HEALTHCARE FRAUD & ABUSE REVIEW 2020

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A LOOK BACK ... A LOOK AHEAD

When we released last year's Healthcare Fraud and Abuse Review in early 2020, none of us could have predicted what the year ahead would bring. By March 2020, we saw healthcare professionals standing at the forefront of one of the greatest health crises in a generation, and we saw our healthcare system quickly stressed to the breaking point by the COVID-19 pandemic. Over the next several months, we saw trillions of stimulus dollars distributed by the federal government to provide economic relief to individuals and businesses. By 2020's end, we saw the beginning of a massive and historic vaccine roll-out designed to stem the continued rising tide of COVID-19 infections against the backdrop of leadership changes at the highest levels of government.

Along the way, we continued to pay close attention to healthcare fraud and abuse issues on behalf of our clients, and we began to anticipate the likely issues that would arise from COVID-19-related relief programs. We negotiated significant False Claims Act (FCA) settlements and corporate integrity agreements from our kitchen tables and bedrooms-turned-offices, and we argued and won key FCA cases on behalf of clients, appearing remotely before appellate courts via video conference.

Civil fraud recoveries by DOJ dipped to $2.2 billion in the fiscal year ending September 30, 2020 (FY 2020) as compared to $3.1 billion in FY 2019, and recoveries attributable to the healthcare industry were $1.8 billion in FY 2020, compared with $2.6 billion in FY 2019.

For its part and not surprisingly, the federal government continued forward with its pursuit of healthcare fraud and abuse issues. The Department of Justice's (DOJ) announced results reflect that the government's healthcare fraud enforcement efforts have continued unabated. Civil fraud recoveries by DOJ dipped to $2.2 billion in the fiscal year ending September 30, 2020 (FY 2020) as compared to $3.1 billion in FY 2019, and recoveries attributable to the healthcare industry were $1.8 billion in FY 2020, compared with $2.6 billion in FY 2019.[1]

Whistleblowers filed 672 new *qui tam* lawsuits under the FCA in FY 2020, which represented an increase compared with the prior year, and brought the total number of FCA *qui tam* lawsuits filed since 2010 to more than 7,000. For their efforts, whistleblowers recovered more than $309 million in relator share awards in FY 2020, bringing the total awards to relators to more than $2 billion in the last five years. It is also noteworthy that 250 new non-*qui tam* civil fraud lawsuits were filed last year, which represented an increase of more than 100 such lawsuits from the prior year.

With respect to criminal healthcare fraud enforcement, cases emerged stemming from fraud associated with COVID-19 relief. DOJ has announced a number of indictments, plea agreements, and sentences associated with respect to COVID-19 fraud schemes.[2] There is no question that enforcement efforts with respect to such fraud schemes will remain robust.

In November 2020, DOJ announced the largest healthcare fraud and opioid criminal enforcement action in DOJ history.[3] The takedown involved 345 charged defendants across 51 federal judicial districts, including more than 100 doctors, nurses, and other licensed medical professionals. The government charged defendants with submitting more than $6 billion in false and fraudulent claims to federal healthcare programs and private

1 *See* https://www.justice.gov/opa/pr/justice-department-recovers-over-22-billion-false-claims-act-cases-fiscal-year-2020; https://www.justice.gov/opa/press-release/file/1354316/download.

2 *See, e.g.*, https://www.justice.gov/opa/pr/two-owners-new-york-pharmacies-charged-30-million-covid-19-health-care-fraud-and-money (announcing indictment related to $30 million COVID-19 healthcare fraud and money laundering scheme by the owners of two pharmacies); https://www.justice.gov/opa/pr/medical-technology-company-president-charged-scheme-defraud-investors-and-health-care-benefit (announcing charging of medical technology company executive charged with defrauding investors and healthcare benefit programs in connection with the submission of $69 million in false and fraudulent claims for allergy and COVID-19 testing); https://www.justice.gov/opa/pr/ceo-medical-device-company-charged-covid-19-related-securities-fraud-scheme (announcing charging of CEO of medical device company with COVID-19-related securities fraud scheme); https://www.justice.gov/opa/pr/florida-man-charged-covid-relief-fraud-and-health-care-fraud (announcing charging of individual who participated in scheme to defraud Medicare of at least $5.6 million and fraudulently seeking Paycheck Protection Program loans).

3 https://www.justice.gov/criminal-fraud/hcf-2020-takedown/press-release.

DOJ reported that 250 new non-*qui tam* civil fraud lawsuits were filed last year, which represented an increase of more than 100 such lawsuits from FY 2019.

insurers, which included more than "$4.5 billion connected to telemedicine, more than $845 million connected to substance abuse treatment facilities" and "more than $806 million connected to other health care fraud and illegal opioid distribution schemes across the country."

During its semiannual reporting period for the period ending September 30, 2020, the U.S. Department of Health and Human Services, Office of Inspector General (HHS-OIG) announced 166 criminal and 414 civil actions against individuals and entities engaged in healthcare fraud-related offenses and reported $1.24 billion in investigative receivables due to HHS and $363.2 million in non-HHS investigative receivables, including civil and administrative settlements or civil judgments related to Medicare, Medicaid, and other government healthcare programs.[4] HHS-OIG cited its use of risk assessment and data analytics to identify, monitor, and target potential fraud, waste, and abuse affecting HHS programs and beneficiaries and to promote the effectiveness of HHS's COVID-19 response and recovery programs. HHS-OIG also noted that hospitals overbilled Medicare $1 billion by incorrectly assigning severe malnutrition diagnosis codes to inpatient hospital claims.[5]

There were key regulatory developments, as well. HHS-OIG and the Centers for Medicare & Medicaid Services (CMS) published final rules in a coordinated effort to modernize regulations implementing the Stark Law, the Anti-Kickback Statute (AKS), and the beneficiary inducement provisions of the Civil Monetary Penalties Law. To increase transparency in drug pricing and lower those prices, HHS-OIG released a final rule to alter the way prescription drug discounts are handled and to protect certain drug-manufacturer payments to pharmacy benefit managers (PBMs), which we discuss throughout the Review.

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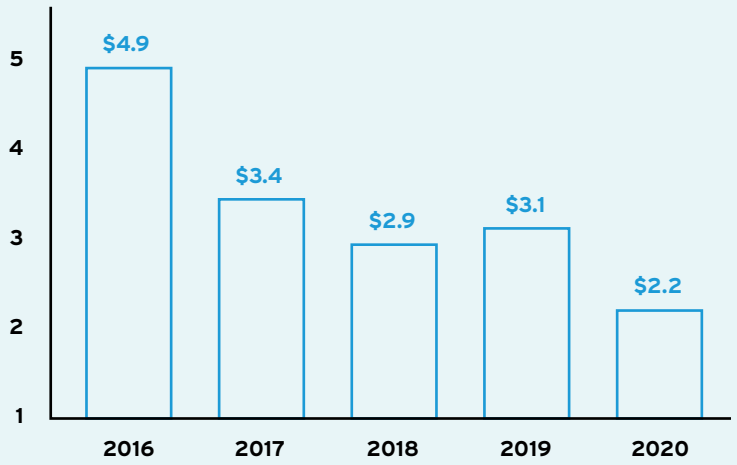
Finally, with the change in administration at the federal level, DOJ, HHS-OIG, and CMS, along with all other federal agencies will have new leadership, new priorities, and undoubtedly new approaches to the pursuit of healthcare fraud and abuse issues.

During these turbulent times, our firm's annual **Healthcare Fraud & Abuse Review** will assist healthcare providers in developing a greater understanding of the civil and criminal enforcement risks they face during a time of great uncertainty for the healthcare industry.

4 https://oig.hhs.gov/reports-and-publications/archives/semiannual/2020/2020-fall-sar.pdf.
5 https://oig.hhs.gov/oas/reports/region3/31700010.pdf.

CIVIL FRAUD RECOVERIES
FY 2016-2020 ($BILLIONS)



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CARES ACT/ COVID-19 RELIEF

In March 2020, Congress passed the $2 trillion Coronavirus Aid, Relief, and Economic Security (CARES) Act for COVID-19-related relief, directing an unprecedented $175 billion to hospitals and healthcare providers. Then, in December 2020, with rising COVID-19 cases, Congress supplemented the initial funding with the Consolidated Appropriations Act, 2021, which included an additional $900 billion for COVID-19 relief, including another $3 billion allocated to the Provider Relief Fund for hospitals and other providers, as well as funds allocated for vaccine distribution, COVID-19 testing and tracing, related mental health resources, and other relief funding.

When the initial funds of $175 billion in the Provider Relief Fund became available to hospitals and providers, former CMS Administrator Seema Verma announced at a White House press conference that "[T]he president wants us to accelerate getting those dollars out. There are no strings attached, so the healthcare providers that are receiving these dollars can essentially spend that in any way they see fit."[6]

However, there are numerous pre- and post-funding requirements in the funding tied to receipt of the relief funds, including areas related to eligibility to request and receive the funds, the determination of actual COVID-19-related expenses, attributable lost revenue related to COVID-19, demonstrable use of COVID-19 funds, and certifications submitted to the government related to any funding provision.

The government has announced its commitment to devote extensive resources and effort to the aggressive pursuit of perceived COVID-19 funding fraud.

The government has announced its commitment to devote extensive resources and effort to the aggressive pursuit of perceived COVID-19 funding fraud. COVID-19 funding presents an enforcement perfect storm; namely, the provision of fast cash in significant amounts to a highly regulated industry, along with poor and evolving government guidance, and assured retrospective scrutiny by the government. Government scrutiny likely will parallel the enforcement efforts that followed stimulus funding in response to the 2008 financial crisis (which was significantly less than COVID-19 funding). There, the government's enforcement efforts resulted in a recovery of $11 billion with respect to stimulus fund recipients, amounting to a return in its recovery enforcement efforts of 31 times the investigation resources expended.[7]

Numerous government resources with directives to investigate pandemic-related compliance issues and fraud allegations are in place, including:

Pandemic Response Accountability Committee (PRAC). PRAC operates within the Council of the Inspectors General on Integrity and Efficiency, and is authorized to conduct audits, conduct its own investigations, issue subpoenas for documents and testimony (including to private individuals), and hold public hearings.

Special Inspector General for Pandemic Recovery (SIGPR). SIGPR is funded with $25 million and has been granted subpoena power and directed to conduct audits and investigations related to the CARES Act.

DOJ, HHS-OIG, and FBI. Each has indicated that COVID-19 investigations are a priority for its respective resources and investigations. DOJ has already identified a "Coronavirus Coordinator" for each of the 93 U.S. Attorneys' Offices who will work together with law enforcement partners across the country by communicating about COVID-19-related investigations and tips in a centralized database called Sentinel, in order to best utilize all components of law enforcement and its tools for this effort.[8]

6 https://www.washingtonpost.com/business/2020/08/04/nursing-home-companies-accused-misusing-federal-money-received-hundreds-millions-dollars-pandemic-relief/.
7 https://www.sigtarp.gov.
8 Memorandum from the Deputy Attorney General, Mar. 19, 2020, available at https://www.justice.gov/file/1268521/download.

Government investigations into COVID-19 funding fraud have already begun, primarily in more apparent, outright fraudulent COVID-19 application and funding schemes. For example, the government has pursued enforcement in connection with Paycheck Protection Program (PPP) loans obtained by allegedly non-existent businesses,[9] for false bank records submitted for funding support,[10] or by claiming hundreds of employees were impacted when no employees exist.[11] Other announced investigations and cases involve allegations of direct misrepresentations related to COVID-19, such as bogus COVID-19 detection claims,[12] false available treatments for COVID-19,[13] and fraudulent personal protective equipment sales.[14]

While blatant fraud cases have dominated early headlines, the government likely will shift its attention to the billions of dollars earmarked for hospitals and other healthcare providers and begin to scrutinize the eligibility, use, and documented support for COVID-19 funds. COVID-19 funding requirements may result in much broader investigations by the government, where the focus may invite more enterprise-wide scrutiny around the need for and use of the funding, rather than a more typical and narrow review concerning a particular service, certain reimbursement codes used for billing, or claims allegedly tainted by an arrangement in violation of the Stark Law or AKS. Companies and providers should consider centralizing and documenting all of the support for COVID-19 funding requests, COVID-19-related expenses, certifications, and how the funding has been utilized, and maintain those records. Investigations, possibly years away, may be generated by whistleblowers, audits, tips, and government COVID-19 funding data.

In a highly regulated industry already accustomed to extensive scrutiny, it is difficult to imagine a more intensive enforcement environment. COVID-19 funding introduces new rules yet to be fully interpreted, with varying and poor government guidance, unprecedented government funding, and the express government directives and devoted resources to pursue issues related to funding concerns. Healthcare companies would be wise to prepare now.

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9 https://www.justice.gov/opa/pr/two-charged-rhode-island-stimulus-fraud.
10 https://www.justice.gov/usao-ndga/pr/reality-tv-star-indicted-federal-charges.
11 https://www.justice.gov/opa/pr/texas-man-charged-5-million-covid-relief-fraud.
12 https://www.justice.gov/opa/pr/ceo-medical-device-company-charged-covid-19-related-securities-fraud-scheme.
13 https://www.justice.gov/usao-wdtx/pr/federal-court-issues-temporary-restraining-order-against-el-paso-man-offering-0.
14 https://www.justice.gov/usao-nj/press-release/file/1320661/download.

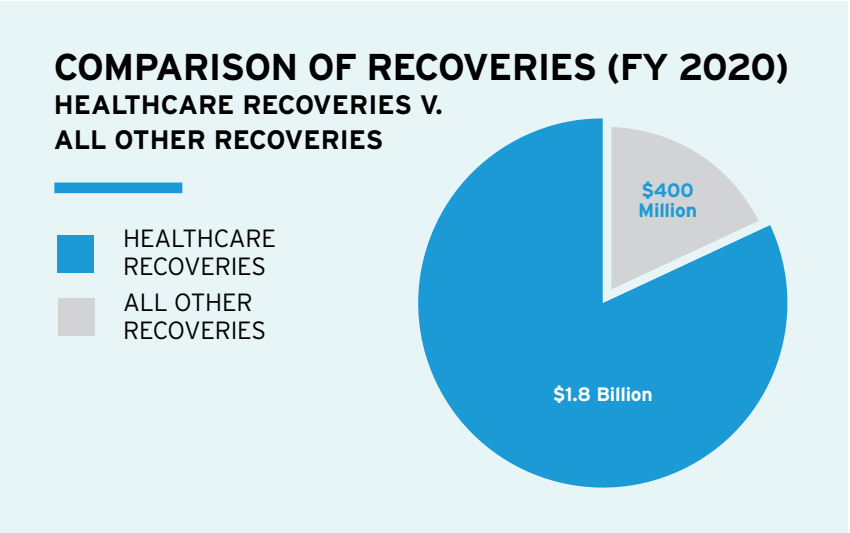
NOTEWORTHY SETTLEMENTS

Following the trend of more than a decade, resolutions in healthcare fraud cases accounted for the vast majority of all FCA recoveries in FY 2020. Of the $2.2 billion in settlements and judgments, recoveries from matters involving the healthcare industry amounted to $1.8 billion (82%).[15]

Newly-filed *qui tam* complaints accounted for the vast majority of new civil fraud matters initiated in FY 2020, which is also typical of recent years. Whistleblowers filed 672 *qui tam* lawsuits in FY 2020 and recoveries from *qui tam* lawsuits accounted for nearly $1.7 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 $1.5 billion of the recoveries from healthcare companies during FY 2020.

The **Appendix** to our Healthcare Fraud & Abuse Review contains a detailed breakdown of key settlements from the past year, many of which are referenced throughout the Review.

15 https://www.justice.gov/opa/pr/justice-department-recovers-over-22-billion-false-claims-act-cases-fiscal-year-2020.



HOSPITALS AND HEALTH SYSTEMS

Hospitals and health systems resolved several notable FCA cases, most of them relating to alleged violations of the Stark Law or AKS. Scrutiny of financial arrangements between hospitals and physician referral sources resulted in settlements totaling $200 million across just six separate cases, which involved allegations of improper remuneration in the form of compensation that exceeded fair market value (FMV) or accounted for the volume or value of physician referrals.[16]

In the year's largest settlement involving hospitals and health systems, psychiatric hospital and behavioral health facility operator Universal Health Services, Inc., UHS of Delaware, Inc., and an affiliated facility agreed to pay $122 million to resolve a variety of FCA allegations, including allegations that they submitted claims for beneficiaries who were ineligible for inpatient or residential treatment and for excessive or improper lengths of stay; failed to provide adequate staffing and training for staff; and improperly used physical and chemical restraints and seclusion. The resolution includes $5 million from an affiliated facility to resolve allegations that it provided free or discounted transportation to induce Medicare and Medicaid beneficiaries to seek treatment at its center.[17]

16 *See* https://www.justice.gov/opa/pr/oklahoma-city-hospital-management-company-and-physician-group-pay-723-million-settle-federal; https://www.justice.gov/opa/pr/west-virginia-hospital-agrees-pay-50-million-settle-allegations-concerning-improper; https://www.justice.gov/opa/pr/texas-heart-hospital-and-wholly-owned-subsidiary-thhbp-management-company-llc-pay-48-million; https://www.justice.gov/usao-ndga/pr/atlanta-hospital-system-pay-16-million-resolve-false-claims-allegations; https://www.justice.gov/usao-wdva/pr/centra-health-inc-and-blue-ridge-ear-nose-throat-and-plastic-surgery-inc-agree-pay; https://www.justice.gov/usao-mdtn/pr/cookeville-hospital-settles-false-claims-act-allegations.

17 https://www.justice.gov/opa/pr/universal-health-services-inc-and-related-entities-pay-122-million-settle-false-claims-act.

Hospitals and health systems also resolved several cases related to medical necessity issues, including allegations of inappropriately coding claims with diagnoses that were not supported by the medical record[18] and billing for procedures that were upcoded or unnecessary.[19]

LONG-TERM CARE PROVIDERS

While settlements involving long-term care providers resulted in more modest recoveries than in recent years, DOJ continued its focus on the medical necessity of services rendered by such providers.[20] Multiple national and multi-state operators of skilled nursing facilities (SNFs) and nursing homes resolved allegations that they billed federal healthcare programs for rehabilitation services that were unreasonable, medically unnecessary, and/or unskilled.[21]

COMPARISON OF TOTAL RECOVERIES:
INTERVENED V. DECLINED CASES SETTLEMENTS AND JUDGMENTS (FY 2016-2020)[22]

YEAR	INTERVENED CASES	DECLINED CASES
2016	$2.92 billion	$108.29 million
2017	$2.54 billion	$602.68 million
2018	$2.00 billion	$135.22 million
2019	$1.94 billion	$295.02 million
2020	$1.49 billion	$193.04 million

18 https://www.justice.gov/usao-mdtn/pr/maury-regional-medical-center-pay-more-17-million-settle-false-claims-act-allegations.

