrepresented. The physician agreed to a three-year exclusion from federal healthcare programs. In August 2021, the government settled with several hospitals for their role in the allegations.[140]	**$775,000**
5/24/2022	Dr. Roger Wang	Rheumatology specialist agreed to pay more than $1 million to resolve FCA allegations that he billed Medicare and Medicaid for non-FDA-approved drugs used to treat osteoarthritis pain and for the related injection procedures.[141]	**$1.03 million**
6/7/2022	James A. Sakr, M.D.	Otolaryngologist agreed to pay more than $600,000 to resolve allegations that he billed Medicare and Medicaid for procedures that were not performed or were not documented in patient medical records.[142]	**$602,661**
6/8/2022	Soaries Maxine Peterson, M.D.	Physician agreed to pay $500,000 to resolve FCA and Controlled Substances Act allegations that she: (1) billed Medicare and Medicaid for services she did not perform, including office visits where patients met only with unlicensed office staff, often to obtain monthly controlled substance prescriptions; and (2) wrote controlled substance prescriptions for illegitimate purposes and outside the scope of her professional practice. The physician surrendered her DEA registration for cause and agreed to never reapply for a new registration. She also pleaded guilty to one count of healthcare fraud.[143]	**$500,000**
6/10/2022	Minas Kochumian, M.D.	Physician agreed to pay over $9.4 million to resolve: (1) civil FCA allegations that he submitted claims to Medicare and Medi-Cal for a variety of procedures, services, and tests that were never performed; and (2) a related guilty plea for one count of healthcare fraud in a separate criminal case. The physician was sentenced to 41 months in prison with two years' supervised release.[144]	**$3.98 million (civil)** **$5.50 million (criminal)**

139 https://www.justice.gov/usao-sdtx/pr/podiatrist-pays-six-figures-settle-allegations-involving-false-procedure.
140 https://www.justice.gov/opa/pr/michigan-doctor-pay-775000-resolve-false-claims-act-allegations.
141 https://www.justice.gov/usao-ndca/pr/san-francisco-physician-pay-more-1000000-settle-allegations-false-medicare-charges.
142 https://www.justice.gov/usao-wdny/pr/dansville-physician-agrees-pay-more-600000-resolve-allegations-he-fraudulently-billed.
143 https://www.justice.gov/Usao-wdmi/pr/2022_0608_Peterson.
144 https://www.justice.gov/usao-edca/pr/los-angeles-doctor-pay-95-million-resolve-allegations-fraud-against-medicare-and-medi.

INDIVIDUAL PROVIDERS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
6/21/2022	Patrick C. Finney, M.D.	Physician agreed to pay $561,800 in a civil consent judgment to resolve FCA allegations that he: (1) entered into financial arrangements with a physician staffing firm and received illegal remuneration in violation of the AKS in exchange for referring Medicare patients for or ordering DME and genetic testing items and services; and (2) improperly billed Medicare for DME and genetic testing claims that were medically unnecessary and tainted by AKS violations. The physician admitted his FCA violations.[145]	**$561,800**
6/28/2022	Louis Coates, D.O.; Jason DeMattia, M.D.; Candice DeMattia, M.D.; Emanuel Paul (E.P.) Descant II, M.D.; Mitchell Finnie, M.D.; Mark Le, M.D.; Richard Le, M.D.; Robert Jeremy Laningham, M.D.; Rodney Jason Laningham, M.D.; Andres Mesa, M.D.; Melissa Miskell, D.O.; Marco Munoz, M.D.; Kozhaya Sokhon, M.D.; Annie Varughese, M.D.; Paul Worrell, D.O.	Fifteen physicians agreed to pay a total of $2.83 million to resolve allegations that they received illegal remuneration disguised as investment returns from nine MSOs in exchange for the physicians' referrals for laboratory tests from three laboratory companies, in violation of the AKS and Stark Law. Cumulatively, the government has recovered over $32 million from 33 physicians, two healthcare executives, and one laboratory through civil settlements involving these FCA allegations. These 15 physicians also agreed to cooperate with the government's ongoing related investigations and litigation, including a separate *qui tam* action pending against healthcare executives and others for their involvement in the allegations (Case No. 4:16-cv-547 (E.D. Tex.)).[146]	**$2.83 million**
7/18/2022	Dr. Gerald M. Sacks	Pain specialist agreed to pay more than $270,000 to resolve allegations that he prescribed certain medications to Medicare beneficiaries in exchange for receiving paid consulting work and speaking engagements from the manufacturers of the medications, in violation of the AKS.[147]	**$271,259**
8/4/2022	Dr. Manish Kumar; Eastern Iowa Dermatology, PLC	Dermatologist and his practice agreed to pay $1.66 million to resolve allegations that they billed Medicare for upcoded dermatology office visits and related services. As part of the settlement, the physician and his practice entered into a three-year IA with HHS-OIG.[148]	**$1.66 million**
8/12/2022	Azizulah (Aziz) Kamali; Aziz Kamali, M.D. Inc.	Physician and his practice agreed to pay almost $2 million to resolve allegations that they: (1) submitted claims to Medicare for the surgical implantation of neurostimulator devices without actually performing the surgery or implanting the device, instead taping non-covered disposable electroacupuncture devices to patients' ears; and (2) violated the AKS by paying a marketing company a percentage of the improper Medicare reimbursements in exchange for patient referrals for the non-covered devices. The physician and his practice entered into a three-year IA with HHS-OIG as part of the resolution.[149]	**$1.96 million**