19 *See, e.g.*, https://www.justice.gov/opa/pr/tenet-healthcare-and-affiliated-california-hospital-pay-141-million-settle-false-claims-act; https://www.justice.gov/usao-sdga/pr/augusta-university-medical-center-agrees-pay-2625-million-settle-false-claims-act; https://www.justice.gov/usao-ndga/pr/atlanta-hospital-system-pay-16-million-resolve-false-claims-allegations; https://www.beckershospitalreview.com/legal-regulatory-issues/uc-health-settles-medicare-fraud-allegations.html.

20 *See, e.g.*, https://www.mass.gov/news/ag-healey-announces-10-million-in-recoveries-from-home-health-care-companies-for-falsely; https://www.justice.gov/usao-edva/pr/capital-caring-pays-31-million-resolve-medicare-billing-claims; https://www.justice.gov/usao-mdtn/pr/skilled-nursing-facility-management-company-agrees-settle-false-claims-act-allegations.

21 https://www.justice.gov/opa/pr/guardian-elder-care-holdings-and-related-entities-agree-pay-154-million-resolve-false-claims; https://www.justice.gov/usao-mdtn/pr/diversicare-health-services-inc-agrees-pay-95-million-resolve-false-claims-act; https://www.justice.gov/usao-edmi/pr/contract-rehab-provider-pay-4-million-resolve-false-claims-act-allegations-relating; https://www.justice.gov/opa/pr/nursing-home-chain-saber-healthcare-agrees-pay-10-million-settle-false-claims-act-allegations; https://www.justice.gov/opa/pr/twenty-seven-skilled-nursing-facilities-controlled-longwood-management-corporation-pay-167.

22 https://www.justice.gov/opa/press-release/file/1354316/download.

Notably, each SNF or nursing home that reached an FCA resolution this year also entered into a corporate integrity agreement (CIA) with HHS-OIG as part of the resolution.[23]

Other settlements involving long-term care providers related to alleged violations of the AKS and Stark Law. As one example, home health agency Doctor's Choice Home Care, Inc., and its two former owners agreed to pay $5.8 million to resolve allegations that the agency paid kickbacks in the form of compensation for sham medical directorships and bonuses to family members of referring physicians, in violation of the AKS and Stark Law.[24]

Scrutiny of financial arrangements between hospitals and physician referral sources resulted in settlements totaling $200 million across just six separate cases.

PHARMACEUTICAL AND MEDICAL DEVICE COMPANIES

The pharmaceutical and medical device industry continued to account for the largest recoveries within the healthcare industry last year. Many of the headliner settlements related to the opioid crisis and many involved allegations of AKS violations, among other issues.

The government's ongoing priority of combatting the opioid crisis resulted in historic settlements. In October 2020, the highly publicized charges against Purdue Pharma LP and the Sackler family resulted in multiple settlements totaling $8.3 billion to globally resolve criminal and civil FCA allegations, including $5.5 billion in criminal fines and forfeiture from Purdue – the largest penalties ever levied against a pharmaceutical company. Purdue pleaded guilty to three felony counts and agreed to emerge from its pending bankruptcy as a public benefit corporation focused on opioid abatement and addiction recovery, with DOJ agreeing to credit up to $1.775 billion against the agreed forfeiture amount based on the value of these services conferred on state and local governments.

Purdue's civil settlement resolved allegations that it caused false claims to be submitted to federal healthcare programs by marketing its opioid drugs to healthcare providers it knew were prescribing opioids for uses that were unsafe, ineffective, and medically unnecessary, and that often led to abuse and diversion. It also resolved allegations that Purdue engaged in three different kickback schemes to induce prescriptions of its opioids, including: (1) paying doctors for sham consultancy or educational speaker fees to induce them to prescribe more OxyContin; (2) paying kickbacks to electronic health record (EHR) company Practice Fusion in exchange for referring, recommending, and arranging for the ordering of Purdue's opioid drugs; and (3) entering contracts with specialty pharmacies

23 https://www.justice.gov/usao-mdfl/pr/united-states-settles-false-claims-act-cases-against-home-health-agency; https://www.justice.gov/usao-mdfl/pr/orlando-skilled-nursing-facility-physician-and-related-providers-agree-pay-15-million.

24 https://www.justice.gov/usao-mdfl/pr/home-health-agency-and-former-owners-pay-58-million-settle-false-claims-act-allegations.

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to fill opioid prescriptions that other pharmacies had rejected for potential lack of medical necessity. The settlement with individual members of the Sackler family resolved allegations that the family directed a marketing program that targeted suspicious prescribers and also transferred assets into family holding companies and trusts that were created to hinder future creditors or were otherwise fraudulent transfers.[25]

In November 2020, Indivior Solutions pleaded guilty to a felony and, along with its parent companies, agreed to pay $589 million to resolve global criminal and civil FCA allegations related to its unlawful marketing of Suboxone. The government alleged that Indivior marketed its products to physicians it knew were prescribing Suboxone where there was no legitimate medical purpose. As part of its guilty plea, Indivior admitted to making false statements to MassHealth related to the safety of its Suboxone Film. Both Indivior's former CEO and global medical director entered guilty pleas in connection to the allegations in 2020,[26] and in July 2019, Indivior's former parent, Reckitt Benckiser Group, agreed to pay $1.4 billion for related allegations. Indivior entered into a five-year CIA with HHS-OIG as part of the resolution.[27]

A number of other pharmaceutical company settlements concerned allegations of using patient assistance programs (PAPs) as conduits to pay kickbacks to patients in order to induce prescriptions. Gilead Sciences, Inc., agreed to pay $97 million, Novartis Pharmaceuticals Corporation agreed to pay $51 million, Biogen, Inc., agreed to pay $22 million, and Sanofi-Aventis U.S., LLC, agreed to pay $11.85 million to resolve allegations related to their respective agreements with purportedly independent foundations.[28]

Novartis also resolved FCA allegations that it paid kickbacks to physicians in the form of speaker fees to unlawfully induce increased prescriptions of its drugs in an agreement to pay more than $591 million, forfeit another $38.4 million, and enter into a five-year CIA with HHS-OIG.[29] Other notable AKS resolutions included durable medical equipment (DME) manufacturer ResMed Corp.'s agreement to pay $37.5 million and enter into a five-year CIA to resolve allegations that it paid DME companies kickbacks in the form of free and below-cost services, including free call center and patient outreach services.[30] Medical device manufacturer Merit Medical Systems, Inc., agreed to pay $18 million and enter into a five-year CIA to resolve similar AKS allegations that it caused the submission of claims tainted by illegal kickbacks it paid in the form of practice development and support, advertising assistance, and unrestricted educational grants to healthcare providers.[31]

ELECTRONIC HEALTH RECORDS VENDORS

Another high-dollar, opioid-related settlement involved EHR vendor Practice Fusion. Practice Fusion agreed to pay $145 million to resolve criminal and civil FCA allegations that the company solicited and received kickbacks from multiple pharmaceutical companies in exchange for implementing alerts in its EHR system designed to influence healthcare providers to increase usage of the respective companies' products. The settlement also resolved allegations that the company knowingly caused users to falsely certify compliance with Medicare incentive payment requirements because the software did not meet all requirements it purported to meet.[32]

LAB AND DIAGNOSTIC SERVICE PROVIDERS

Multiple lab companies settled allegations related to medical necessity and AKS and Stark Law violations. In one such settlement, Genova Diagnostics, Inc., agreed to pay $43 million and enter into a five-year CIA to resolve allegations that it submitted claims to federal healthcare programs for medically unnecessary tests and compensated three phlebotomy vendors in violation of the Stark Law, among other allegations.[33] Progenity, Inc., agreed to pay $49 million and enter into a five-year CIA related to allegations that it billed TRICARE and the Federal Employees Health Benefit Program (FEHBP) for non-reimbursable prenatal

25 https://www.justice.gov/usao-me/pr/justice-department-announces-global-resolution-criminal-and-civil-investigations-opioid.
26 https://www.justice.gov/usao-wdva/pr/opioid-manufacturer-indivior-s-former-global-medical-director-pleads-guilty-connection.
27 https://www.justice.gov/opa/pr/indivior-solutions-pleads-guilty-felony-charge-and-indivior-entities-agree-pay-600-million.
28 https://www.justice.gov/opa/pr/gilead-agrees-pay-97-million-resolve-alleged-false-claims-act-liability-paying-kickbacks; https://www.justice.gov/usao-sdny/pr/acting-manhattan-us-attorney-announces-678-million-settlement-fraud-lawsuit-against; https://www.justice.gov/usao-ma/pr/biogen-agrees-pay-22-million-resolve-allegations-it-paid-kickbacks-through-two-co-pay; https://www.justice.gov/usao-ma/pr/sanofi-agrees-pay-1185-million-resolve-allegations-it-paid-kickbacks-through-co-pay.
29 https://www.justice.gov/usao-sdny/pr/acting-manhattan-us-attorney-announces-678-million-settlement-fraud-lawsuit-against.
30 https://www.justice.gov/opa/pr/resmed-corp-pay-united-states-375-million-allegedly-causing-false-claims-related-sale.
31 https://www.justice.gov/usao-nj/pr/medical-device-maker-pay-18-million-settle-allegations-improper-payments-physicians.
32 https://www.justice.gov/opa/pr/electronic-health-records-vendor-pay-145-million-resolve-criminal-and-civil-investigations-0.
33 https://www.justice.gov/usao-wdnc/pr/testing-laboratory-agrees-pay-43-million-resolve-allegations-medically-unnecessary.

testing using a fraudulent billing code and offered improper incentives to patients and doctors to use its laboratory services, in violation of the AKS.[34] And, Logan Laboratories, Inc., Tampa Pain Relief Centers, Inc., and two executives agreed to pay $41 million to resolve FCA allegations that they submitted or caused the submission of false claims to federal healthcare programs for presumptive and definitive urine drug testing that was not medically reasonable or necessary.[35]

BEHAVIORAL HEALTH

There was a marked uptick in FCA resolutions involving behavioral health and substance abuse treatment providers and related individuals. Many of the settlements resolved allegations related to inflating bills for services rendered, including resolutions reached by Preferred Family Healthcare ($6.5 million), Tree of Life, Inc. ($1.65 million), and East Tennessee Recovery ($530,000).[36]

INDIVIDUAL PROVIDERS

The government continued its focus on individual actors and their roles in healthcare fraud schemes, including opioid-related schemes. In one notable case, a physician agreed to pay $2.8 million to resolve civil FCA and Controlled Substances Act allegations that his business submitted claims for controlled substances dispensed without regard for medical necessity and for services that were not actually provided. The physician also pleaded guilty to related criminal charges for which he will pay an additional $3.5 million in restitution and consented to a 20-year exclusion from Medicare and Medicaid and permanent exclusion from prescribing controlled substances.

In another case against an individual involving both civil and criminal charges, a primary care physician agreed to pay more than $316,000 to resolve allegations that he submitted inflated bills to Medicare for visits to patients at nursing homes representing that he had spent more time with the patients than he actually did.[37] The physician pleaded guilty to related criminal charges and was sentenced to two months in prison and to pay a fine of more than $117,000.

More practice extenders have been implicated in FCA resolutions, as well. A physician assistant agreed to pay $25,000 to resolve allegations that she received kickbacks such as food, meals, gift cards, gifts, and speaking and consulting fees from a pharmaceutical company to prescribe the company's dermatology drugs.[38] Another physician assistant agreed to pay more than $620,500 to resolve FCA allegations that he received kickbacks disguised as medical director fees from a compounding pharmacy in exchange for prescribing and recommending the pharmacy's pain creams.[39]

Finally, there were also multiple settlements by individuals relating to medically unnecessary testing. In one such case, a doctor, his wife, and his medical practice agreed to pay $5.5 million and relinquish $3.3 million in assets to resolve allegations that they billed Medicare for what the government called an "astronomical" number of medically unnecessary diagnostic tests, paid outside physicians who interpreted the tests less than the practice's Medicare reimbursement in violation of the federal Anti-Markup Rule, and upcoded billing for office visits, among other allegations.[40]

34 https://www.justice.gov/usao-sdca/pr/san-diego-laboratory-admits-fraudulent-tricare-billing-agrees-pay-49-million.

35 https://www.justice.gov/usao-edpa/pr/florida-based-laboratory-pain-clinic-and-two-former-executives-agree-pay-41-million.

36 https://arkansasag.gov/media-center/news-releases/rutledge-announces-settlements-with-preferred-family-health-totaling-6.5-million/; https://www.justice.gov/usao-edpa/pr/united-states-obtains-165-million-resolution-fraudulent-medicaid-billing-against; https://www.justice.gov/usao-edtn/pr/addiction-recovery-physician-pays-530000-resolve-false-claims-act-allegations-billing.

37 https://www.justice.gov/usao-ndia/pr/northern-iowa-doctor-sentenced-federal-prison-making-false-statements-and-will-pay-more.

38 https://www.justice.gov/usao-edpa/pr/physician-assistant-pay-25000-resolve-allegations-receiving-kickbacks-pharmaceutical.

39 https://www.justice.gov/usao-ndok/pr/physician-assistant-agrees-pay-620-500-allegedly-engaging-illegal-kickback-scheme-0.

40 https://www.justice.gov/usao-ednc/pr/prominent-physician-dunn-north-carolina-agrees-pay-88-million-resolve-allegedly.

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.

GOVERNMENT DISMISSAL AUTHORITY

Following issuance of the Granston Memo in January 2018, the increasing frequency of the government's request to dismiss *qui tam* actions pursuant to its authority under § 3730(c)(2)(A)[41] has brought renewed attention to a long-existing circuit split concerning the appropriate standard when deciding whether to grant such a request made by the government. This split centers on whether the government's dismissal authority under the FCA is "unfettered" and thus, not subject to judicial review, as the D.C. Circuit held in ***Swift v. United States***, or instead is contingent on the government demonstrating that its dismissal request bears a "rational relationship" to a valid government interest, as the Ninth Circuit held in ***U.S. ex rel. Sequoia Orange Co. v. Baird-Neece Packing Corp.***

41 Which allows the government to dismiss a relator's *qui tam* complaint over the relator's objection if the relator is provided notice and an opportunity for a hearing.

Following issuance of the Granston Memo in January 2018, the increasing frequency of the government's request to dismiss *qui tam* actions pursuant to its authority under § 3730(c)(2)(A) has brought renewed attention to a long-existing circuit split concerning the appropriate standard when deciding whether to grant such a request made by the government.

In ***U.S. ex rel. CIMZNHCA, LLC v. UCB, Inc.***, the relator alleged that a pharmaceutical company illegally provided kickbacks to physicians for prescribing or recommending certain prescription drugs.[42] The alleged illegal kickbacks took the form of free education services provided by nurses to physicians and their patients and free reimbursement support services.

The Seventh Circuit became the latest appellate court to wade into the debate when it reversed a district court's denial of the government's motion to dismiss, in which the district court determined that the government's motion was "arbitrary and capricious," and determined that the government's motion to dismiss should be granted.

Rather than pick between the standard articulated by the D.C. Circuit or the Ninth Circuit, the Seventh Circuit effectively created a third standard in evaluating the government's dismissal authority. It determined that the government had amply supported its motion to dismiss the relator's complaint particularly in light of Rule 41(a) of the Federal Rules of Civil Procedure, which allows for dismissal any time "before the opposing party serves either an answer or a motion for summary judgment." The Seventh Circuit found the dismissal right under Rule 41(a) to be absolute under the circumstances because the government had intervened and no answer or motion for summary judgment had been filed. While it characterized its standard as much closer to ***Swift*** than ***Sequoia Orange***, the Seventh Circuit left for another day the question of the appropriate standard to apply if those preconditions were not met, as increasingly is the case in declined FCA cases where the government seeks dismissal after litigation has commenced.

42 970 F.3d 835 (7th Cir. 2020).

The Third Circuit also is considering the dismissal standard in ***U.S. ex rel. Polansky v. Executive Health Resources, Inc.***, which was argued on November 18, 2020, with a decision expected in 2021. The relator alleged that the defendant assisted hospitals in billing claims as inpatient that should have been billed as outpatient. After the United States declined intervention, the relator litigated the case for years before the United States moved to dismiss the case because it considered the expense of responding to discovery to outweigh any potential recovery. The district court granted dismissal and the relator appealed, stating that the dismissal was "shocking" after he and his attorneys had invested years and $20 million in the case. On appeal, the relator has argued that once the United States declines intervention, then the relator's control over the case is exclusive. The United States has countered that claims brought under the FCA ultimately are under the control of the United States.

None of the competing appellate court standards has served as a serious impediment to the government's ability to intervene and dismiss a relator's *qui tam* lawsuit. But, it is worth continuing to watch how courts grapple with this issue as the government continues to exercise this statutory authority.[43]

LONG-AWAITED STARK LAW/AKS CHANGES

Late last year, CMS and HHS-OIG published final rules in a coordinated effort to modernize regulations implementing the Stark Law, the AKS, and the beneficiary inducement provisions of the Civil Monetary Penalties Law. At the same time, in an effort to increase transparency in drug pricing and lower those prices, HHS-OIG separately released a final rule to alter the way prescription drug discounts will be handled and to protect certain drug-manufacturer payments to PBMs.[44] Changes in the final rules include:

- New value-based exceptions and safe harbors;
- Enabling technology infrastructure improvements;
- New rules, definitions, and clarifications aimed at modernizing the Stark Law and AKS; and
- Changes covering pharmaceutical rebates and PBM service fees under the AKS.

43 Despite the fact that the United States rarely invokes its dismissal authority and only in fairly egregious cases, Senator Chuck Grassley nevertheless indicated last summer that "this is not the right approach" and indicated that he was considering legislation to require DOJ to state its reason for seeking dismissal and provide relators a chance to respond to any proposed dismissal before the court decides. Charles E. Grassley, U.S. Sen., Grassley Celebrating Whistleblower Appreciation Day, Address on U.S. Sen. Floor (July 30, 2020).

44 85 Fed. Reg. 77492 (Dec. 2, 2020), https://www.govinfo.gov/content/pkg/FR-2020-12-02/pdf/2020-26140.pdf (Stark); 85 Fed. Reg. 77684 (Dec. 2, 2020), https://www.govinfo.gov/content/pkg/FR-2020-12-02/pdf/2020-26072.pdf (AKS and CMP Law); 85 Fed Reg. 76666 (Nov. 30, 2020).

IN-DEPTH ANALYSIS

CMS & OIG ISSUE FINAL STARK AND AKS RULES

READ NOW

A detailed discussion and analysis of the final rules are included in the white paper we released on December 21, 2020, available here. Together, the final rules implement a framework to support transitions to value-based payment models, promote improvements in technology infrastructure, and create much needed flexibility and clarity. Although the regulations remain complex, healthcare providers should be pleased with the new flexibilities that will support innovation, the avenues to protect financial relationships with referral sources, and the clarifications to help fend off frivolous whistleblower lawsuits.