145 https://www.justice.gov/usao-wdky/pr/paducah-doctor-admits-violating-false-claims-act-and-being-liable-millions-his-role.
146 https://www.justice.gov/opa/pr/fifteen-texas-doctors-agree-pay-over-28-million-settle-kickback-allegations.
147 https://www.justice.gov/opa/pr/california-pain-specialist-agrees-settle-alleged-receipt-kickbacks-pharmaceutical-companies.
148 https://www.justice.gov/usao-sdia/pr/united-states-settles-166-million-healthcare-fraud-claim-against-iowa-dermatologist.
149 https://www.justice.gov/usao-edca/pr/stockton-doctor-and-medical-practice-agree-pay-nearly-2-million-resolve-allegations.

INDIVIDUAL PROVIDERS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
9/6/2022	Dr. Craig M. Morgan; Eye Consultants of Huntington Inc.	Ophthalmologist and his practice agreed to pay more than $900,000 to resolve allegations that they submitted false claims for medically unnecessary eye injections. HHS-OIG identified the physician as one of the top outliers for billing Medicare across all medical specialists in West Virginia.[150]	**$907,074**
9/7/2022	Dr. Ronald Bergman; Bergman Cosmetic Surgery, P.C.	Cosmetic surgeon and his practice agreed to pay $800,000 to resolve allegations that he billed federal healthcare programs for: (1) services that were provided by other individuals and in which he was not involved to the extent necessary to bill under his name or which were provided when he was not present; and (2) the application of skin substitute products that were not medically necessary or unreasonable.[151]	**$800,000**
10/20/2022	Mangesh Kanvinde, M.D.	Physician agreed to pay $720,000 to resolve allegations that he billed Medicare for medically unnecessary DME and genetic tests and received illegal kickbacks from physician staffing agencies and telehealth companies in exchange for ordering the medically unnecessary DME and genetic tests and services. As part of the resolution, the physician agreed to exclusion from federal healthcare programs for 15 years and to make additional payments contingent upon his income over the next five years.[152]	**$720,000**
10/24/2022	Ahmad M. Mehdi; Ahmad M. Mehdi, M.D., P.C.	Physician and his practice agreed to pay $900,000 to resolve FCA and CSA allegations that they billed federal healthcare programs for: (1) upcoded medical services, (2) inadequately documented smoking cessation counseling services; and (3) improperly prescribed opioids.[153]	**$900,000**
11/18/2022	Dr. Thomas Raley, Jr.; Advanced Spine and Pain, PLLC	Physician and his practice agreed to pay more than $3.1 million to resolve FCA allegations that he wrote and referred compounded drug prescriptions in exchange for illegal kickback payments from pharmacists involved in the alleged scheme. In addition to the civil settlement, Raley was sentenced to three years in prison for his participation in the kickback scheme. Three others involved in the alleged scheme previously received prison sentences ranging from one year and a day to four years.[154]	**$3.15 million**
11/28/2022	Dr. Musaddiq Nazeeri	Physician agreed to pay more than $86,000 to resolve allegations that he billed Medicare for inflated E&M services that were not sufficiently supported by the medical record, including claims for E&M services when the only service provided was the COVID-19 vaccination.[155]	**$86,506**