The Stark Law and AKS final rules aimed at modernization, clarification, and value-based arrangements have an effective date of January 19, 2021, except for the changes to the Stark group practice regulations at 42 CFR § 411.352(i),[45] which have an effective date of January 1, 2022. The changes creating new AKS safe harbors for pharmaceutical point-of-sale price reductions and PBM service fees have an effective date of January 29, 2021, and the changes related to eliminating pharmaceutical rebates from the AKS discount safe harbor have an effective date of January 1, 2022. The delayed effective dates are in recognition of the time needed to make necessary changes to current industry practices to implement the new rules.

OBJECTIVE FALSITY IN FCA CASES

For several years, courts have wrestled with the question of whether subjective clinical decisions about the types and amounts of treatment patients may need can be false for purposes of establishing FCA liability. Healthcare providers have long argued that they cannot.

In 2018, the Sixth Circuit, in ***United States v. Paulus,***[46] and the Tenth Circuit, in ***U.S. ex rel. Polukoff v. St. Mark's Hospital***,[47] dealt significant blows to that argument, with each finding that it is possible for a subjective medical judgment to be false or fraudulent under the FCA. Then, in 2019, the Eleventh Circuit issued the much-anticipated decision in ***U.S. ex rel. Paradies v. AseraCare, Inc.***,[48] in which it held that "a clinical judgment of terminal illness warranting hospice benefits under Medicare cannot be deemed false, under the FCA, when there is only a reasonable disagreement between medical experts as to the accuracy of that conclusion, with no other evidence to prove the falsity of the assessment." Many viewed the Eleventh Circuit's opinion as adopting a so-called "objective falsity" standard.

The debate over whether the FCA requires a showing of objective falsity continued last year, with both the Third and Ninth Circuits weighing in on the issue. In ***U.S. ex rel. Druding v. Care Alternatives***, the Third Circuit analyzed the same hospice certifications considered

45 Regarding the distribution of profits that are related to participation in a value-based enterprise.

46 894 F.3d 267 (6th Cir. 2018).

47 895 F.3d 730 (10th Cir. 2018).

48 938 F.3d 1278 (11th Cir. 2019).

by the Eleventh Circuit in ***AseraCare***, but reached an opposite conclusion.[49] The relators, who were former employees of the hospice care provider, filed a *qui tam* action alleging that the hospice provider defrauded Medicare and Medicaid by routinely certifying patients who were not terminally ill for hospice care. The relators' expert examined the medical records of nearly 50 patients and concluded that the documentation did not support a hospice-eligible certification for approximately 35% of those patients. For its part, the hospice provider produced its own expert who testified that a physician could have reasonably concluded that the patients at issue were terminally ill and needed hospice care.

The district court granted summary judgment, adopting an "objective falsity" test for the FCA's falsity element and concluding, as in ***AseraCare***, that a difference of expert opinions was insufficient for the relators to survive summary judgment. The Third Circuit, however, reversed and expressly declined to adopt the district court's objective falsity standard. Instead, the Third Circuit concluded that a hospice provider's claim for reimbursement could be legally false under the FCA based upon an expert opinion that there was no reasonable basis for certification of a terminal illness prognosis. In other words, the relators' expert proof created a triable issue of fact regarding the issue of falsity.

Weeks later, in ***Winter ex rel. U.S. v. Gardens Reg'l Hosp. & Med. Ctr., Inc.***, the Ninth Circuit followed suit in a case examining whether a doctor's certification that inpatient hospitalization was medically necessary could be false or fraudulent under the FCA.[50] The Ninth Circuit revived a dismissed FCA suit alleging that a hospital, its management company, which also operated a nursing home, and various physicians orchestrated medically unnecessary inpatient admissions resulting in the submission of more than $1.2 million in false claims to Medicare. The Ninth Circuit explained that a physician's certification that admission is medically necessary may be false for the same reason any opinion may be false – the physician may make a subjectively dishonest certification. The Ninth Circuit found that the relator's complaint satisfied Rule 9(b)'s particularity pleading requirement, in light of the relator's allegations that the defendants had a motive to certify falsely – to increase Medicare reimbursements – and that hospitalizations increased sharply after the nursing home's management company gained control over the hospital. The relator further detailed information regarding 65 patients the hospital admitted without medical necessity. These allegations, the Ninth Circuit concluded, were sufficient to survive a motion to dismiss.

> We noted last year that *Medrano* might be a sign of things to come with respect to *qui tam* lawsuits and enforcement directed at private equity firms. This year, there were several notable cases involving private equity-owned healthcare companies.

49 952 F.3d 89 (3d Cir. 2020).
50 953 F.3d 1108 (9th Cir. 2020).

While it may be difficult to square ***AseraCare*** with ***Druding*** and ***Winter***, both the Third Circuit and the Ninth Circuit attempted to draw distinctions. In ***Druding***, the Third Circuit noted that ***AseraCare*** had focused solely on factual falsity, while ignoring legal falsity. Under a legal falsity theory, the Third Circuit explained that a medical opinion that differs from the certifying physician's opinion is relevant evidence of whether the latter was supported by the clinical information and documentation required by Medicare to accompany the certification. Such evidence creates an issue for the jury. In ***Winter***, the Ninth Circuit pointed out that the question in ***AseraCare*** was not whether a medical opinion could *ever* be false, but rather whether a reasonable disagreement between physicians "without more" was sufficient to prove falsity. According to the Ninth Circuit, this left open the possibility that subjective statements could be false under the FCA in certain circumstances.

There now appears to be a circuit split regarding the issue of objective falsity, and it is possible the Supreme Court could weigh in on this issue. In ***Druding***, the defendant filed a petition for a writ of certiorari highlighting the uncertainty among the circuits as to whether a subjective judgment can be false under the FCA. The petition asks the Supreme Court to clarify the falsity standard in the context of hospice certifications. If the Supreme Court were to hear this case, it may well provide clarity regarding the standard for determining falsity under the FCA more broadly.

INTERSECTION OF HEALTHCARE FRAUD ENFORCEMENT AND PRIVATE EQUITY

With increased private equity investment activity in the healthcare industry has come the possibility of increased enforcement scrutiny. Last year, we discussed ***Medrano v. Diabetic Care Rx, LLC***, where a compounding pharmacy and its private equity owner agreed to pay $21.05 million to settle allegations that they had paid illegal kickbacks to maximize reimbursement from TRICARE.[51] The case drew significant attention, as it was one of the first instances where DOJ intervened in an FCA action against a private equity firm relating to the conduct of one of its portfolio companies. We noted last year that ***Medrano*** might be a sign of things to come, and it appears we were right. This year, there were several notable cases involving private equity-owned healthcare companies.

In ***U.S. ex rel. Cho and Baker v. Surgery Partners, Inc.***, the relators filed a *qui tam* suit against Surgery Partners, and several related entities, including the prior and current private equity owners of Surgery Partners, alleging that Surgery Partners engaged in a scheme involving medically unnecessary urine drug testing.[52] DOJ intervened and settled with Surgery Partners and its related entities. While DOJ declined to intervene against the private equity owners, the relators amended their complaint against one of the owners and continued with the lawsuit. The district court ultimately dismissed the relator's complaint on first-to-file grounds, but it seems reasonable to assume the result in ***Medrano*** may have emboldened a pursuit of the private equity firm that might not have occurred in years past.

51 No. 15-62617-CIV-BLOOM (S.D. Fla.).
52 No. 8:17-cv-983-T-17AEP (M.D. Fla.).

More recently, in ***U.S. ex rel. Johnson v. Therakos, Inc.***, the government settled an FCA lawsuit alleging that drug manufacturer Therakos engaged in improper off-label marketing by promoting a cancer treatment for use in pediatric patients.[53] The government alleged that the off-label marketing scheme began under Therakos' prior ownership, but continued after a private equity firm acquired the company. The complaint lacked any specific details supporting the government's allegation that the private equity firm caused Therakos to submit false claims to government payors. In the end, the parties settled the case with Therakos' prior owners agreeing to pay $10 million and the private equity firm agreeing to pay $1.5 million.

These cases are the latest in a developing trend of FCA enforcement actions against private equity firms that are actively involved in running and/or managing their healthcare holdings. It goes without saying that private equity firms must conduct thorough due diligence with respect to potential acquisitions to make sure they are not buying potential FCA liability and must evaluate the adequacy of any existing compliance programs to address any shortcomings. After all, if the past is any indication, private equity firms should expect continued FCA scrutiny going forward.

NURSING HOME ENFORCEMENT INITIATIVES

Long-term care providers have been on the front lines of the most significant public health crisis in our lifetimes. At the same time, these providers must navigate an unprecedented increase in enforcement efforts. A wave of new initiatives and pronouncements by HHS-OIG and DOJ have placed such providers on notice that scrutiny of their operations and the appropriateness of their receipt of government funds and reimbursement for services will intensify in the coming years.

The significant operational difficulties and tragic outcomes experienced amidst the pandemic by some long-term care providers have been well documented. A number of nursing homes have faced extraordinary staffing challenges, critical supply shortages, and a lack of adequate testing for COVID-19. Providers' actions in the face of the current crisis may very well be judged by regulators or scrutinized by whistleblowers with the benefit of hindsight in evaluating the effectiveness of their response to the pandemic. Systemic breakdowns within nursing facilities will be the subject of much second-guessing as to the appropriateness of staffing, the adequacy of training, and the availability of supplies, notwithstanding this challenging environment. We already have seen criminal enforcement against a number of nursing home operators following tragic outcomes.[54]

In the midst of this crisis, DOJ announced its National Nursing Home Initiative in furtherance of its previously-announced Elder Justice Initiative.[55] In no uncertain terms, DOJ has forecasted increased civil and criminal enforcement efforts focused on nursing homes where grossly substandard care to residents has been provided. This announcement followed a number of CMS pronouncements warning of increased scrutiny on long-term care providers and their preparedness concerning infection control and other quality measures.[56] While nursing home and elder care initiatives at the federal and state level are nothing new, the current crisis will result in a much sharper focus on these issues. Increased resources devoted to investigations and more aggressive civil, criminal and administrative enforcement by regulators certainly will follow.

Regulators and whistleblowers can be expected to pivot from fraud theories once largely premised on the overprovision of therapy to theories premised on the assertion that providers submitted false claims for reimbursement because they failed to provide adequate levels of patient care.

DOJ and CMS pronouncements will not be the only drivers of the increased scrutiny that long-term care providers will face. Many providers facing acute financial pressure as a result of the COVID-19 pandemic received much needed financial relief through government stimulus and relief funds. As discussed previously, those funds present their own heightened enforcement risks, as they come with certification requirements concerning the necessity of the funds. Enhanced oversight following such a significant and expedited distribution of government funds will not be far behind, led by government regulators such as SIGPR and DOJ. For providers, maintaining contemporaneous documentation supporting the need for the funding and detailing how the funds were used will be critical to rebutting assertions that certifications of necessity were inaccurate when made or that the funds themselves were misused.

Even before the COVID-19 outbreak, government regulators were expected to shift their enforcement focus toward quality of care concerns and whether long-term care residents were receiving adequate care. This change in focus stemmed from reimbursement changes that went into effect last fall, as reflected in the Patient Driven Payment Model (PDPM), which is now used to classify SNF patients in covered Part A stays.

Notably, industry response to the implementation of PDPM was marked by the reporting of widespread staffing reductions in the wake of the new Medicare payment model, particularly with respect to therapy staff. Regulators and whistleblowers can be expected to pivot from fraud theories once largely premised on the overprovision of therapy to theories premised on the assertion that providers submitted false claims for reimbursement because they failed to provide adequate levels of patient care. The much-publicized staffing reductions undoubtedly will be used to bolster such fraud claims, just as the government and whistleblowers previously pointed to performance metrics and targets in prior cases challenging the medical necessity of therapy services.

53 No. 12-cv-1454 (E.D. Pa.).
54 https://www.mass.gov/news/ag-healey-announces-criminal-charges-against-superintendent-and-former-medical-director-of.
55 https://www.justice.gov/opa/pr/department-justice-launches-national-nursing-home-initiative.
56 https://www.cms.gov/medicareprovider-enrollment-and-certificationsurveycertificationgeninfopolicy-and/guidance-infection-control-and-prevention-coronavirus-disease-2019-covid-19-nursing-homes-revised; https://www.cms.gov/newsroom/press-releases/cms-urging-nursing-homes-follow-established-covid-guidelines-holiday-season.

HHS-OIG is expected to seek more opportunities in the near future to hold drug and device manufacturers, as well as healthcare professionals accountable for their participation in speaker programs. Open Payments undoubtedly will be a fruitful resource for HHS-OIG investigators looking to identify a company's highest-paid providers.

There is no question that the current COVID-19 crisis will accelerate regulators' focus on quality of care issues. Until adequate metrics are in place to monitor quality of care issues in a more transparent way, government regulators will do what they have always done – monitor news reports of quality issues at facilities, focus on reports from whistleblowers, and rely on reports from government agencies on the frontlines of monitoring quality issues. Providers would be well served to monitor quality metrics and complaints regarding quality of care and work to address any identified shortcomings as proactively and fulsomely as possible.

SPECIAL FRAUD ALERT ON SPEAKER PROGRAMS

Last November, HHS-OIG published a Special Fraud Alert highlighting fraud and abuse risks inherent to speaker programs held and organized by pharmaceutical and medical device companies.[57] The alert explained that Open Payments data from the prior three years alone showed that physicians and other healthcare professionals (collectively, HCPs) were paid nearly $2 billion for speaker-related services by drug and device companies, an amount that undoubtedly put speaker programs high on HHS-OIG's radar. The alert made clear that HHS-OIG has become increasingly skeptical about the educational value and intent of speaker programs when there are other ways for HCPs to obtain information about products and diseases that do not involve remuneration, such as online resources, package inserts, third-party educational conferences, and journals.

While the alert focused on the conduct and liability of the "bigger fish" – the drug and device companies holding and organizing such speaker programs – it is important to keep in mind that the AKS is a two-way street capable of ensnaring the "smaller fish" on the receiving end of inducements to refer. In addition to drug and device manufacturers, other industry stakeholders that engage HCPs for speaking engagements such as specialty pharmacies and group purchasing organizations should heed the warning of the alert as well.

Recent enforcement actions concerning sham speaker programs gained traction last year and put into context the application of OIG's recent alert. For example, a New York physician certified in pain management and anesthesiology was sentenced for conspiring to violate the AKS in connection with a scheme to prescribe the now-infamous Subsys in exchange for bribes and kickbacks in the form of speaker program fees from Subsys' manufacturer Insys Therapeutics.[58] The provider, who had never prescribed Subsys before entering into the speaker program arrangement with Insys, became one of the highest-prescribing providers nationally, receiving approximately $143,000 in purported speaking fees in just one quarter – a little more than 10% of the $1.132 million in net sales he generated during the same time frame. Similar cases involving Insys Therapeutics' "speaker bureau" soon followed.[59]

While such cases may reflect instances of egregious behavior, the alert suggests an intent by HHS-OIG to seek more opportunities to hold drug and device manufacturers, as well as HCPs, accountable for their participation in speaker programs. Open Payments undoubtedly will be a fruitful resource for HHS-OIG investigators looking to identify a company's highest-paid providers. Further investigation likely will follow suspect payments. And, invitations to speak at education events in lavish settings with an option to invite friends, staff, or family members should be reminders to providers of the old adage that if an offer to speak at an event seems too good to be true, it probably is.

DOJ COMPLIANCE GUIDANCE UPDATE

Last year, DOJ's Criminal Division again updated compliance guidance first issued in 2017 and entitled "Evaluation of Corporate Compliance Programs."[60] DOJ announced that its update was intended to reflect additions based on DOJ's own experience and "feedback from the business and compliance communities."[61] DOJ uses the guidance to assist prosecutors in assessing the effectiveness of a company's compliance program at the time of the alleged offense and at the time of the charging decision or resolution. As part of the consideration of any resolution, the guidance assists prosecutors in evaluating whether to impose a monitor or other compliance obligations with respect to any resolution, among other things.

DOJ's guidance is premised on three "fundamental questions" a prosecutor should ask: (1) whether the corporation's compliance program is well designed; (2) whether the compliance program is "adequately resourced and empowered to function effectively;"

57 https://oig.hhs.gov/fraud/docs/alertsandbulletins/2020/specialfraudalertspeakerprograms.pdf.

58 https://www.justice.gov/usao-sdny/pr/manhattan-doctor-convicted-manhattan-federal-court-accepting-bribes-and-kickbacks.

59 https://www.justice.gov/usao-mdfl/pr/sarasota-pain-doctor-and-former-insys-sales-representative-charged-health-care-fraud.

60 https://www.justice.gov/criminal-fraud/page/file/937501/download.

61 https://www.wsj.com/articles/justice-department-adds-new-detail-to-compliance-evaluation-guidance-11591052949.

and (3) whether the company's compliance program works in practice. DOJ provides sample topics and questions to guide prosecutors' inquiries, but recognizes that those topics and questions are intended "neither [as] a checklist nor a formula."

In looking at the design of a company's compliance program, the updated guidance offers a number of significant updates. For example, the guidance stresses that "prosecutors should endeavor to understand why the company has chosen to set up the compliance program the way it has" and how the company's compliance program has evolved over time. It also raises the question of whether risk assessments central to the compliance function have been limited to a "snapshot" in time or based on continuous access to operational data and information across functions. And, the guidance stresses the significance of incorporating "lessons learned" from either the company's own issues or those of other companies in the same industry and/or region and consideration of whether the company has taken steps to measure employees' awareness of compliance hotlines and how comfortable employees feel using the hotline.

DOJ's updated compliance guidance stresses the importance of incorporating lessons learned into a company's compliance program whether a result of the company's own mistakes or those of companies facing similar risks.

In evaluating whether a company's compliance program is adequately resourced and empowered, the updated guidance stresses the fostering of ethics and compliance at all levels of the company. The significance of access to relevant sources of data to allow for timely and effective monitoring and testing of controls also has been added as a key element of a well-functioning compliance program. And, DOJ's guidance notes the importance of the company's investment into training and development of compliance and control personnel.

Finally, in considering whether the company's compliance program works in practice, the updated guidance stresses the importance of incorporating lessons learned into the compliance program whether a result of its own mistakes or those of companies facing similar risks.

We know there is a wealth of resources available to companies in assisting them in designing, implementing, and evaluating their compliance programs. Nonetheless, companies would be well-served to closely consider DOJ's updated guidance as an important component of their compliance function.

FALSE CLAIMS ACT UPDATE

The FCA continues to be the federal government's primary civil enforcement tool for imposing liability on healthcare providers that defraud federal healthcare programs. As in previous years, there continues to be 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

In 2016, the Supreme Court held in *Escobar* that in implied certification cases, a "misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be material to the Government's payment decision[62] in order to be actionable under the False Claims Act."[63] The Supreme Court went on to say that materiality is "rigorous" and "demanding" and "looks to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation." Relevant factors in determining materiality are whether the government has expressly identified compliance with the particular requirement as a condition of payment; whether the government consistently refuses to pay claims in other cases based on noncompliance; whether the government, with actual knowledge of noncompliance, paid claims; and whether noncompliance is "minor or insubstantial" or goes "to the very essence of the bargain" for paying the claim.

Since *Escobar*, plaintiffs and defendants have clashed fiercely over application of the materiality standard. Although the Supreme Court stated that materiality is not "too fact intensive" for courts to dismiss FCA cases at the pleading stage, many courts have shied away from dismissing lawsuits for failure to plead materiality. In ***U.S. ex rel. Zissa v. Santa Barbara Cty. Alcohol, Drug & Mental Health Servs.***, the district court had dismissed an earlier version of the complaint without prejudice because the relator had acknowledged that the government had continued to pay claims despite knowledge that the defendant was not maintaining client treatment plans or providing medication support services.[64] After the relator filed an amended complaint, the district court reversed course, finding that the relator adequately pleaded materiality because the regulations allegedly violated were conditions of payment, the relator alleged a state agency disallowed invalid claims found during audits, and the alleged noncompliance was not minor or insubstantial. The district court noted that the parties disagreed regarding the extent of the government's knowledge of alleged violations when it paid the claims in question, but that was a dispute that could not be decided at the pleading stage.

Some courts find even largely conclusory allegations of materiality to be sufficient. In ***U.S. ex rel. McIver v. Act for Health, Inc.***, the relators alleged that the defendant hired unqualified and not properly licensed home health workers and otherwise failed to comply with state licensure requirements.[65] The defendants moved to dismiss on the ground that relators had failed to allege that compliance with state licensure requirements was material to payment of claims. The relator argued that it was not necessary for her to allege "conclusively that, were it aware of the falsity, the government would not have paid." Rather, she argued that she need only plead that "the government *may* not have paid" the claims. The district court did not disagree and denied the motion to dismiss.

Given that whether the legal requirement is labeled as a condition of payment is not dispositive to the materiality analysis, most disputes at the pleading stage focus on whether the plaintiff has alleged some basis for concluding that the government consistently refuses to pay claims based on the alleged noncompliance or that the government continued to pay claims even with actual knowledge of the specific defendant's noncompliance. In ***U.S. ex rel. Silbersher v. Allergan Inc.***, the relator alleged that pharmaceutical companies' fraudulent conduct in obtaining patents to prevent generics from entering the market caused the government to pay inflated prices for their drugs.[66] The district court denied the defendant's motion to dismiss for lack of materiality, holding that the fact that the government had

62 In an important non-healthcare decision, the Second Circuit held that "payment decision" should be interpreted broadly to include both the eligibility determination or decision to award a contract in the first instance as well as the ultimate decision to pay under the contract. *United States v. Strock*, 982 F.3d 51 (2nd Cir. 2020). Even though the United States had not pleaded a single instance where the government had refused to pay a claim or terminated a contract based on a company misrepresenting that it was owned by a service-disabled veteran, the Second Circuit nevertheless reversed dismissal of the case because the complaint adequately alleged that the government never would have awarded the contract in the first place had it known defendant did not meet eligibility criteria.

63 136 S. Ct. 1989 (2016).
64 2020 WL 4369629 (C.D. Cal. Mar. 25, 2020).
65 2021 WL 50879 (D. Colo. Jan. 6, 2021).
66 2020 WL 7319407 (N.D. Cal. Dec. 11, 2020).

In an effort to water down *Escobar*'s focus on whether CMS actually denies payment of claims based on noncompliance, the government and relators have continued to argue that the standard is not whether the government would have refused to pay the claim had it known of the alleged falsity but, rather, whether the falsity had the "natural tendency to influence" a reasonable person.

continued to pay for the drugs after the *qui tam* was filed did not demonstrate a lack of materiality because there was no allegation that the government was aware of the alleged fraud on the Patent Office at the time that it paid for the drugs.

In an effort to water down and distract from *Escobar*'s focus on whether CMS actually denies payment of claims based on noncompliance, DOJ has continued to argue that the standard is not whether the government would have refused to pay the claim had it known of the alleged falsity but, rather, whether the falsity had the "natural tendency to influence" a reasonable person.[67] Some courts, such as the district court in ***McIver***, have accepted the government's strained argument. Other courts, such as ***U.S. ex rel. Gardner v. Vanda Pharmaceuticals, Inc.***, have rejected it.[68] In ***Vanda***, the relator alleged that the defendant pharmaceutical company caused the submission of false claims through promotion and marketing of two drugs for off-label uses. The district court dismissed the lawsuit on the grounds that the relator failed to plead materiality. Focusing on the *prescribing* of drugs for unapproved uses, which the court said was "commonplace" and "ubiquitous" in medical practice, as opposed to the *marketing* of drugs of off-label uses, which has been the valid basis of numerous FCA enforcement actions, the district court held that the relator supplied no factual support that government payors would not have covered prescriptions had they known about off-label uses.

Although DOJ's "natural tendency" standard has helped some plaintiffs get past motions to dismiss, the standard has not fared as well at the summary judgment stage where courts have tended more to focus on whether the government actually has denied claims based on the noncompliance in question versus whether the noncompliance *might* affect the government's payment decision. Courts routinely grant summary judgment in favor of defendants where there is proof that the noncompliance had no effect on the government's payment decision.

67 *See, e.g.*, the Statement of Interest (SOI) filed by the United States in *U.S. ex rel. Gardner v. Vanda Pharmaceuticals, Inc.*, No. 17-cv-464 (D.C.D.C. Dec. 1, 2020). In this SOI and similar statements filed in other declined cases, DOJ has argued that there can be no requirement for relators to allege that government payors would not have paid claims had they known of the noncompliance because the materiality standard is "natural tendency to influence" and not "would have refused to pay."

68 2020 WL 2542121 (D.C.D.C. May 19, 2020).

In one of 2020's most important FCA decisions, ***U.S. ex rel. Janssen v. Lawrence Memorial Hospital***, the relator alleged that the defendant hospital had falsified patient arrival times to increase its Medicare payments under CMS pay-for-reporting and pay-for-performance programs.[69] Although the relator had introduced "numerous pieces of evidence" that the hospital knowingly falsified patient records and misrepresented patient arrival times, the Tenth Circuit affirmed summary judgment for the hospital, holding that the relator had failed to establish that this misconduct was material to payment of claims.

The relator argued that materiality should be judged based on the likely impact of the legal violation on a "reasonable person" or on what the defendant knew or had reason to know in connection with making the alleged misrepresentation. The Tenth Circuit rejected both of those standards, holding that the materiality analysis requires evaluation of the effect on the likely or actual behavior of the government recipient of the alleged misrepresentation. Thus, information that the government was aware of conduct by the defendant or similar conduct by similarly-situated parties, yet did not seek return of payment is relevant proof that the violation was not material. In the instant case, the Tenth Circuit noted that before filing the *qui tam*, the relator had called CMS's fraud hotline to report the conduct, but that CMS had taken no action.

Additionally, the Tenth Circuit rejected the relator's argument that the government's reaction to noncompliance is not relevant unless the defendant can show that the government had knowledge of actual noncompliance. Rather, the Tenth Circuit held that government inaction in the face of noncompliance was sufficient for summary judgment purposes.

Finally, even though the Tenth Circuit did not disagree that accurate data reporting was of central importance to the effective operation of the quality and value-based programs at issue, it still held that did not mean compliance went to the "essence of the bargain" given the availability of administrative procedures designed to ensure hospitals remained in compliance. To hold otherwise would make the FCA into an "all-purpose antifraud statute or a vehicle for punishing garden-variety breaches of contract or regulatory violations."

Courts have routinely granted summary judgment in favor of defendants where there is proof that the noncompliance had no effect on the government's payment decision.

In another closely-followed appellate decision, the Eleventh Circuit in ***U.S. ex rel. Ruckh v. Genoa Healthcare, LLC***, reinstated the bulk of a $348 million judgment entered following a jury verdict against the defendants found to have inflated billing levels for Medicare therapy patients and falsely certified that the SNFs had created timely and adequate patient care plans required by Medicaid.[70] Following the judgment, the district court judge took

69 949 F.3d 533 (10th Cir. 2020).

70 963 F.3d 1089 (11th Circ. 2020).

the extraordinary step of overturning the judgment on materiality grounds. The Eleventh Circuit reversed the district court's decision on the Medicare claims, but upheld dismissal of the Medicaid claims.

As to the Medicare claims, the Eleventh Circuit held that where an SNF billed Medicare for a higher level of service than what was actually provided, that constituted a material misrepresentation. However, for the Medicaid claims, the Eleventh Circuit noted that when the relator had complained about lack of care plans, her employer had self-reported the deficiencies to the state, but the state did not stop reimbursing Medicaid claims or seek recoupment. Because there was not proof otherwise at trial that the state had ever declined payment of claims for lack of care plans, the Eleventh Circuit agreed that the relator had failed to prove materiality. The Eleventh Circuit reinstated $85 million of the jury's $115 million single damages verdict, which could be trebled to $255 million.

Similar to ***Ruckh***'s handling of the Medicaid claims, the district court in ***U.S. ex rel. Gugenheim v. Meridian Sr. Liv., LLC***, held that the government's payment of claims with knowledge of the alleged noncompliance demonstrated non-materiality.[71] In this case, the relator alleged that the defendants falsely billed North Carolina Medicaid for more hours of personal care services (PCS) than staff had provided in the defendants' adult care homes. Although North Carolina Medicaid guidance required PCS to be billed in time units, the defendants adduced testimony from Medicaid officials that payment for PCS in the adult home setting was based on completion of the service and not the time spent performing the service. Given evidence that North Carolina Medicaid had knowledge that the defendants were not tracking the amount of time spent providing PCS and raised no questions about the defendants' billing practices during previous government audits, the district court held that the relator had failed to create a genuine issue of material fact that the defendants submitted materially false claims.

In ***U.S. ex rel. Armstrong v. Andover Subacute & Rehab Ctr. Servs. One, Inc.***, the relator alleged that the defendant nursing homes fraudulently billed for per diem services provided to patients even though the defendants' physicians did not visit patients as often as required by law.[72] In 2019, the district court denied the defendants' motion to dismiss for failure to allege materiality, noting then that the government's continued payments to the defendants after the *qui tam* was filed did not negate materiality because the complaint did not allege that the government continued to pay the claims knowing that the physicians were not supervising their patient as required. However, at the summary judgment stage, the relator had come forward with no proof that the government took any action against the defendants following filing of the *qui tam* complaint and, thus, "continued payments therefore support a conclusion of non-materiality."

On the other hand, the district court in ***U.S. ex rel. Montcrieff v. Peripheral Vascular Assocs., P.A.***, denied summary judgment to a defendant in a declined case holding that the government's continued payment of claims after the filing of the relators' *qui tam* was probative, but not dispositive of materiality.[73] The district court held that there were "simply too many possible explanations for an agency's action or inaction to impute a decision on the merits of an allegation of fraud" and that without evidence of the government's "actual knowledge" of fraud, the court would not "apply the strong presumption of immateriality highlighted by *Escobar*." Even though *Escobar* stresses that what the government does in practice is more important than what the government says, the district court held that the government's continued payment of the defendants' claims despite the fraud allegations was contradicted by CMS's statement of interest that billing for services not provided was an example of fraud.

A similar result occurred in ***U.S. ex rel. Johnson v. Golden Gate Nat'l Sr. Care, L.L.C.***, where relators alleged that the defendants failed to ensure proper supervision of therapy assistants and failed to document the supervision.[74] The defendants sought summary judgment on the grounds that the relators had brought forward no facts showing that the government routinely denies or recoups payments based on breaches of the supervision requirement. The district court denied summary judgment, holding that while the government's continued payment of claims was a factor in considering materiality, it was not dispositive and that the materiality inquiry was too "fact-intensive and complex" to grant summary judgment.

Finally, in ***U.S. ex rel. Gohil v. Sanofi U.S. Servs. Inc.***, the defendant moved for summary judgment as to the relator's claims that the defendant engaged in a kickback scheme to induce doctors to prescribe its cancer drug by providing free assistance to doctors to submit reimbursement claims and pursue appeals and by providing free replacement drugs when appeals failed.[75] Although the relator argued that AKS violations are *per se* material, the district court stated that proving an AKS violation would satisfy falsity, but materiality is a separate element that still must be established. To that end, the court held that compliance with the AKS was a condition of payment that went to the "essence of the bargain." Although Medicare paid claims knowing that the defendant had assisted doctors with claims appeals, Medicare did not pay claims with actual knowledge of any AKS violation. While the United States' decision to decline intervention might be of "some relevance" as to materiality, it did not warrant summary judgment given that enforcement decisions and payment decisions are made by different government officials and involve different considerations.

DEVELOPMENTS IN PLEADING STANDARDS

Because FCA complaints include allegations of fraud, they are subject to the pleading requirements of Rule 9(b) of the Federal Rules of Civil Procedure. Rule 9(b) requires detailed allegations of a fraud "scheme" carried out by the defendant and detailed allegations tying that scheme to some request for reimbursement from the government. Defendants have continued to seek dismissal of FCA complaints that failed to satisfy these requirements with some degree of success.

Pleading the Details of a Fraudulent Scheme

Complaints asserting FCA claims must identify the particular details – such as the "who, what, when, where and how" – of a defendant's specific fraud scheme to survive a motion

71 2020 WL 1932435 (E.D.N.C. Apr. 21, 2020).
72 2020 WL 7640535 (D.N.J. Dec. 22, 2020).
73 2020 WL 7342662 (W.D. Tex. Dec. 14, 2020).
74 2020 WL 1915612 (D. Minn. Apr. 20, 2020).
75 2020 WL 4260797 (E.D. Pa. July 24, 2020).

to dismiss under Rule 9(b). This pleading requirement can pose a significant obstacle to relators who do not possess sufficient factual details regarding the alleged fraud scheme and particularly where the relator fails to connect such details to alleged false claims.

In ***U.S. ex rel. McClain v. Nutritional Support Servs., L.P.***, the district court dismissed a relator's complaint alleging that the defendant long-term care pharmacy unlawfully filled "thousands" of prescriptions with less expensive generic medications while billing for more expensive alternative medications stocked in its automated dispensing system.[76] The district court found the complaint failed to allege a scheme that "necessarily" led to the submission of false claims because it did not "connect the dots" between the defendant's alleged conduct and any government payment. The complaint described a dozen medications allegedly dispensed by the defendant as part of its scheme, but it did not connect those medications to any false claims for reimbursement from government healthcare programs. The complaint also failed to allege facts showing that the dispensed drugs were, in fact, cheaper than the drugs for which the pharmacy billed the government. The relator conceded that the defendant submitted its claims to the government through intermediaries if at all and his complaint had no details about the claims-submission process, leaving open the possibility that the intermediaries never submitted the claims or billed the government the correct amount, or that the government declined to overpay on the claims.

In ***U.S. ex rel. Nicholson v. MedCom Carolinas, Inc.***, the district court had no difficulty in granting the defendants' motion to dismiss where the relator – a sales employee of a competing medical device company – alleged that the defendants improperly paid commissions to contractors in exchange for selling their devices, in violation of the AKS.[77] The sum of the relator's allegations about the scheme consisted of just four paragraphs loosely referring to "1099 sales representatives" who were allegedly paid commissions. As the district court pointed out, simply alleging the existence of a commission-for-sale scheme is not enough. Because the relator failed to explain who the "1099 sales representatives" were, who actually paid their alleged remuneration, whether they entered into formal or informal agreements with the defendants, what percentage of their sales were paid in commissions, or any details revealing the payments' intent, the complaint was dismissed for failing to satisfy Rule 9(b)'s pleading requirements.

On the other end of the spectrum, in ***U.S. ex rel. Harnett v. Physicians Choice Lab Servs., LLC***, the defendants sought to challenge the United States' complaint following intervention, which alleged that the defendants violated the AKS by providing loans, payments, and free equipment to doctors in exchange for referrals.[78] The district court denied the defendants' motion, noting that the United States had identified by name the participants in the kickback scheme (the "who"), the remuneration used to induce the physicians, along with the number of claims submitted and the amounts paid by Medicare for those claims (the "what"), when the violations occurred and when the subsequent tainted claims were submitted (the "when"), the physician practice locations that provided referrals to the defendants' lab (the "where"), and the defendants' actions in planning and implementing the scheme (the "how").

76 2020 WL 2464655 (D.S.C. Mar. 16, 2020).
77 2020 WL 1245374 (M.D.N.C. Mar. 16, 2020).
78 2020 WL 571322 (W.D.N.C. Feb. 5, 2020).

Several district courts emphasized that a relator did not have to have every single detail of a fraud scheme pleaded in their complaint in order to have *sufficient* detail to survive a Rule 9(b) challenge. For instance, in ***U.S. ex rel. Behnke v. CVS Caremark Corp.***, a former Aetna actuary alleged that Caremark – Aetna's PBM – negotiated discounted prices with retail pharmacies on Aetna's behalf, but was not passing those discounts on to Aetna, and, as a result, Aetna was reporting incorrect drug prices to CMS.[79] Caremark moved to dismiss the complaint, arguing that it failed to include facts about the "specific" pharmacy contracts, the "specific" pharmacies involved, the "specific" prices for the "specific" drugs negotiated, and the "specific" employees involved in negotiating with the pharmacies. As Caremark noted, the relator never even identified any actual negotiated price paid to a pharmacy by Caremark that was different than what was reported to CMS by Aetna. Yet, despite these missing details, the district court denied the motion, finding that the "theory" had been pleaded with particularity because the relator alleged that the prices set by Caremark were "higher" than the prices actually paid to pharmacies, that the "lower" prices were never reported to CMS, that Caremark had admitted to negotiating lower prices with pharmacies that were not passed through to Aetna, and that Caremark knew Aetna was reporting incorrect prices to CMS. To require more, the district court held, "would be one small step shy of requiring production of actual documentation with the complaint."

Similarly, in ***U.S. ex rel. Sturgeon v. PharMerica Corp.***, the relators alleged that in order to increase its rebates and reimbursements, PharMerica had fraudulently dispensed different medications than those prescribed by patients' physicians without consulting the physicians.[80] PharMerica moved to dismiss the complaint on several grounds, including that the relators had failed to identify *by name* those who "concocted" the alleged scheme or "oversaw its implementation," the pharmacists who altered the prescriptions, or the nursing home employees who signed for and administered the altered prescriptions. The district court disagreed, holding that a careful review of the complaint revealed that the relators had adequately identified and explained how the pharmacy's technology, policies, and employees all interacted with one another to alter prescriptions without appropriate physician consent. As for the failure to identify specific individuals, the district court held that "the generic identities of those involved (*i.e.*, data clerks, pharmacists, etc.)" were sufficient and there was "no authority for the proposition that Relators must identify *by name* the particular PharMerica employees who designed the [software] or those who allegedly altered prescriptions." When paired with other details, like the specific time frame of the scheme, the number and type of prescription alterations revealed by an audit, and specific examples identified by Rx number, these allegations were enough to satisfy Rule 9(b).[81]

79 2020 WL 1953626 (E.D. Penn. Apr. 23, 2020).
80 438 F. Supp. 3d 246 (E.D. Penn. Feb. 2, 2020).
81 *See also U.S. ex rel. STF, LLC v. Vibrant Am., LLC*, 2020 WL 4818706 (N.D. Cal. Aug. 19, 2020) (holding that the relator's descriptions of the "what" and "how" of the alleged fraud scheme, paired with generic titles of the actors, was enough to place the defendant on notice of the claim and allow the defendant to determine the relevant identities); *U.S v. Crescendo Bioscience, Inc.*, 2020 WL 2614959 (N.D. Cal. May 23, 2020) (holding that while the relator had not provided details of any particular kickback transaction or identified any particular physicians involved, the complaint "doesn't need to allege a precise time frame or describe in detail a specific transaction, as long as it alleged details of a scheme sufficient enough to 'give defendants notice of the particular misconduct which is alleged to constitute the fraud.'").