150 https://www.justice.gov/usao-sdwv/pr/united-states-attorney-announces-90707464-health-care-fraud-settlement.
151 https://www.justice.gov/usao-ndia/pr/iowa-plastic-surgeon-agrees-pay-800000-resolve-allegations-inappropriate-billing-and.
152 https://www.justice.gov/usao-wdky/pr/doctor-pays-720000-and-agrees-15-year-exclusion-federal-health-care-programs-violating.
153 https://www.justice.gov/usao-ndny/pr/central-new-york-doctor-settles-improper-billing-and-controlled-substance-act-claims.
154 https://www.justice.gov/usao-edva/pr/doctor-sentenced-accepting-illegal-kickback-payments-return-writing-prescriptions.
155 https://www.justice.gov/usao-mdpa/pr/medical-doctor-pay-8650630-resolve-civil-liability-alleged-violations-false-claims-act.

INDIVIDUAL PROVIDERS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
12/5/2022	Dr. Victor Savinov	Physician agreed to pay $50,000 to resolve FCA allegations that he referred Medicare beneficiaries to certain home health agencies in exchange for free office space, the use of a medical assistant, and a credit card payment, in violation of the AKS.[156]	**$50,000**
12/14/2022	Vijesh Patel, M.D.; Laju Patel	Physician and his office manager/wife agreed to pay $422,789 to resolve FCA allegations that they received kickbacks from three laboratories in exchange for referrals, in violation of the AKS. The Patels allegedly received kickback payments disguised as investment returns, commercially unreasonable space rental payments, and commercially unreasonable urine specimen collection fees.[157]	**$422,789**
12/22/2022	David B. DiMarco, M.D.; D.B. DiMarco, M.D., P.C.; DiMarco Vein Centers LLC	Physician and two affiliated practices agreed to pay over $2.13 million to resolve FCA allegations that they submitted over 1,000 claims to Medicaid for procedures that lacked adequate documentation as to whether they were actually performed or medically necessary. As part of the resolution, the physician also agreed to withdraw from the New York State Medicaid program.[158]	**$2.13 million**

156 https://www.justice.gov/usao-edmi/pr/dr-victor-savinov-pays-50000-resolve-false-claims-act-allegations-relating-unlawful.
157 https://www.justice.gov/opa/pr/physician-and-office-manager-agree-pay-over-420000-settle-kickback-allegations-involving-ne-1.
158 https://ag.ny.gov/press-release/2022/attorney-general-james-secures-over-2-million-medicaid-settlement-western-new.