District courts often allow relators an opportunity to cure deficient allegations through the filing of an amended complaint. While defendants may challenge the adequacy of an amended pleading under Rule 9(b), district courts often provide relators a roadmap as to the types of factual details necessary to address the pleading deficiencies.

In ***U.S. ex rel. Hernandez v. Team Fin. LLC***, the relators, who were former emergency department clinicians, alleged that the defendants violated the FCA by improperly submitting claims for services performed by nurse practitioners and physician assistants under various physicians' National Provider Identifier (NPI) numbers and by upcoding services to "critical care" when those services either weren't actually performed or weren't medically necessary.[82] The defendants had successfully obtained dismissal of the relators' prior complaint under Rule 9(b) because it failed to include the necessary details of these schemes. The district court, however, refused to dismiss the amended version on the same grounds because the relators' amendments adequately filled in the missing pieces. For example, the relators' prior complaint failed to identify any specific hospitals, practice groups, or clinicians involved in either scheme, whereas the amended version provided a list of individual participants involved in both schemes along with details describing their involvement. Likewise, the prior complaint alleged only that the schemes transpired over the span of several years, whereas the amended version identified patient charts which included specific dates of service and specific dates on which the relators were encouraged to code critical care when not medically necessary. And, where the prior complaint alleged only that the schemes were "nationwide," the amended version tied the relators' individual experiences to the defendant's administrators across the country. Finally, the district court noted that where the prior complaint was missing details as to why the services billed as critical care were not medically necessary, the amended version included specific instances and examples where doctors were pressured to code *all* cases of certain symptoms, like "chest pain," as requiring critical care even though chest pain alone would not *always* indicate critical care is required. Accordingly, the district court denied the defendants renewed motion to dismiss.

Courts continued to grapple with determining when a plaintiff can satisfy Rule 9(b)'s particularity requirement even if they are unable to identify any specific, representative false claim.

But, not every opportunity to amend yielded similar results. In ***U.S. ex rel. Prose v. Molina Healthcare of Illinois, Inc.***, the relator alleged that the defendants procured a managed care contract through a bid process in which they described their SNF services to be provided to beneficiaries.[83] Several years after securing the contract, the defendants allegedly ceased providing those SNF services, although they continued to receive high capitation payments for certain beneficiaries as if they were in nursing homes and receiving the SNF care. The district court granted the relator leave to amend after dismissing his first complaint, but the amended filing fared no better. As the district court explained, the relator's renewed allegations continued to rely almost entirely on his review of the initial contract – which the district court found contained no false statements – and his assumptions that later misrepresentations must have occurred based on the original contract's terms. Because his amended complaint could not confirm or add detail regarding the assumed future misrepresentations, including whether they actually occurred, the amended complaint was dismissed for failing to satisfy Rule 9(b).

Pleading the Submission of False Claims

Courts continued to grapple with determining when a plaintiff can satisfy Rule 9(b)'s particularity requirement even if they are unable to identify any specific, representative false claim. As in years past, some courts were willing to accept details of a scheme to submit false claims coupled with "reliable indicia" leading to a "strong inference" that claims were actually submitted; though, the bar for any "relaxed" pleading standard remains high in several circuits.

In one of the most significant FCA cases last year, the Eighth Circuit weighed in on the Rule 9(b) pleading requirement in the context of allegations that paying excessive compensation to employed physicians constitutes illegal kickbacks. In ***U.S. ex rel. Benaissa v. Trinity Health,*** the relator alleged that Trinity violated the AKS and Stark Law by paying its five highest-earning physicians in excess of the 90th percentile for their specialties, resulting in the submission of false claims.[84] The district court granted Trinity's motion to dismiss, and the Eighth Circuit affirmed, holding that the relator's "general allegations" that the health system's compensation arrangements with certain highly paid physicians "most likely resulted in the presentment of claims for payment" did not satisfy Rule 9(b). The relator, a former surgeon at one of the system's hospitals, argued on appeal that because approximately 29% of the defendant's revenue came from Medicare reimbursements, and any claims submitted by the physicians in question were tainted by AKS and Stark Law violations, it was more likely than not that the defendant submitted tainted claims for payment to the government. Although Eighth Circuit precedent allowed a relator to satisfy the presentment element by pleading details of a scheme paired with "reliable indicia that lead to a strong inference that claims were actually submitted," the Eighth Circuit held that the relator's "general inference" was not sufficient without pleading first-hand knowledge and details of the defendant's billing practices. The Eight Circuit rejected the relator's argument that under this rule, only billing department or financial services employees could ever serve as relators, reasoning that although an insider may have an easier time obtaining information about billing practices and satisfying this pleading requirement, nothing "precluded others with reliable allegations from serving as relators."

Relators have continued to attempt to use Medicare data and statistical analysis to bolster otherwise deficient allegations. For example, in ***U.S. ex rel. Levine v. Vascular Access Ctrs., L.P.***, the relator alleged that in his experience working at other vascular access centers, he witnessed a common self-referral practice where surgical specialists inappropriately scheduled follow-up appointments with patients although the applicable

82 2020 WL 731446 (E.D. Tex. Feb. 13, 2020).
83 2020 WL 3050342 (N.D. Ill. June 8, 2020).
84 963 F.3d 733 (8th Cir. 2020).

Relators have continued to attempt to use Medicare data and statistical analysis to bolster otherwise deficient allegations.

regulations left that decision to the patients' primary nephrologists.[85] The relator claimed that the defendant must have been engaged in this practice based on a review of the defendant's Medicare data from 2012 through 2017, which showed high numbers of procedures and office visits compared to other physicians. The district court found that the relator's allegations about the frequency and quantity of the defendant's procedures and office visits were insufficient to satisfy Rule 9(b) on their own, noting that the relator was relying on his own experiences to "surmise" that some portion of the defendant's procedures and visits "must have been" fraudulent. The district court concluded that "[a] range of years and aggregated billings untethered to allegations of particularized conduct by [the defendant] is insufficient."

Similarly, in ***U.S. ex rel. Integra Med Analytics, L.L.C. v. Baylor Scott & White Health***, the Fifth Circuit affirmed the dismissal of a complaint filed by Integra alleging that Baylor's "clinical document improvement program" pressured physicians to include unjustified complications and comorbidities in patients' records in order to inflate Baylor's diagnosis-related group (DRG) codes.[86] Integra's allegation was based, in large part, on a statistical analysis of Baylor's inpatient claims data, which allegedly showed that Baylor was claiming certain major complications and comorbidities above the national average. The Fifth Circuit held that while Integra's statistical analysis could be viewed as consistent with a theory of fraudulent upcoding, it did not satisfy Rule 9(b)'s pleading requirements because a "legal and obvious alternative explanation" for the statistics existed; namely, that Baylor was simply ahead of the curve in adopting CMS's new guidelines for complete and accurate documentation of complications and comorbidities. The same was true of the alleged "pressure" from Baylor's clinical documentation improvement program, which the Fifth Circuit concluded could have been "entirely consistent" and even "encouraged" by CMS's new DRG rules. Integra had also relied on statements from a former coder at Baylor, who claimed she was "told things that were totally not true" and was "pressured directly from … leadership to code unethically." Noting that the complaint failed to provide the contents of any actual statements made to the former employee, the Fifth Circuit found these vague statements about unethical and untruthful directives too generic to satisfy Rule 9(b). In addition, Integra alleged Baylor was providing medically unnecessary treatment in order to code higher-value comorbidities, but the Fifth Circuit found that the only support in Integra's complaint for this claim was the fact that Baylor's patients undergoing major heart surgery were placed on ventilators at more than twice the national average, which the court described as a "conclusory allegation" supported by a "single statistic."

In ***U.S. ex rel. Johnson v. Bethany Hospice & Palliative Care, LLC***, the district court reasoned that it "cannot rely on mathematical probability to conclude that" a defendant hospice company must have submitted false claims based on the number of Medicare referrals it received from physicians.[87] After holding that the relators failed to plead an AKS violation based on below FMV investment opportunities for referring physicians, the court pointed out that even if relators had done so, they still had not stated a claim under the FCA. Though coupled with purported claims data showing that physicians referred 100% of their Medicare patients to the defendant, allegations that the relators attended meetings where management discussed site productivity and had conversations with employees about fraudulent claims were not enough to establish indicia of reliability that false claims were actually submitted.

Likewise, in ***U.S. ex rel. Solis v. Millennium Pharmaceuticals, Inc.***, after dismissing relator's off-label promotion claims and some AKS claims under the FCA's public disclosure bar, the district court also dismissed the relator's claim that defendants paid physicians kickbacks in the form of meals, speaker fees, and travel expenses to prescribe a particular medication.[88] The relator argued that he set forth reliable indicia supporting an inference that claims for the drug were actually submitted by pointing to a sales spreadsheet tracking Medicare and Medicaid patients for the purpose of determining a defendant's effectiveness at getting the drug on hospital formularies. The district court disagreed, pointing out that "whether or not [the drug] was placed on a hospital's formulary still says nothing about whether actual 'claims were submitted.'"

The Sixth Circuit allows for the possibility that a relator's personal first-hand knowledge of a defendant's billing practices to plead presentment of a claim for payment may meet Rule 9(b)'s requirements. In applying this standard, district courts within the Sixth Circuit reached different conclusions in considering the defendants' motions to dismiss. In ***U.S. ex rel. Sharma v. Miraca Life Sciences, Inc.***, the relator laid out facts, and even cited emails, detailing an alleged scheme to have unlicensed individuals fraudulently sign out studies under licensed pathologists' names or sign pathology studies without reviewing underlying data.[89] In determining that the Sixth Circuit's relaxed pleading standard did not apply, the district court dismissed the claims because the relator did not allege that he possessed first-hand knowledge of the defendants' billing practices or otherwise indicate that the defendants actually submitted false claims.

In contrast, in ***U.S. ex rel. Lynch v. University of Cincinnati Medical Center, LLC***, the district court held that a procedure case log that identified patient initials, medical record numbers, Current Procedural Terminology (CPT) codes, procedure dates, invoice numbers, and governmental insurance carriers provided "strong support" that claims that failed to comply with a national coverage determination requirement were actually submitted to the government.[90] The relator alleged the existence of an email thread discussing the completion of a medical record note for the purpose of billing the government and pointed to an employment agreement indicating who was responsible for billing. Taken together, the relator "provided the necessary factual predicates to convince the Court that in all likelihood, [the defendant] submitted actual false claims by billing for the procedures detailed in the log."

85 2020 WL 5534670 (S.D.N.Y. Sept. 15, 2020).
86 816 F. App'x 892 (5th Cir. 2020), *cert. denied sub nom.*, 2020 WL 7132371 (U.S. Dec. 7, 2020).
87 2020 WL 1542339 (S.D. Ga. Mar. 31, 2020).
88 445 F. Supp. 3d 786 (E.D. Cal. 2020), *appeal filed sub nom. Solis v. Millennium Pharm., Inc.*, 20-15863 (9th Cir. May 6, 2020).
89 2020 WL 3977351 (N.D. Ohio July 14, 2020).
90 2020 WL 1322790 (S.D. Ohio Mar. 20, 2020).

The Eleventh Circuit requires an "indicia of reliability" to support an allegation that actual claims were submitted for payment. In ***U.S. ex rel. Olhausen v. Arriva Medical, LLC***, after dismissing many of the relator's claims against a medical supply company under the FCA's first-to-file bar, the district court held that the relator also failed to plead with particularity his claims that Arriva sent patients supplies without properly signed forms and did not disclose locations that required independent accreditation and supplier numbers when it applied for and executed Medicare contracts.[91] The district court noted that the relator's purported "high-level position" as the former Senior Vice President of Business Development and Marketing at Arriva did not excuse him from the Eleventh Circuit's requirement that a relator identify the submission of a fraudulent bill to the government to state a claim under Rule 9(b). Specifically, the district court explained that his attendance at "weekly meetings" and interactions with other Arriva employees were not akin to the type of direct, first-hand knowledge of a defendant's billing operations that is required to show "reliable indicia" that claims were actually submitted.

In ***U.S. ex rel. Schultz v. Naples Heart Rhythm Specialists, P.A.***, a different result was reached.[92] The operative complaint attached photos of medical equipment in which patient names and dates of admission were visible. The relator alleged that she witnessed the physician-defendant perform medically unnecessary cardiac lead extractions and personally add billing codes for these procedures. She also alleged that she overheard that the billing employee at the practice was instructed to bill the CPT codes for those procedures, and that she observed that the lead extractions were included on procedure notes, which indicated they would automatically be billed by the practice. The district court held that taken together, "these first-hand observations … provided the required indicia of reliability" to satisfy Rule 9(b). The district court reached this conclusion again a month later, denying the practice's motion to dismiss on the same grounds.[93]

In ***U.S. ex rel. Ernst v. HCA Healthcare, Inc.***, the district court first held that the relator did not plead the submission of any actual false claims under the standard articulated by the Tenth Circuit in ***U.S. ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah***.[94] The district court, however, raised the possibility that the Tenth Circuit had "retreated somewhat from its strict requirement in ***Sikkenga*** that details of the false claims be pleaded." Under a subsequent Tenth Circuit opinion, the district court noted the possibility that a relator need only plead the specifics of a fraudulent scheme and "an adequate basis for a reasonable inference that false claims were submitted as part of that scheme." The district court held the relator did not satisfy this standard either, because although there "may be a basis to infer that claims were submitted," the relator failed to adequately explain how the claims contained false statements.

91 2020 WL 5077170 (S.D. Fla. Aug. 27, 2020); *see also U.S. ex rel. Martin v. Specialist Doctors' Group, LLC*, 2020 WL 5797652 (M.D. Fla. Sept. 29, 2020) (holding physician-relator sufficiently alleged employer's scheme of upcoding E&M codes or billing for E&M services never rendered, but failed to set forth with particularity any basis for his allegations that defendant actually submitted false claims for payment for such services).
92 2020 WL 1852432 (M.D. Fla. Apr. 13, 2020).
93 2020 WL 2473456 (M.D. Fla. May 13, 2020).
94 2020 WL 6868775 (D. Kan. Nov. 23, 2020).

In ***U.S. ex rel. Suarez v. Abbvie, Inc.***, the district court also acknowledged the possibility of applying a relaxed pleading standard under Seventh Circuit precedent, but concluded it need not consider its application, since the relator's allegations regarding the defendant's support services for its drug Humira "connect[ed] a specific Humira prescriber with a specific Medicare patient, suggest[ed] that Relator's work with that patient influenced the doctor's decision to keep prescribing Humira, and suggest[ed] that a claim was submitted to Medicare for the patient."[95]

DEVELOPMENTS REGARDING FALSITY

This past year brought several notable holdings from appellate and district courts concerning the issue of falsity in FCA litigation.

Objective Falsity in Medical Necessity Cases

As discussed previously, a growing divide has developed among the circuits regarding whether a disagreement as to subjective clinical decisions about patient treatment can be "false" and may give rise to FCA claims. Key decisions by the Third Circuit in ***Druding***[96] and the Ninth Circuit in ***Winter***[97] held that unreasonably held medical opinions or subjectively dishonest certifications could give rise to FCA liability. These decisions dealt a significant blow to healthcare providers, who have long argued that subjective disagreements as to patient care cannot support FCA liability.

> In a number of noteworthy cases, district courts dismissed *qui tam* actions in which relators had alleged nothing more than reasonable disagreements between physicians as a basis for falsity.

At least two district court cases, however, dismissed *qui tam* actions in which relators had alleged nothing more than reasonable disagreements between physicians as a basis for falsity. In ***United States v. DaVita Inc.***, the district court dismissed a third amended complaint alleging that DaVita, a dialysis provider, improperly and prematurely prescribed certain drugs and initiated dialysis for Medicare Advantage patients several months before the treatment could have any feasible medical benefit, citing to various studies on drug use and prophylactic dialysis.[98] The district court held that the relator failed to plead express or implied false certification because relator's theory failed to account for reasonable disagreements between "physicians applying their own clinical judgment." The district court explained that a "clinical judgment regarding treatments under Medicare cannot be deemed false, for

95 2020 WL 7027446 (N.D. Ill. Nov. 30, 2020).
96 952 F.3d 89 (3d Cir. 2020).
97 953 F.3d 1108 (9th Cir. 2020).
98 2020 WL 3064771 (C.D. Cal. Apr. 10, 2020).

purposes of the False Claims Act, when there is only a reasonable disagreement between medical experts as to the accuracy of [a] conclusion, with no other evidence to prove the falsity of the assessment."

In ***U.S. ex rel. Tali Arik v. DVH Hospital Alliance***, a district court dismissed a relator's claim alleging that Desert View Hospital defrauded the federal government by seeking reimbursement for medically unnecessary and improper services and falsely certifying compliance with the Emergency Medical Treatment and Labor Act (EMTALA) and Critical Access Hospital (CAH) regulations.[99] Turning first to false certification, the district court held that the relator failed to point to any rule expressly conditioning payment of claims on certifications relating to CAH and EMTALA requirements. As to the alleged provision of medically unnecessary services, the district court held that the relator merely alleged a subjective disagreement with other doctors' clinical judgments, which are not actionable under the FCA. The district court did grant the relator leave to amend if he were able to allege, in pertinent part, material certification of medical services seeking reimbursement for improper treatment, sufficient indicia that false claims were actually submitted to and reimbursed by the federal government, and "facts demonstrating more than mere disagreement with the diagnoses and treatments of the hospital's staff."

Presentment and Certification

Courts issued important decisions on the presentment and certification elements of falsity. In ***Benaissa***, discussed previously with respect to the Rule 9(b) pleading standard, the Eighth Circuit made clear that allegations creating a "general inference" that claims were presented to the government for payment are insufficient absent additional details of the defendant's billing practices.[100] In considering implied false certification in the context of a claim asserted under § 3729(a)(1)(B), the Eight Circuit noted that there is no presentment element for such a claim, but the relator must nevertheless "plead a connection between the alleged fraud and an actual claim made payable to the government." As a result, the relator's failure to allege with particularity that the defendant submitted a claim for payment to the government was fatal to his false certification claim as well.[101]

The Ninth Circuit reached a similar conclusion in ***Vatan v. QTC Med. Servs., Inc.***, affirming a grant of summary judgment in favor of defendant QTC Medical Services, as the plaintiff failed to establish any false statement or course of conduct as required for liability under the FCA.[102] The plaintiff had argued that QTC falsely certified that its "entire claims folder" was reviewed when QTC's analysts answered "yes" to that question on a checklist that was submitted with QTC's requests for payment. The Ninth Circuit confirmed that nothing in the record indicated that analysts were required to review "every page of every document in order to truthfully certify 'yes' on this question."[103] The Ninth Circuit similarly rejected the plaintiff's "worthless service" claim based on evidence that QTC's client – the U.S. Department of Veterans Affairs – was pleased with QTC's work and had "no complaints whatsoever."

District courts also closely scrutinized FCA claims premised on an implied false certification theory. For example, in ***U.S. ex rel. Kuzma v. Northern Arizona Healthcare Corp.***, the district court emphasized *Escobar*'s admonition that the violation of a regulatory obligation can support an implied false certification theory only if the submission of a claim for payment actually implicates the relevant obligation.[104] The district court dismissed the relator's FCA claim at the pleading stage, because even assuming the relator had adequately pleaded a violation of certain Medicaid regulations related to provider donations, he failed to allege how the submission of any claim for payment falsely implied compliance with the regulations or otherwise implicated the alleged violation.

In ***U.S. ex rel. Quartararo v. Catholic Health System of Long Island***, the district court held that the relator had pleaded a viable implied false certification claim where the relator alleged that the defendants had illegally diverted Medicaid funds to uses other than providing services to Medicaid beneficiaries.[105] The district court determined that a federal statute required Medicaid funding to be used only for the benefit of the intended beneficiaries, and that the relator had plausibly alleged that the act of submitting claims to Medicaid implied compliance with that statute, which was a precondition of payment.

In one particularly expansive application of the implied false certification theory, in ***U.S. ex rel. Silbersher v. Allergan Inc.***, the district court declined to dismiss FCA claims premised on the theory that a drug manufacturer's implied certification that its prices for certain drugs were "fair and reasonable" was false because the manufacturer's longstanding patents for the drugs were invalid.[106] The relator alleged that the invalidity of the patents had allowed the manufacturer to obtain unlawful monopoly power over the drugs, which had inflated the drugs' prices and resulted in the prices no longer being "fair and reasonable." Emphasizing that it would not take "a circumscribed view of what it means for a claim to be false or fraudulent," the court held that the relator had plausibly alleged a viable theory of falsity at the pleading stage.

In a number of cases, courts confirmed that claims submitted in violation of the AKS typically will be considered false or fraudulent even in the absence of an identifiable false certification. For example, in ***United States v. Vora***, the district court cited 42 U.S.C. § 1320a-7b(g) for the rule that "an AKS violation automatically meets all requirements of a 'false or fraudulent claim,' as the term is defined in the FCA."[107] For that reason, the district court explained, "certification simply is not an element [of establishing falsity] when proceeding under an AKS theory of liability."

99 2020 WL 6173528 (D. Nev. Oct. 21, 2020).
100 963 F.3d 733 (8th Cir. 2020).
101 The relator's allegations in *U.S. ex rel. Sharma v. Miraca Life Sciences, Inc.* suffered from a similar flaw. There, the district court explained that although the relator had alleged that "Defendants made false or fraudulent statements as part of their allegedly fraudulent *scheme*" – which involved billing for services provided by unlicensed pathologists – there were "no allegations connecting these statements to any *claim* that was actually made to the Government." 472 F. Supp. 3d 429 (N.D. Ohio 2020) (emphasis supplied).
102 812 F. App'x 485 (9th Cir. 2020).
103 *See also U.S. ex rel. O'Laughlin v. Radiation Therapy Servs., P.S.C.*, 2020 WL 6152977 (E.D. Ky. Oct. 20, 2020) (dismissing counts alleging defendants falsely certified that "incident-to" radiation oncology services were supervised by a radiation oncologist because relator did not identify a regulation or statute that required a radiation oncologist, as opposed to another type of physician, to supervise the services).
104 2020 WL 5819571 (D. Ariz. Sep. 30, 2020).
105 2020 WL 3960514 (E.D.N.Y. July 13, 2020).
106 2020 WL 7319407 (N.D. Cal. Dec. 11, 2020).
107 2020 WL 5646900 (W.D. Ky. Sep. 22, 2020).

Likewise, in ***U.S. ex rel. Gohil v. Sanofi U.S. Servs. Inc.***, the district court noted that "[c]laims tainted by AKS violations are automatically 'false' under the FCA."[108] AKS violations may also supply a basis for invoking a false certification theory of liability, at least if the defendant certified compliance with the AKS in connection with the submission of claims.[109]

Finally, in ***U.S. ex rel. Sirls v. Kindred Healthcare***, the relator asserted FCA claims against operators of SNFs based on three distinct theories of falsity, alleging that defendants: (1) submitted factually false claims that misrepresented patients' acuity levels; (2) made express false certifications regarding the accuracy of certain patient data; and (3) impliedly falsely certified their compliance with federal laws and regulations governing staffing of their facilities and the allocation and use of government funds.[110]

The district court separately analyzed each theory of alleged liability. The district court held that the relator could proceed on the factual falsity theory because the allegedly false statements about patient acuity levels would have "direct[ly] resulted" in an "inflated" rate of reimbursement. Similarly, the district court held that the relator's express false certification theory was viable because the data that the defendants allegedly falsely certified as accurate also directly affected reimbursement. The district court, however, dismissed the relator's implied false certification theory. Although the district court agreed that a false certification of compliance with federal staffing requirements could establish the falsity element of an FCA claim, it nevertheless held that compliance with those requirements was immaterial to payment. As for the defendants' alleged implied false certifications of compliance with regulations governing the use of government funds, the district court held that those allegations did not suffice because the relator failed to identify any specific regulations with which the defendants allegedly failed to comply.

> The Supreme Court has described the FCA's scienter requirement as "rigorous," and explained that "what matters is … whether the defendant knowingly violated a requirement that the defendant knows is material to the Government's payment decision."

The Continued Intersection of *Escobar* and Falsity

In a notable, non-healthcare opinion, a district court held that the Supreme Court's materiality standard articulated in *Escobar* was limited to FCA claims alleging falsity under the implied false certification theory and did not apply to claims based on a fraud-in-the-inducement theory of falsity. In ***Scollick ex rel. U.S. v. Narula***,[111] the relator alleged that the defendants engaged in an ongoing scheme to defraud the federal government by securing contracts for construction jobs by falsely representing their eligibility to bid on those contracts. In moving to dismiss, the defendants argued that the complaint failed to meet the materiality standard set out in *Escobar*.

The district court rejected the defendants' argument, holding instead that, "by pleading falsity under the fraud in the inducement theory, plaintiff-relator's allegations against [the defendants] fall outside the ambit of *Escobar*." In distinguishing fraud-in-the-inducement and implied false certification theories of falsity, the district court reasoned that "plaintiffs suing under the fraud in the inducement theory need only allege that false statements induced the government to *award the contract*, not also that those false statements were material to the government's *decision to pay the party under the contract*." The district court went on to state that claims arising under the fraud-in-the-inducement theory of falsity already have "a strict materiality requirement baked in … [as] a misrepresentation in the defendant's bid must have caused the government to award the defendant the contract." Against this backdrop, the district court held that the relator satisfied the requirements for pleading falsity under the fraud-in-the-inducement theory, as the complaint included allegations of the time, place, and content of the alleged false misrepresentation, as well as the facts that were allegedly misrepresented and led to the resulting contracts being awarded to the defendants.

DEVELOPMENTS REGARDING KNOWLEDGE AND SCIENTER

To establish an FCA violation, a relator or the government must plead and prove that the defendant acted with actual knowledge, reckless disregard, or deliberate indifference of the conduct that caused the submission of false claims. The Supreme Court described the FCA's scienter requirement as "rigorous," and explained that "what matters is … whether the defendant knowingly violated a requirement that the defendant knows is material to the Government's payment decision."[112] Nonetheless, Rule 9(b) allows plaintiffs to allege knowledge generally at the pleading stage. This tension has led to differing outcomes when courts scrutinize the FCA's scienter requirement.

In denying motions to dismiss FCA claims for failure to plead scienter, district courts have acknowledged that FCA plaintiffs may plead scienter in numerous ways. In ***United States v. Strock***, the Second Circuit reversed in part and affirmed in part the district court's dismissal of the government's complaint alleging that a small business fraudulently claimed that it was owned by a service-disabled veteran in order to obtain funds reserved for service-disabled, veteran-owned small businesses. The Second Circuit held that the complaint pleaded scienter as to the defendant who orchestrated the scheme because it alleged he took "elaborate steps" to make it appear as though the business complied with veteran-ownership requirements, including recruiting and installing a disabled veteran as the business's figurehead owner. The Second Circuit, however, affirmed dismissal as to another defendant, as there were no allegations to establish that the defendant knew the purported veteran-owner was just a front.[113]

108 2020 WL 4260797 (E.D. Pa. July 24, 2020).
109 *See, e.g., U.S. ex rel. Bechtold v. Asfora*, 2020 WL 5547920 (D.S.D. Sep. 16, 2020) (holding that FCA claims were adequately pleaded where the relator alleged that the defendants made "false certifications on provider enrollment forms and claim forms that they were in compliance with the [AKS]").
110 469 F. Supp. 3d 431 (E.D. Pa. 2020).
111 2020 WL 6544734 (D.D.C. Nov. 6, 2020).
112 *Escobar*, 136 S. Ct. at 1996, 2002.
113 928 F.3d 51 (2d Cir. 2020).

In ***United States v. Ellis***, the government accused a pain management clinic, its physician-owner, and its practice manager of submitting false claims for thousands of drug tests that were medically unnecessary or never performed. The district court denied the defendants' motion to dismiss, finding that the government sufficiently pleaded that the defendants acted with at least reckless disregard or deliberate indifference by creating automatic billing shortcuts that added pre-determined tests to the clinic's claims regardless of whether those tests were ordered by the patients' physicians or actually performed by the clinic.[114]

In ***U.S. ex rel. Sirls v. Kindred Healthcare, Inc.***, the district court held that the relator sufficiently pleaded scienter where he alleged that the defendant imposed policies at subsidiary companies that operated nursing facilities under which the facilities were encouraged to recruit residents with high acuity levels while intentionally understaffing the facilities. That scheme allegedly caused the facilities to receive reimbursement for services that facility employees did not provide. The district court reasoned that the relator alleged scienter because the defendants knew the services needed by high acuity residents exceeded the work capacity of the facilities' staff.[115]

In ***U.S. ex rel. STF, LLC v. Crescendo Bioscience, Inc.***, the district court denied the defendants' motion to dismiss where the relator alleged that the defendants paid illegal kickbacks in the form of inflated physician "processing fees" and patient co-pay waivers to physicians who ordered blood tests sold by the defendants. The district court found the relator's allegations of scienter survived the defendants' motion to dismiss because the relator alleged the defendants knew their processing fees were illegal and instructed company employees never to discuss patient co-pay waivers in emails.[116]

In ***U.S. ex rel. Drummond v. BestCare Lab. Servs. LLC***, the Fifth Circuit affirmed the district court's grant of summary judgment in favor of the United States despite the defendants' argument that they lacked intent to submit claims in violation of certain rules that govern the billing of travel costs for clinical testing services. The Fifth Circuit determined that the relevant statute "clearly forbids" the defendants' billing practices, and it described the defendants' argument that they did not fully understand the statute's requirements as "border[ing] on the absurd." The Fifth Circuit also rejected the defendants' argument that non-binding, sub-regulatory guidance created ambiguity in the meaning of the relevant statute.[117]

In ***U.S. ex rel. Silbersher v. Allergan, Inc.***, the district court denied the defendants' motion to dismiss claims that they knowingly provided false information to the U.S. Patent Office to obtain patents for two Alzheimer's drugs. The district court found that the relator established scienter as to one set of defendants by alleging that they intentionally omitted the disclosure of a related patent from their patent application. The district court was not persuaded by the defendants' argument that they had an objectively reasonable belief that applicable regulations did not require the disclosure of the related patent, finding that defense inappropriate for resolution at the motion to dismiss stage. The district court found the relator also established scienter as to a second set of defendants by alleging that they intentionally submitted a series of declarations that provided false information to mislead the Patent Office. The district court dismissed the defendants' argument that scienter could not be established because they later filed corrected declarations with accurate information, holding that it remained plausible to infer that the defendants intended to mislead the Patent Office.[118]

Where the relevant statutory provision establishing falsity is ambiguous on its face, however, scienter may be harder to plead. In ***U.S. ex rel. Sheldon v. Forest Laboratories, LLC***, the district court held that because the defendant's interpretation of the statute was objectively reasonable, the relator could not establish scienter unless he could demonstrate that the defendant had been warned about its interpretation and nonetheless continued to submit claims in accordance with that interpretation. The district court granted the defendant's motion to dismiss because rather than warn the defendant away from its interpretation, CMS had accounted for the complexity of the statute and reporting requirements and encouraged manufacturers to make "reasonable assumptions" under the statute.[119]

In two cases considering the same scienter issue, ***U.S. ex rel. Proctor v. Safeway, Inc.***[120] and ***U.S. ex rel. Schutte v. Supervalu, Inc.***,[121] the district court granted summary judgment in favor of the defendants under the Supreme Court's opinion in ***Safeco Ins. Co. v. Burr***, which held that liability cannot be established where the defendant adopts an objectively reasonable, even if mistaken, interpretation of a statute.[122] In each case, the relators alleged that the defendants' pharmacies submitted false claims by improperly reporting the "usual and customary" prices for their prescription medications, allegedly resulting in the government overpaying for drugs provided to Medicare and Medicaid beneficiaries. In granting summary judgment in favor of the defendants in each case, the district court held that the defendants could not be liable for violating the FCA because at the time of their conduct between 2006 and 2015, there was no clear authority setting forth how "usual and customary" prices should be determined. The district court was unpersuaded by the relator's reliance on a Seventh Circuit opinion from 2017 setting forth an interpretation of how "usual and customary" prices should be determined, explaining that the Seventh Circuit's opinion could not have warned the defendants away from their interpretation because it was not issued until after the defendants' alleged conduct.

Application of ***Safeco*** was also considered in ***U.S. ex rel. Suarez v. Abbvie, Inc.*** The district court found that the relator's allegations of scienter survived the defendant's motion to dismiss where the relator alleged that Abbvie provided kickbacks to prescribing physicians through an "ambassador program" that gave free professional services to the physicians.[123] The defendants urged the district court to apply the standard from ***Safeco***, but the district court declined to do so, noting its discomfort with holding that an FCA defendant can escape liability by identifying a reasonable interpretation of the applicable statute, regardless of its subject intent at the time of its conduct. Instead, the district court ruled that even

114 2020 WL 4642837 (M.D. Ga. Aug. 11, 2020).
115 2020 WL 3529438 (E.D. Pa. June 29, 2020).
116 2020 WL 2614959 (N.D. Cal. May 23, 2020).
117 950 F.3d 277 (5th Cir. 2020).
118 2020 WL 7319407 (N.D. Cal. Dec. 11, 2020).
119 2020 WL 6545854 (D. Md. Nov. 6, 2020).
120 2020 WL 3132397 (C.D. Ill. June 12, 2020).
121 2020 WL 3577996 (C.D. Ill. July 1, 2020).
122 551 U.S. 47 (2007).
123 2020 WL 7027446 (N.D. Ill. Nov. 30, 2020).

if the ***Safeco*** standard were applied, the relator had still shown scienter because the AKS unambiguously prevents pharmaceutical companies from offering remuneration in exchange for prescriptions.

In ***U.S. ex rel. Adomitis v. San Bernardino Mountains Community Hospital District***, the Ninth Circuit affirmed the district court's ruling that the relator failed to plausibly allege scienter because he offered only conclusory allegations that the defendant hospital knowingly failed to satisfy certain regulatory requirements of the CAH program. The Ninth Circuit explained that while Rule 9(b) allows plaintiffs to allege scienter generally, a relator still must plead scienter with the plausibility required by Rule 8(a). The relator had alleged that the hospital's senior officials must have known that the hospital did not meet the "mountainous terrain" requirement for the program based on their own travel to and from the hospital. The Ninth Circuit held that this allegation amounted to "mere speculation," which was "too vague and conclusory to make plausible" the relator's conclusion that the hospital acted with the requisite scienter.[124]

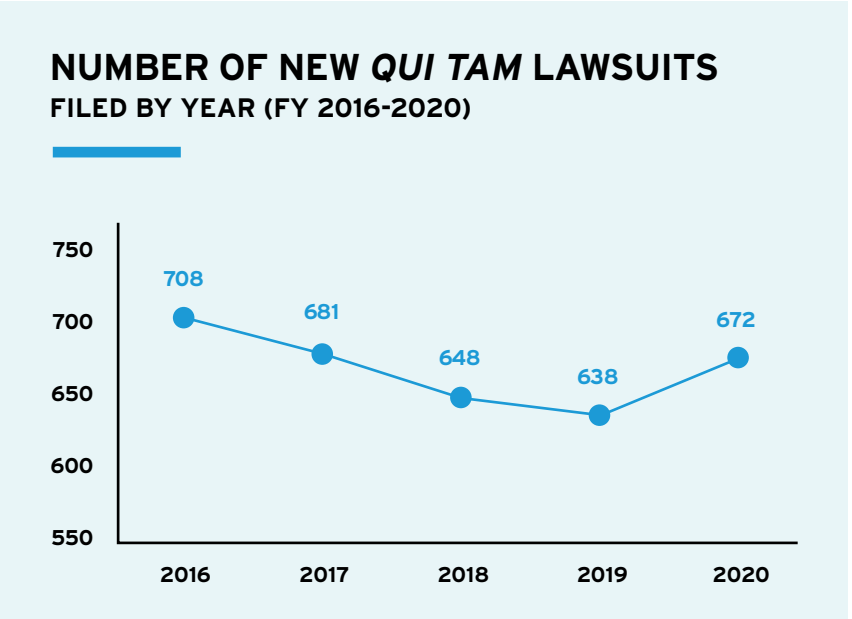
In ***U.S. ex rel. Complin v. N.C. Baptist Hospital***, the Fourth Circuit affirmed the dismissal of FCA claims based on the alleged submission of false cost reports by two hospitals because the relator failed to adequately allege that the hospitals knew the cost reports were false. The Fourth Circuit explained that the relator asked the court "to infer scienter from [an] alleged regulatory violation itself," which is not sufficient in the FCA context. The Fourth Circuit also opined that "ambiguity" in the relevant regulation made it especially inappropriate to infer scienter.[125]

In ***United States v. Dynamic Visions, Inc.***, the D.C. Circuit's ruling with respect to establishing scienter turned on the basis for the falsity of each type of claim. The United States alleged that the defendants submitted claims for reimbursement without adequate supporting documentation. The D.C. Circuit affirmed the district court's grant of summary judgment for claims for which the patient files contained no plans of care, untimely or unsigned plans of care, or plans of care that authorized fewer services than were provided. The D.C. Circuit held that the defendants failed to offer facts sufficient to create a genuine dispute for those claims as to whether valid plans of care were maintained and that "even the shoddiest recordkeeping would have revealed that false submissions were being made." For claims that allegedly were false due to forged physician signatures, however, the D.C. Circuit reached the opposite conclusion as to scienter and held that a genuine issue of material fact existed about whether the defendants forged the signatures.[126]

REVERSE FALSE CLAIMS

Under the FCA's "reverse false claim" provision, 31 U.S.C. § 3729(a)(1)(G), liability may arise when a defendant: (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

124 816 F. App'x. 64 (9th Cir. 2020).
125 818 F. App'x. 179 (4th Cir. 2020).
126 971 F.3d 330 (D.C. Cir. 2020).