OTHER

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
1/27/2022	Stepping Stones Healthcare, LLC; Clayton Deardorff	Management services company and its owner agreed to pay $589,000 to resolve FCA allegations related to an arrangement with a Critical Access Hospital (CAH) whereby they charged the CAH a fixed monthly fee plus a percentage of billed charges in exchange for the recruitment and referral of intensive outpatient therapy patients, in violation of the AKS.[159]	**$589,000**
2/14/2022	Grapevine Billing and Consulting Services Inc.; Ted Albin	Medicare reimbursement consulting firm and its owner who provided services to a diabetic testing supplier agreed to pay $50,000 to resolve intervened FCA allegations that they caused the submission of claims to Medicare that: (1) were tainted by kickbacks to beneficiaries in the form of "no cost" glucometers or the waiver of co-payments and/or (2) related to beneficiaries ineligible to seek reimbursement for the glucometers. The settlement amount is expressly based on the defendants' ability to pay. The diabetic testing supplier and its parent previously agreed to pay $160 million for their role in the alleged scheme in August 2021.[160]	**$50,000**
9/27/2022	Public Consulting Group LLC	Consulting company hired by the state of New Jersey to manage a program whereby schools could obtain Medicaid funds for providing covered services to Medicaid-eligible students agreed to pay $2.5 million to resolve FCA allegations that it caused school districts to submit claims for evaluation services that were not covered by Medicaid.[161]	**$2.5 million**
10/3/2022	Active Day of Lowell	Adult day health provider agreed to pay $386,861 to resolve allegations that it billed MassHealth for COVID-19 emergency-related retainer payments equal to the full per diem rate for each day a member would have been scheduled to attend, at higher frequencies than members were actually scheduled to attend. The center allegedly submitted claims for members who were in nursing homes or other inpatient settings and therefore not able or scheduled to attend.[162]	**$386,861**
11/1/2022	Modernizing Medicine Inc.	EHR vendor agreed to pay $45 million to resolve intervened FCA allegations that it violated the AKS through three marketing programs: (1) recommending a specific pathology laboratory to its customers in exchange for payments from the laboratory; (2) working with the laboratory to donate EHR to providers in an effort to increase orders to the lab and its own user base; and (3) paying kickbacks to existing customers and other sources to recommend its EHR to potential new customers.[163]	**$45 million**

159 https://www.justice.gov/usao-sdms/pr/clayton-deardorff-and-stepping-stones-healthcare-llc-agree-pay-589000-resolve-false.
160 https://www.justice.gov/opa/pr/florida-based-medicare-reimbursement-consultant-resolves-litigation-allegedly-causing-false.
161 https://www.justice.gov/usao-nj/pr/massachusetts-company-enters-settlement-agreement-resolve-claims-medicaid-over-billing.
162 https://www.mass.gov/news/lowell-adult-day-health-provider-resolves-allegations-of-overbilling-masshealth-for-covid-19-payments.
163 https://www.justice.gov/opa/pr/modernizing-medicine-agrees-pay-45-million-resolve-allegations-accepting-and-paying-illegal.

OTHER

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
11/9/2022	Omega Healthcare Investors, Inc.; MRT of Lakeway TX – ACH, LLC; Lakeway Realty, LLC	Real estate investment trust agreed to pay $3 million to resolve FCA allegations that its predecessor in interest offered physicians low-risk, high-reward investment opportunities in a realty group in exchange for referring patients to the hospital it owned, in violation of the AKS.[164]	**$3 million**
11/14/2022	Florida Birth-Related Neurological Injury Compensation Plan; Florida Birth-Related Neurological Injury Compensation Association	Legislatively-created compensation plan established to provide compensation for the care of children who suffer certain categories of birth-related neurological injuries and the plan administrator agreed to pay $51 million to resolve FCA allegations that they caused program participants to submit claims to Medicaid instead of to the program itself, in violation of Medicaid's status as the payor of last resort under federal law.[165]	**$51 million**
12/15/2022	Ocenture LLC; Carelumina LLC	Marketing company and its subsidiary agreed to pay $3 million to resolve FCA allegations that they paid and received kickbacks in connection with genetic cancer tests, in violation of the AKS. Ocenture allegedly solicited genetic testing samples directly from Medicare beneficiaries, paid physicians to attest to the medical necessity of the testing, and arranged for laboratories to process and bill Medicare for the testing. The laboratories then paid a portion of the reimbursements to Ocenture.[166]	**$3 million**

164 https://www.justice.gov/usao-wdtx/pr/omega-healthcare-investors-inc-agrees-pay-3-million-settle-civil-false-claims-act.
165 https://www.justice.gov/opa/pr/florida-birth-related-neurological-injury-compensation-plan-and-association-pay-51-million.
166 https://www.justice.gov/opa/pr/ocenture-llc-and-carelumina-llc-settle-allegations-false-claims-unnecessary-genetic-testing.