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. Although courts have reached differing outcomes regarding the extent to which a defendant's failure to report or return money obtained through "direct" violations of § 3729(a)(1)(A) or (a)(1)(B) of the FCA can support liability for reverse false claims, courts typically continue to require that some additional allegations or evidence be presented to support reverse false claim liability.

In ***U.S. ex rel. Kuzma v. Northern Arizona Healthcare Corp.***, the defendants moved for dismissal of the relator's reverse false claim allegations on the grounds that the claim was "nothing more than an improper recasting of [the relator's] affirmative claims" under § 3729(a)(1)(A) and (a)(1)(B). Although he agreed that the reverse false claim allegations arose from the same scheme as the other FCA counts, the relator argued that the facts underpinning a reverse false claim theory of liability are distinct because that theory focuses on the decision to avoid a payment obligation, rather than on the submission of the false claim. The district court acknowledged differing approaches on that issue, citing another district court that allowed claims under both theories to proceed on largely the same facts because "Congress may have intended to allow the government to pursue both direct and reverse false claims under these circumstances." Nonetheless, the district court granted the defendant's motion to dismiss because the relator offered no additional factual allegations specifically to support his claim under § 3729(a)(1)(G). The district court reasoned that a relator must plead with particularity that the defendant made or used a

false record or statement material to a payment obligation or specifically plead how the defendant knowingly concealed or avoided a payment obligation, separate and apart from the allegations pleaded to support the direct false claims.[127]

The district court's ruling in ***United States v. Biotronik, Inc.***, further underscores the need for additional, independent factual allegations to plead a violation of § 3729(a)(1)(G). In that case, the district court ruled that the relator did not sufficiently allege that the defendant either submitted a false claim for payment under § 3729(a)(1)(A) or made a false statement or record in furtherance of such a claim under § 3729(a)(1)(B). Because the relator also failed to plead that the defendant had any separate payment obligation to the government or made any false statement to avoid such an obligation, the relator failed to plead a violation of § 3729(a)(1)(G).[128]

PUBLIC DISCLOSURE BAR

The FCA's public disclosure bar is intended to prevent "parasitic" lawsuits based on publicly available information, barring a relator from maintaining a *qui tam* complaint that alleges substantially the same information as previously disclosed to the public.[129] The public disclosure bar was amended in 2010 under the Patient Protection and Affordable Care Act (PPACA), to slightly narrow the scope of public information that may bar complaints, though the analysis undertaken by courts considering the issue largely remains the same. In applying the public disclosure bar, courts must determine: (1) whether a public disclosure has occurred; (2) whether that disclosure was substantially similar to the relevant FCA allegations; and (3) if a substantially similar public disclosure has occurred, whether the relator is nevertheless an "original source" of the FCA allegations.

What Qualifies as a Public Disclosure?

As an initial step in a typical public disclosure bar analysis, a district court must examine what sources of information constitute a "public disclosure" under the FCA. The FCA's public disclosure bar applies to public information "in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party," "in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation," and "from the news media."

Courts have continued to evaluate the contours of the statutory threshold for what constitutes a public disclosure. In ***Silbersher v. Valeant Pharmaceuticals International***, the district court dismissed a lawsuit alleging that the defendants fraudulently obtained a patent, which allowed them to raise the price of a prescription drug by wrongfully excluding generic competitors.[130] The district court applied the public disclosure bar where previous patent litigation by the relator and the resulting Patent Trial and Appeal Board (PTAB) opinion formed the foundation of the fraud complaint. Though patent litigation does not qualify generally as a "Federal criminal, civil, or administrative hearing," the district court found that the PTAB proceedings did qualify as an "other Federal report, hearing, audit, or investigation" under § 3730(e)(4)(A)(ii). The district court was unwilling to read that section as duplicative and applied a broader application that includes patent litigation in front of PTAB. Given the publicity around the litigation, the district court also found there were sufficient grounds to dismiss under the "news media" provision.

Though the statutory grounds for a disclosure are relatively straightforward, a circuit split remains, regarding when those disclosures become "public." The majority view held by the First, Fourth, Sixth, Ninth, Tenth, Eleventh, and D.C. Circuits is that documents, audits, or reports held only by the government are insufficient to invoke the public disclosure bar. In contrast, the Seventh Circuit remains steadfast in affirming that the government's possession of information exposing a fraud is alone sufficient to trigger the public disclosure bar because "the purpose of a public disclosure is to alert the responsible authority that fraud may be afoot."[131] In ***U.S. ex rel. Howard v. KBR***, the district court reached the same conclusion, finding that the defendants' alleged breach of contract and substantial non-performance of a contract was subject to multiple audits, reports, and reviews by the government, which were substantially the same as the allegations in the relator's complaint.[132] Though the district court ultimately found that the relators were original sources, as discussed on the next page, this noted departure from the majority view suggests that this issue may be ripe for consideration by the Supreme Court in the future.

Though the statutory grounds for a disclosure are relatively straightforward, a circuit split remains, regarding when those disclosures become "public."

When Are Disclosures Sufficient to Bar FCA Allegations?

Following the identification of a public disclosure, a district court then must determine whether the public disclosure is "substantially similar" to the relevant FCA allegations to put the government on notice of potential fraud. Consideration of whether a public disclosure is "substantially similar" to FCA allegations continues to lead to varied outcomes. While some courts find "substantial similarity" based on a high-level analysis of the theory of liability, others delve into a much deeper factual analysis, allowing suits to move forward even when they allege the same ultimate theory of liability, but based upon a different set of facts.

As a baseline matter, the public disclosure must include sufficient information to put the government on notice of the potential fraud. Most courts have now come to rely on the test first articulated by the D.C. Circuit, which asks: "[I]f X + Y = Z, Z represents the

127 2020 WL 5819571 (D. Ariz. Sept. 30, 2020).
128 2020 WL 1911465 (M.D. Fla. Apr. 20, 2020); *see also U.S. ex rel. Gardner v. Vanda Pharmaceuticals, Inc.*, 2020 WL 2542121 (D.D.C. May 19, 2020) (the district court "easily dispose[d]" of the reverse false claims allegations because the relator alleged nothing to suggest that the defendant owed any payments to the government other than the conclusory allegation that the defendant caused false claims to be submitted and "took action to conceal its fraud").
129 31 U.S.C. § 3730(e)(4).
130 445 F. Supp. 3d 393 (N.D. Cal. 2020).
131 *Cause of Action v. Chicago Transit Auth.*, 815 F.3d 267 (7th Cir. 2016).
132 471 F.Supp. 3d 846 (C.D. Ill. July 9, 2020).

allegation of fraud and X and Y represent its essential elements. In order to disclose the fraudulent *transaction* publicly, the combination of X and Y must be revealed, from which readers or listeners may infer Z, *i.e.*, the conclusion that fraud has been committed."[133]

Applying the foregoing test, in ***U.S. ex rel. Sheldon v. Forest Laboratories, LLC***, the district court held that the public disclosure bar did not apply even though the relator's complaint was based, in part, on a government report, various regulations, and the defendants' publicly available sales data. The relator alleged that the defendants provided false price reports to the government, which caused the government to overpay for certain drugs. The district court determined that the disclosed documents "stop short of making an allegation of fraud or improper conduct." At best, the sales data reflected the "allegedly false set of facts," but did not ultimately show whether the defendant violated statutory requirements.[134]

In ***U.S. ex rel. Taylor v. Perni***, the district court took a similarly narrow approach, finding that even where the emergency department visit at issue in the *qui tam* suit was reviewed in a federal audit, the public disclosure bar did not apply. The district court held that while the visit at issue was disclosed to the government, the audit focused only on delays in generating medical records and not any of the fraudulent conduct alleged in the *qui tam* suit.[135]

Courts have continued to struggle to identify bright line rules in determining whether there is "substantial similarity" between the disclosure and the underlying suit and have taken different approaches to these issues, with some focusing on the end result – asking if the suit ultimately results in the same general liability – and others taking a much more fact-specific approach.

For example, in ***U.S. ex rel. Holloway v. Heartland Hospice***, the Sixth Circuit affirmed the dismissal of a *qui tam* action under the public disclosure bar because the relator raised substantially the same allegations as those in several earlier *qui tam* complaints.[136] Although the earlier complaints had been dismissed voluntarily in 2008 and focused on a single defendant's facilities, the Sixth Circuit determined that the relator's allegations of corporate-wide misconduct from 2004 to 2018 were substantially the same as those in the earlier complaints.

Additional details added to a previously disclosed scheme are insufficient. The Sixth Circuit affirmed application of the FCA's public disclosure bar in ***U.S. ex rel. Maur v. Hage-Korban***, even though the relator's *qui tam* action alleged a fraud scheme involving defendants and patient examples that differed from those in a previous *qui tam* action. Despite those differences, the Sixth Circuit reasoned that the relator alleged the "exact scheme" disclosed in that previous action and, in fact, "copie[d] much of the [prior] complaint verbatim."[137]

133 *U.S. ex rel. Springfield Terminal Ry. Co. v. Quinn*, 14 F.3d 645 (D.C. Cir. 1994).
134 2020 WL 6545854 (D. Md. Nov. 6, 2020). Similarly, in *U.S. ex rel. Levine v. Vascular Access Ctrs., L.P.*, the district court held that the public disclosure bar did not apply where the only publicly disclosed information did not identify or relate to the defendant at all. 2020 WL 5534670 (S.D.N.Y. Sept. 15, 2020).
135 2020 WL 2499544 (S.D.W. Va. May 14, 2020). In *U.S. ex rel. Jones v. Sutter Health*, the district court similarly held that the public disclosure bar applied where the relator's claims regarding upcoding and un-bundling of certain surgical services were based exclusively on Medicare billing records that she received in response to a Freedom of Information Act request to CMS and where the disclosures sufficiently disclosed the "allegations and transactions of fraud." 2020 WL 6544412 (N.D. Cal. Nov. 6, 2020).
136 960 F.3d 836 (6th Cir. 2020).
137 981 F.3d 516 (6th Cir. 2020).

Similarly, in ***U.S. ex rel. Banigan v. PharMerica, Inc.***, the First Circuit applied the public disclosure bar where an earlier *qui tam* action alleged similar kickbacks for certain antidepressant drugs. The First Circuit found that the relator's allegations were "indistinguishable in all material respects" to the previous complaint and additional details or an additional time period for the conduct was not sufficient to overcome this similarity.[138]

By contrast, other courts have taken a much more fact-specific approach and allowed *qui tam* complaints to move forward where they identify separate "schemes" or theories of liability. In ***U.S. ex rel. Shahinian v. Kimberly-Clark Corp.***, the Ninth Circuit held that the FCA's public disclosure bar did not apply where the relator "made allegations about a new fraud."[139] The Ninth Circuit determined that the relator alleged a "new fraud" because his allegations focused on a product made by the defendant that was different from the product previously disclosed in an earlier *qui tam* action. The Ninth Circuit's holding result is nearly irreconcilable with the decision reached by the Sixth Circuit, discussed previously.

Similarly, in ***Sturgeon v. PharMerica Corp.***, the district court partially dismissed a *qui tam* suit where the complaint alleged fraudulent prescription substitutions by a long-term care pharmacy. The district court used a particularized, fact-specific approach in determining that a previous suit naming the defendant did not include allegations of similar conduct. While the previous suit related to emergency use of narcotics, narcotic boxes in place at facilities, and dispensing medications based only on a request by the facility, the subsequent *qui tam* complaint made allegations regarding an entirely separate fraud scheme involving the substitution of prescriptions for higher-paying formulations. The district court allowed the subsequent suit to move forward, refusing to find high-level similarities about potential liability sufficient to bar the suit.[140]

When is a Relator an Original Source?

Even if a relator's allegations were substantially the same as a prior public disclosure, the public disclosure bar does not apply where the relator qualifies as an "original source." Prior to March 2010, the FCA defined an "original source" as a person with "direct and independent knowledge of the information" in the complaint who "voluntarily provided" that information to the government before the complaint's filing.[141] Since March 2010, an "original source" is a person who either "voluntarily disclosed" the information in a complaint prior to any public disclosure or has "knowledge that is independent of and materially adds to" the public disclosures and "voluntarily provided" that information to the government before the complaint's filing.[142] Both versions of the "original source" exception remain a source of division among courts.

With the prior version of the "original source" exception, courts have reached differing conclusions as to whether a relator possesses "direct and independent" information. The primary distinction has turned on whether the relator must have direct experience with the fraudulent conduct, or whether the relator must have direct knowledge of the

138 950 F.3d 134 (1st Cir. 2020). The First Circuit allowed the relators to move forward as "original sources."
139 807 F. App'x 710, 711 (9th Cir. 2020).
140 438 F. Supp. 3d 246 (E.D. Pa. 2020).
141 31 U.S.C. § 3730(e)(4)(B) (2010).
142 31 U.S.C. § 3730(e)(4)(B).

information regarding fraudulent conduct. In ***Banigan***, the First Circuit concluded that the relator satisfied the original source exception, possessing "direct" and "independent" knowledge of the fraud.[143] More specifically, the First Circuit held that, although the relator did not personally observe the fraud and learned of the fraud "after the fact," the relator still qualified as an original source by learning of the fraud through conversations with coworkers and reviewing documents.

By contrast, in ***U.S. ex rel. Solis v. Millennium Pharmaceuticals, Inc.***, the district court held that the relator was not an original source because the relator lacked "direct and independent knowledge" having learned of the fraud through third parties.[144] The relator failed to qualify as an original source because his "conversations with third parties" and reliance on public studies were not "direct" information.

Since PPACA's amendments to the FCA's public disclosure bar in 2010, courts also have wrestled with what information "materially adds" to publicly disclosed information to meet the "original source" definition. In ***Howard***, the district court held that the relators were original sources who "materially added" to the publicly disclosed information.[145] The district court cited numerous "allegations and documents" that added to publicly disclosed audits and reports, including emails and documents showing the defendants' attempts to hide damaging evidence and knowledge of the fraud.

In ***Vierczhalek v. MedImmune Inc.***, however, the Second Circuit held that a relator was not an original source under the post-2010 definition because the relator's allegations neither "materially add[ed]" to nor were "independent" of prior publicly disclosed allegations.[146] The relator's allegations were not materially additive as she merely alleged other locations of the alleged fraud scheme and were not independent because the allegations were taken from prior public filings.

In ***Silbersher***, the district court likewise held that a relator did not qualify as an original source, since "adding a few details is hardly the stuff of an original source" under the post-2010 definition.[147] Notably, the district court also expressed deep ethical concerns in allowing the relator to qualify as an original source, given that the relator obtained the information for his FCA suit for his client while serving as a lawyer in patent litigation. The district court worried that allowing the relator to be an original source could incentivize lawyers to prioritize personal reward over their ethical duties of loyalty and candor to their clients.

143 950 F.3d 134 (1st Cir. 2020).
144 445 F. Supp. 3d 786 (E.D. Cal. 2020).
145 471 F. Supp. 3d 846 (C.D. Ill. 2020); *see also United States v. Specialist Doctors' Grp., LLC*, 2020 WL 7138566 (M.D. Fla. Dec. 7, 2020) (determining that a relator who "was directly involved in" the alleged fraud and "recorded" the fraud adequately alleged knowledge that was independent of and materially added to publicly disclosed data).
146 803 F. App'x 522 (2d Cir. 2020); *see also United States v. Shamir USA, Inc.*, 2020 WL 7087706 (C.D. Cal. Oct. 27, 2020) (holding that a relator was not an original source since his allegations were "readily apparent from multiple public disclosures" and provided only "additional … examples" of alleged fraud already "contained in previous public disclosures").
147 445 F. Supp. 3d 393 (N.D. Cal. 2020).

FIRST-TO-FILE

Under the FCA's first-to-file bar, no person other than the government may "bring a related action based on the facts underlying" an already "pending" FCA action.[148] As in past years, courts continue to address whether the bar is jurisdictional in nature, whether a relator may cure a violation of the first-to-file bar by amendment, and when the bar should apply.

In ***In re Plavix Mktg., Sales Practices & Prod. Liab. Litig. (No. II)***, the Third Circuit added to an ongoing circuit split regarding the jurisdictional nature of the first-to-file bar.[149] The Fourth, Fifth, Sixth, Ninth, and Tenth Circuits have held that the bar is jurisdictional while the First, Second, and D.C. Circuits have reached the opposite conclusion. Joining the First, Second, and D.C. Circuits, the Third Circuit held that the first-to-file bar is not jurisdictional. Applying the Supreme Court's "clear statement rule," which requires a clear congressional statement for a statutory provision to be jurisdictional, the Third Circuit observed that "no language" in the first-to-file bar clearly demonstrated that the bar is jurisdictional. In addition, the Third Circuit highlighted the first-to-file bar's location within the FCA as a further indication of the bar's non-jurisdictional nature, observing that "[i]f Congress had meant to make the first-to-file bar jurisdictional, it would have logically placed the bar in one of two other sections that mention jurisdiction and were added at the same time as it."[150]

Not only have courts split over the first-to-file bar's jurisdictional nature, courts also have been divided as to whether a violation of the first-to-file bar may be cured by the filing of an amended complaint after a first-filed action is dismissed.

Not only have courts split over the first-to-file bar's jurisdictional nature, courts also have been divided as to whether a violation of the first-to-file bar may be cured by the filing of an amended complaint after a first-filed action is dismissed. The First Circuit has held that, although a first-filed action may be "pending" when a relator files a related action, the relator may cure that first-to-file bar violation through amendment after the dismissal of the first-filed action. By contrast, the Second and D.C. Circuits conclude that a complaint filed during the pendency of a first-filed action cannot be amended to avoid the first-to-file bar's application.

148 31 U.S.C. § 3730(b)(5).
149 974 F.3d 228 (3d Cir. 2020).
150 Notably, the Third Circuit also concluded that a new relator could be added to an amended FCA complaint without violating the first-to-file bar. *Id.* at 233 ("So long as the new party is named in the (likely amended) complaint, there is no problem."). By contrast, the district court ruled in *U.S. ex rel. Tali Arik v. DVH Hospital Alliance,* that a relator "amend[ing] his complaint to include new relators" violates the first-to-file bar. 2020 WL 6173528, at *9 (D. Nev. Oct. 21, 2020) ("[The first-to-file] bar is 'exception-free' and applies regardless of whether the new relator seeks to intervene or join the action, or seeks to file a successive or separate action.").