ABOUT BASS, BERRY & SIMS

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

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

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

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

- An innovative, searchable database featuring nearly 1,700 significant FCA settlements from the last decade.
- Inside the False Claims Act blog.
- Current and past editions of the Healthcare Fraud & Abuse Annual Review.
- A video library with conferences and webinars highlighting the latest compliance and enforcement developments.

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

TOP-RANKED NATIONAL HEALTHCARE PRACTICE

Ranked the fourth largest healthcare firm in the U.S. by the American Health Law Association (2022).

Healthcare practice and Healthcare Government Investigations and Fraud attorneys recognized by *Chambers USA* (2022).

Firm recognized by Law360 as a Practice Group of the Year winner in the Health Care category (2020).

MEMBERS & COUNSEL

ANGELA L. BERGMAN

Counsel | 615.742.7738 | abergman@bassberry.com

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

KRISTIN M. BOHL

Member | 202.827.2987 | kristin.bohl@bassberry.com

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

J. TAYLOR CHENERY

Member | 615.742.7924 | tchenery@bassberry.com

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

MATTHEW M. CURLEY

Co-chair, Healthcare Fraud & Abuse Task Force | Member
615.742.7790 | mcurley@bassberry.com

Matt Curley is co-chair of the Bass, Berry & Sims Healthcare Fraud & Abuse Task Force and represents clients in connection with internal and governmental investigations and related civil and criminal proceedings, particularly involving matters of fraud and abuse within the healthcare industry. Matt has considerable experience in litigating matters under the FCA and in representing clients in actions and investigations brought by government regulators, including DOJ, HHS-OIG, and various state agencies. Matt previously was Assistant U.S. Attorney with the U.S. Attorney's Office for the Middle District of Tennessee, where he served as Civil Chief and coordinated enforcement efforts arising under the FCA. He is an adjunct professor at Vanderbilt Law School and has taught Healthcare Fraud & Abuse there for more than a decade.

JOHN C. EASON

Member | 615.742.7830 | jeason@bassberry.com

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

LINDSEY BROWN FETZER

Member | 202.827.2964 | lfetzer@bassberry.com

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

LAUREN M. GAFFNEY

Member | 615.742.7824 | lgaffney@bassberry.com

Lauren Gaffney represents healthcare clients concerning regulatory compliance and healthcare fraud matters. She counsels clients through internal investigations and related resolutions such as self-disclosures and voluntary repayments. She also counsels clients in connection with responding to audits and appeals by government contractors.

SCOTT D. GALLISDORFER

Member | 615.742.7926 | scott.gallisdorfer@bassberry.com

Scott Gallisdorfer represents healthcare clients in government investigations and complex litigation, with a particular emphasis on fraud and abuse matters. He routinely counsels clients on responding to FCA allegations, making self-disclosures, and investigating compliance issues.

JEFF H. GIBSON

Member | 615.742.7749 | jgibson@bassberry.com

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

ANNA M. GRIZZLE

Member | 615.742.7732 | agrizzle@bassberry.com

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

BRIAN IRVING

Member | 615.742.7769 | birving@bassberry.com

Brian Irving represents businesses and individuals in complex litigation and government investigations, focusing on healthcare fraud, securities fraud, and business disputes. Brian's clients span a variety of industries, including healthcare, pharmaceuticals, government contracting, and financial services. Brian is the editor of the firm's Inside the False Claims Act blog.

STEWART W. KAMEEN

Member | 202.827.2962 | stewart.kameen@bassberry.com

Stewart Kameen advises healthcare clients on all aspects of federal and state healthcare laws and regulations, with a particular emphasis on fraud and abuse regulatory counseling, corporate compliance, internal investigations and government enforcement actions, *qui tam* litigation, and transactional matters. Stewart is able to counsel providers drawing on his unique perspective informed by his experience working at HHS-OIG as Senior Counsel in the Office of Counsel to the Inspector General – Industry Guidance Branch – where he handled OIG advisory opinion requests, drafted several proposed and final regulations associated with the Regulatory Sprint to Coordinated Care, and consulted with DOJ relating to various enforcement matters.

TRAVIS G. LLOYD

Member | 615.742.6208 | travis.lloyd@bassberry.com

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

WILLIAM T. MATHIAS

Member | 202.827.2982 | bill.mathias@bassberry.com

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

JENNIFER E. MICHAEL

Member | 202.827.2960 | jennifer.michael@bassberry.com

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

LISA S. RIVERA

Member | 615.742.7707 | lrivera@bassberry.com

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

BRIAN D. ROARK

Co-chair, Healthcare Fraud & Abuse Task Force | Member
615.742.7753 | broark@bassberry.com

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

GLENN B. ROSE

Member | 615.742.6273 | grose@bassberry.com

Glenn Rose represents clients in complex business disputes and healthcare litigation, including defending FCA lawsuits, conducting internal investigations, and assisting clients with risk management issues.

MOLLY K. RUBERG

Member | 615.742.7862 | mruberg@bassberry.com

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

DANIELLE M. SLOANE

Member | 615.742.7763 | dsloane@bassberry.com

Danielle Sloane helps life sciences and healthcare clients navigate federal and state healthcare laws and regulations. She frequently advises clients on compliance, fraud and abuse, reimbursement, and operational matters, including in the context of transactional diligence and structuring, reimbursement, contractual relationships, compliance reviews, self-disclosures, and voluntary repayments.

JULIA K. TAMULIS

Member | 202.827.2999 | jtamulis@bassberry.com

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

SENIOR ATTORNEYS & ASSOCIATES

MICHAEL K. BASSHAM

Michael Bassham represents healthcare clients in government enforcement and compliance actions concerning the federal and state Stark Laws, AKS, and FCA. He works closely with providers to help them navigate the complex Medicaid requirements in relation to fraud and abuse regulations. Michael spent more than seven years as Chief Deputy General Counsel and then General Counsel of the Bureau of TennCare, the Tennessee Medicaid program. Before that, he prosecuted civil healthcare fraud cases for more than a decade at the Tennessee Attorney General's Office.

NATHAN F. BROWN

Nathan Brown is an associate in the Litigation & Dispute Resolution Practice Group. He focuses his practice on representing clients in investigations and related litigation, and government actions, particularly involving the FCA, AKS and Stark Law. In addition, Nathan assists corporate clients with internal compliance assessments and internal investigations regarding regulatory compliance matters.

GARRAH CARTER-MASON

Garrah Carter-Mason is an associate in the Litigation & Dispute Resolution Practice Group where she represents clients in complex business litigation and government investigations. She completed a clerkship with the Honorable Judge Eli J. Richardson of the U.S. District Court for the Middle District of Tennessee.

HANNAH CHOATE

Hannah Choate advises clients related to government and internal investigations, with a particular focus on fraud and abuse matters in the healthcare industry. Hannah works with clients to respond to allegations of healthcare fraud and abuse from various regulators, including HHS-OIG, DOJ, and various U.S. Attorneys' Offices. Hannah draws on her experience as a former Assistant United States Attorney at the U.S. Attorney's Office for the Western District of Kentucky, where she focused on Affirmative Civil Enforcement matters and managed a caseload of civil fraud matters from investigation through resolution.

MALEAKA N. GUICE

Maleaka Guice provides healthcare regulatory counsel as it relates to compliance, operational and transactional matters. She assists national healthcare providers by offering practical guidance as they navigate complex healthcare issues related to the Stark Law, AKS, and state laws on fraud and abuse, licensure, and corporate practice of medicine.

DEE HARLESTON

Dee Harleston provides healthcare regulatory counsel on mergers, acquisitions, compliance, and operational matters. He also represents healthcare-focused private equity clients and their portfolio companies in buy-side and sell-side mergers and acquisitions. In addition, Dee advises clients related to compliance with federal healthcare laws such as HIPAA, AKS, Stark Law, and CMP and in matters of medical licensure.

SHEANIVA H. MURRAY

Sheaniva Murray represents clients in response to government actions, investigations, and other litigation related to claims brought under various federal and state regulations. In addition, Sheaniva regularly counsels healthcare companies on healthcare fraud and abuse matters related to alleged violations under the FCA, AKS, Stark Law, and Medicare and Medicaid reimbursement rules.

HEATHER M. PEARSON

Heather Pearson provides healthcare regulatory and transactional counsel as it relates to compliance, operational matters, and mergers and acquisitions. Heather draws on her experience as a public health analyst at RTI International, focusing on program evaluation and health system financing for CMS, and her judicial clerkships in the Minnesota Court of Appeals and the U.S. District Court for the Northern District of Indiana. During law school, she summered at the Center for Health Law & Policy Innovation at Harvard Law School and in the Office of the Chief Counsel at the FDA.

Heather Pearson is admitted only in Minnesota; practice supervised by D.C. Bar Members.

BRIANNA R. POWELL

Brianna Powell provides healthcare compliance and fraud and abuse counsel on regulatory, operational, and transactional matters, including counsel on compliance with state and federal healthcare statutes and regulations such as the Stark Law, AKS, FCA, and Emergency Medical Treatment and Labor Act. Additionally, Brianna assists clients in conducting internal investigations and responding to and appealing commercial and government payor audits.

PETER RATHMELL

Peter Rathmell is an associate in the Litigation & Dispute Resolution Practice Group where he represents clients in complex business litigation, government investigations, and related litigation, particularly focusing on the FCA, AKS, and Stark Law. He also counsels clients on internal investigations concerning regulatory compliance matters.

TAYLOR M. SAMPLE

Taylor Sample focuses his practice on representing clients in government actions, investigations, and related litigation, particularly involving the FCA, Stark Law, and AKS. He also assists clients with internal compliance assessments and internal investigations regarding regulatory compliance issues.

RHEA SHINDE

Rhea Shinde provides healthcare regulatory and transactional counsel as it relates to mergers, acquisitions, compliance and operational matters. Rhea draws on her previous experience as a health law fellow in the office of general counsel at a nonprofit health system where she reviewed and advised clients on contracts with providers, suppliers and research sponsors; she also investigated and analyzed relationships with providers and partners for compliance with the AKS.

PAGE MINTON SMITH

Page Minton Smith provides healthcare regulatory counsel as it relates to compliance and healthcare fraud matters. She advises clients on payor reimbursement audits and appeals and assists clients with internal investigations and in responding to potential legal and regulatory violations and government investigations.

BRIANA SPRICK SCHUSTER

Briana Sprick Schuster concentrates her practice on complex litigation matters, helping healthcare companies achieve cost-effective, creative, and favorable resolutions no matter how challenging the dispute. Briana also counsels clients in their contract and business negotiations to help them avoid costly future disputes, advising clients related to breach of contract, fraud, misrepresentation, interference with business relations, and other business torts.

JAMIE GORDON STEAKLEY

Jamie Gordon Steakley counsels healthcare clients on transactional matters as well as compliance, regulatory and operational issues. She works with a range of clients, including hospitals and health systems, physician practice management companies, private equity firms, long-term care providers and others.

HANNAH E. WEBBER

Hannah Webber represents hospitals and other healthcare providers in connection with government enforcement actions, investigations, and related litigation. She routinely counsels clients in compliance matters, FCA litigation, and responses to state and federal government inquiries. She also has experience representing providers in the not-for-profit and academic medicine spaces.

ABBY YI

Abby Yi regularly assists healthcare plans, risk-bearing provider groups, hospital systems, and vendors with investigations and compliance reviews considering issues, including Medicare Advantage risk-adjustment coding, marketing practices, kickback allegations, cybersecurity, and data privacy. Abby also defends healthcare companies in response to government enforcement actions involving potential FCA violations before DOJ, U.S. Attorneys' Offices, and HHS.

BASS BERRY SIMS

CENTERED TO DELIVER.