Following the Second and D.C. Circuits, in ***U.S. ex rel. Cho v. H.I.G. Capital, LLC***, the district court held that a relator could not cure a violation of the first-to-file bar by amending his complaint after the dismissal of a related first-filed complaint.[151] According to the district court, because the first-to-file bar prevents a relator from later "bring[ing]" a related action, an amendment to the later-filed action cannot change that the relator brought the related action. The district court also noted that allowing the amendment of a complaint to cure a first-to-file bar violation would lead to "anomalous outcomes" because a relator's ability to amend would be "based on the pure happenstance of whether the district court reached [the later-filed] case while the first-filed suit remained pending."

Beyond the foregoing circuit splits, the first-to-file bar's application remains a subject of frequent litigation, with courts trending toward its application. In ***U.S. ex rel. Olhausen v. Arriva Medical, LLC***, the district court held the first-to-file bar prevented a relator from proceeding with his action.[152] The relator argued that a first-filed action was not "related" to his own because the first-filed action related only to "some" of the defendants' clients rather than "all" their clients, covered a slightly different time period, and contained different legal theories. None of those distinctions, however, negated the "material relatedness" of the relator's action to the similar first-filed action.

Similarly, in ***U.S. ex rel. Doghramji v. Cmty. Health Sys., Inc.***, the district court held that the first-to-file bar precluded several relators' claims for attorneys' fees.[153] While the relators argued their complaints alleged a "nationwide" scheme that was broader than the scheme alleged in a first-filed action, the district court disagreed, determining that the first-filed action was sufficiently broad in scope to bar the relators' claims for fees.

SETTLEMENT

Cases considering legal issues arising from FCA settlements were largely overshadowed by the attention paid to the government's dismissal authority under the FCA. Two cases, however, highlighted issues that can arise in connection with the settlement of FCA lawsuits.

The Eleventh Circuit's opinion in ***U.S. ex rel. Broadnax v. Sand Lake Cancer Ctr.*** considered issues that arise when parties are unable to reduce a settlement "term sheet" following mediation to a final settlement agreement.[154] In FCA cases where the United States has declined intervention, the relator and defendant may pursue mediation as an ordinary part of the litigation process. It is very common for a relator and defendant who reach resolution as part of a mediation of FCA claims to reduce their terms of the settlement to a term sheet with exchange of a formal settlement agreement to follow. In ***Broadnax***, the Eleventh Circuit considered whether the parties' term sheet was enforceable when the parties were unable to reach a final settlement agreement. While the defendant argued that the term sheet was only a "tentative understanding," the Eleventh Circuit concluded that Florida law rendered the term sheet an enforceable settlement agreement even though certain terms, such as the timing of payment and consequence of breach were missing from the term sheet. The Eleventh Circuit found nothing about the "nature and complexity" of FCA cases that precluded enforcement of the term sheet under Florida law.

In ***U.S. ex rel. Horsley v. Comfort Care Home Health, LLC***, the district court considered the issue of the government's dismissal authority over a relator's objection where the government and the defendant reached a settlement on fewer than all of the claims asserted by the relator.[155] The relator opposed the government's motion to dismiss all of the relator's unreleased claims, arguing that the government failed to articulate a reasonable basis for the settlement and neglected to provide a rational and valid basis for dismissal of the unreleased claims. The district court considered the settlement reached by the government and the defendant to be fair, adequate, and reasonable based on the extensive investigative work undertaken by the government. The district court then considered the issue of whether the government has an "unfettered right" to dismiss any unreleased claims or whether the government should be required to show both a valid purpose and a rational relationship between dismissal and accomplishment of that valid purpose, citing the D.C. Circuit's opinion in ***Swift*** and the Ninth Circuit's opinion in ***Sequoia Orange***. The district court expressed its belief that the Eleventh Circuit would adopt the D.C. Circuit's ***Swift*** standard, but rejected the relator's arguments under either standard. The district court determined that the government articulated a valid purpose rationally related to the dismissal of the unreleased claims, including: (1) preservation of government resources; (2) avoiding the risk of adverse case law; and (3) the dismissal of the relator's unreleased claims was an express condition of the settlement with the defendant. As such, the district court rejected the relator's arguments against dismissal of the unreleased claims.

STATUTE OF LIMITATIONS

The statute of limitations can significantly limit or even 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 2019, in ***Cochise Consultancy v. U.S. ex rel. Hunt***, the Supreme Court held that both limitations periods apply to a declined *qui tam* action.[156] In other words, a relator may proceed with a declined action filed more than six years after the FCA violation occurred if the action were filed within three years of when the relevant government official – and not the relator – should have known the material facts.

On remand to the district court following the Supreme Court's decision in ***Hunt***, the defendants again sought to dismiss the complaint as time barred. Pressing a new argument not considered by the Supreme Court, the defendants argued that the district court should consider a government employee involved in perpetrating the fraud to be the "official charged with responsibility to act." And, the defendants argued that the complaint was untimely because it was filed more than three years after the employee had become involved

151 2020 WL 5076712 (M.D. Fla. Aug. 26, 2020).
152 2020 WL 5077170 (S.D. Fla. Aug. 27, 2020).
153 2020 WL 1640423 (M.D. Tenn. Apr. 1, 2020).
154 819 Fed. App'x. 799 (11th Cir. 2020).
155 2020 WL 4002004 (N.D. Ala. July 15, 2020).
156 139 S. Ct. 1507 (2019).

in the alleged scheme. The district court rejected this argument, explaining that it would lead to "absurd and unfair results" if the limitations period could be shortened whenever a government official were involved in the alleged fraud. Without further interpreting the phrase "official charged with responsibility to act," the district court found the complaint timely.[157]

Consistent with the Supreme Court's opinion in ***Hunt***, in ***United States v. Hart***, the district court held that a *qui tam* complaint is timely if it satisfies either prong of § 3731(b).[158] In that case, the defendants argued that the plaintiffs' claims should be dismissed because the complaint was filed more than three years after the government learned about the material facts. The district court reasoned, however, that the complaint was timely because it was filed within six years of when the false claims allegedly were submitted.

In ***United States v. Arriva Medical, LLC***, the district court held that it could not resolve certain defendants' statute-of-limitations arguments at the pleading stage. The moving defendants first argued that the government's complaint did not plead any claims against them within the limitations period. But, the district court found that the government alleged a continuing fraud scheme that plausibly extended, at least in part, within the limitations period. It reasoned that further discovery was required to determine whether the moving defendants could be liable for claims submitted within the limitations period. The moving defendants also argued that the government should have known about the alleged underlying conduct more than three years before the complaint was filed. But, the district court held that without further information about the government's investigation, *when* the government should have known about the defendants' conduct was a question of fact that could not be resolved on a motion to dismiss.[159]

In contrast to these cases, the district court determined that the FCA's statute of limitations barred the relator's claims in ***U.S. ex rel. Wood v. Allergan Inc.*** There, the relator accused Allergan of FCA violations stemming from an alleged kickback scheme occurring between 2003 and 2011. After two similar actions by the relator were dismissed under the first-to-file bar, the relator filed a third action in May 2019. Applying § 3731(b), however, the district court granted the defendant's motion to dismiss on the ground that the complaint was untimely. In reaching this decision, the district court rejected the relator's argument that the limitations period should have been equitably tolled for the six-year period during which the government investigated the relator's first action before declining to intervene. The district court reasoned that the 10-year limitation in § 3731(b) is a statute of repose not subject to equitably tolling.[160]

CIVIL INVESTIGATIVE DEMANDS

The Civil Investigative Demand (CID) is a powerful pre-litigation tool that the government frequently utilizes to investigate potential allegations of FCA liability. Under 31 U.S.C. § 3733, the U.S. Attorney General, or his designee, is authorized to serve a CID before commencing a civil FCA proceeding when there is reason to believe that the person or entity may be in possession, custody, or control of any documentary material or information relevant to an FCA investigation.

The government may use a CID as a tool "to determine whether enough evidence exists[s] to warrant the expense of filing, as well as to prevent the potential Defendant from being dragged into court unnecessarily." CIDs must be issued prior to commencement of formal civil proceedings; once litigation has commenced, the government must turn to traditional civil discovery tools to gather information. And, CIDs may compel: (1) the production of documents; (2) written responses to interrogatories; and (3) sworn oral testimony related to the documents or information requested.

Prior to amendments to the FCA in 2009, the U.S. Attorney General was the only person authorized to issue CIDs, and that authority could not be delegated. In May 2009, the Fraud Enforcement and Recovery Act (FERA) authorized the U.S. Attorney General to delegate that authority to others within DOJ. In March 2010, DOJ issued a rule that extended authority to issue CIDs to all U.S. Attorneys.

Since 2010, the rate of the issuance of CIDs has increased significantly. Furthermore, in recent years, the scope of information requested in CIDs has become increasingly broad. There are limited judicial opinions, however, considering the appropriate parameters of a CID. The authority that does exist, however, recognizes some, albeit limited, boundaries to the government's CID authority.[161] Last year, there were again very few cases adding to the sparse case law considering the scope of the government's CID authority and the rights of parties receiving a CID.

In perhaps the most significant case, the district court in ***General Medicine, P.C. v. United States***, held that a third party has standing to challenge a CID issued to another entity.[162] In that case, the government had been investigating General Medicine, an employer of physicians and nurse practitioners, for a number of years for possible FCA violations. Several years into that investigation, the government issued a number of CIDs to third-party healthcare facilities, and General Medicine sought to set aside those CIDs for a number of reasons, including the relevance of the information sought, the breadth and scope of the CIDs, and the argument that the government issued the CIDs in bad faith. As grounds for its motion, General Medicine cited to the impact of the government's investigation on its business, including the loss of employees and loss of business relationships, and its assertion that the government in fact was conducting one-sided discovery through the issuance of the third-party CIDs. In response, the government challenged General Medicine's standing to move to set aside the CIDs and countered that the government had issued the CIDs for a valid investigative purpose. The district court rejected the government's standing argument and determined that General Medicine established that the CIDs infringed on its legitimate business interest sufficient to allow it to challenge the CIDs. The district court

157 2020 WL 5408212 (N.D. Ala. Sept. 9, 2020).
158 2020 WL 6051599 (S.D. Iowa Apr. 1, 2020).
159 2020 WL 1433861 (M.D. Tenn. Mar. 4, 2020).
160 2020 WL 3073293 (S.D.N.Y. June 10, 2020).

161 For example, a district court opinion from 2012 held that the government could not issue a CID under the FCA after a complaint had been filed. *See United States v. Kernan Hospital*, 2012 WL 5879133 (D. Md. 2012). And, in August 2016, another district court considered whether to quash a CID based on arguments that: (1) actions taken by the United States had constituted a *de facto* commencement of a formal civil proceeding and, accordingly, the CID was no longer a proper tool for information gathering; and (2) the CID was overly burdensome in that it requested information that, in large part, was already in the possession of the United States. *See In re Civil Investigative Demand 15 – 349*. No. 5:16-mc-3 (W.D. Va. Aug. 12, 2016).
162 2020 WL 7209278 (S.D. Ill. Dec. 7, 2020).

could not conclude, however, that the government had issued the CIDs in bad faith or that the issuance of the CIDs amounted to an abuse of process, as General Medicine failed to present evidence that the government issued the CIDs to harm its business. While the district court denied General Medicine's petition, the decision is noteworthy, as it supports the notion that a third party may have an opportunity to challenge CIDs that seek the third-party's information.

In ***U.S. ex rel. Silva v. VICI Marketing, LLC***, the district court considered whether a party could object to the issuance of the CIDs because the CIDs related to a pending FCA case in which the United States already had intervened.[163] The district court noted that the government issued CIDs to the objecting parties in contemplation of filing a separate action. Accordingly, the district court concluded that "intervening against one or more parties named in a *qui tam* [case] does not divest the United States of authority to issue a CID to a non-party it is investigating."

Finally, in ***United States v. Cross Senior Care, LLC***, the Eleventh Circuit affirmed the district court's opinion to grant the government's petition to enforce a CID over the objections of Cross Senior Care, which asserted that its dismissal from the underlying *qui tam* action mooted the government's CID.[164] The Eleventh Circuit explained that the dismissal of Cross Senior Care from the *qui tam* action had no bearing on the government's ability to bring its own FCA suit against Cross Senior Care. The Eleventh Circuit also noted in a footnote that the magistrate judge ruled that Cross Senior Care waived its objections to the CID because of its failures to raise defenses and objections to the CID within the 21-day time frame set forth in 31 U.S.C. § 3733(j)(2), but that "the government retreated from its waiver position" on appeal.

LITIGATION FUNDING

In recent years, a number of relators have turned to third parties to obtain funding to pursue *qui tam* actions. Such agreements are referred to as litigation funding agreements and typically provide funds to a relator in exchange for a percentage of the relator's proceeds from the case.

This was the case in ***Ruckh v. Salus Rehab., LLC***, where, in connection with an appeal from a jury verdict in favor of the relator, the relator entered into a litigation funding agreement with ARUS, a third-party company that described itself as a "privately owned limited liability company focused on litigation funding."[165] In exchange for the necessary funds, the relator agreed to sell ARUS "less than 4% of her share of the judgment originally entered by the district court, if the jury verdict were upheld on appeal, assuming a 30% share to the relator." As part of the appeal of the jury verdict, the defendants argued that by entering into the litigation funding agreement, the relator had partially reassigned her interest in the FCA action, violated the intent of both the Constitution and the FCA, and therefore forfeited her standing to pursue claims on behalf of the United States. Specifically, the defendants argued that the relator was "no longer the assignee of the United States."

In rejecting the defendants' arguments, the Eleventh Circuit focused on two specific aspects of the litigation funding agreement. First, the relator only assigned "less than 4%" of her recovery, which, according to the Eleventh Circuit, constituted "only a small interest." Second, because the agreement clearly stated that the relator retained all decision-making ability in the litigation, the relator retained "sufficient interest to meet the irreducible constitutional minimum of standing under Article III."

> The Eleventh Circuit held that the FCA does not explicitly prohibit relators from entering into litigation funding agreements.

The Eleventh Circuit also held that the FCA does not explicitly prohibit relators from entering into such litigation funding agreements. The Eleventh Circuit noted that the FCA allows "a person" to file suit under the FCA, and there are only three explicitly excluded types of persons.[166] As a result, the Eleventh Circuit was "reluctant to imply additional exceptions in the absence of clear legislative intent to the contrary." The Eleventh Circuit denied the defendants' motion to dismiss the appeal on standing grounds.

DOJ has taken notice of litigation funding agreements, with former Principal Deputy Assistant Attorney General Ethan P. Davis discussing the issue in a June 2020 speech to the Institute for Legal Reform.[167] Davis noted that often the government attorneys pursuing or monitoring the *qui tam* action do not know the extent to which third-party funders are funding relators. Davis stated that it is also unknown whether relators are sharing information with the third-parties or allowing those third parties to exercise control over the litigation. Finally, Davis mentioned that concerns have been raised that such agreements can result in conflicts of interest and present questions of fairness in litigation and accountability.

To learn more information about the pervasiveness of litigation funding agreements, Davis stated that DOJ instructed its attorneys to begin asking the following questions when meeting with relators:

- Does the relator or his or her counsel have an agreement with a third-party funder?
- If so, what is the identity of that funder?
- Has the relator shared any information relating to the *qui tam* allegations with that funder?
- Does a written agreement exist?
- Does the agreement entitle the funder to exercise any direct or indirect control over the relator's litigation or settlement decisions?

163 2020 WL 1677335 (M.D. Fla. Apr. 6, 2020).
164 2020 WL 7647360 (11th Cir. Dec. 23, 2020).
165 963 F.3d 1089 (11th Cir. 2020).

166 *See* 31 U.S.C. § 3730(d)(3), (e)(1), & (e)(2).
167 Speech to the Institute for Legal Reform, U.S. Chamber of Commerce, June 26, 2020, https://www.justice.gov/civil/speech/principal-deputy-assistant-attorney-general-ethan-p-davis-delivers-remarks-false-claims.

DOJ also will ask that relators update DOJ should the answers to any of those questions change throughout the course of the litigation. Notably, Davis mentioned that the list of questions, at least for the time being, is purely for informational purposes in order to study the use of such agreements.

RETALIATION

The FCA protects whistleblowers who report potential FCA violations from retaliation by their employer.[168] To establish liability under the anti-retaliation provision, an employee must show that: (1) the employee engaged in protected activity; (2) the employer knew that the employee engaged in protected activity; and (3) the employer took an adverse employment action against the employee as a result.

Protected Activity and Underlying Fraud

The FCA defines protected activity as an employee's lawful actions "in furtherance of" an FCA action or "other efforts to stop one or more violations" of the FCA.[169] Courts have continued to reason that in order to be a qualifying protected activity, the employee's actions must relate to a fraud against the government and not merely general compliance or regulatory concerns.

In ***U.S. ex rel. Benaissa v. Trinity Health***, the Eighth Circuit held that it is not sufficient for the employee's actions to relate merely to "ethical" concerns instead of fraud.[170] There, the plaintiff alleged that he complained internally on two different occasions about a certain physician performing unnecessary surgeries. The Eighth Circuit noted that the plaintiff's allegations show "his concern was with the medical propriety and ethical ramifications" of those unnecessary surgeries, but that the plaintiff did "not allege that he connected his complaint to a concern over improper billing or the submission of false claims to the government." Because the plaintiff's complaints only related to ethical concerns and not fraud, they did not constitute protected activity. The Eighth Circuit affirmed the district court's granting of the defendant's motion to dismiss the plaintiff's retaliation claim.

> In FCA retaliation cases, the plaintiff must be specifically concerned about *fraud* – not merely improper business practices.

In ***Trupp v. Roche Diagnostics Corp.***, the district court reached a similar result, when it concluded that the plaintiff "ha[d] never held the subjective belief that [defendant] was committing fraud against the government," and that this "doom[ed] her FCA retaliation claim."[171] The district court based this conclusion on the plaintiff's own deposition testimony, in which she "unequivocally testified that she was not concerned that [defendant] was engaged in any fraud[.]" Instead, the district court found that "the evidence overwhelmingly established" that the plaintiff was concerned.

In ***U.S. ex rel. McClain v. Nutritional Support Servs., L.P.***, the district court likewise confirmed that the plaintiff must be specifically concerned about fraud – not merely improper business practices.[172] The plaintiff alleged that he raised concerns "on multiple occasions" about the defendant falsely submitting claims for payment. He further said his concerns were not merely about "generalized misconduct" because he based those concerns on recent developments in a separate *qui tam* action alleging healthcare fraud. But, the district court pointed out that the other *qui tam* case remained under seal until after the plaintiff was terminated from his employment, so the case could not have formed the plaintiff's basis for his internal complaints. Moreover, even if the plaintiff did believe the defendant was violating the FCA, the plaintiff's generalized allegations that he expressed concerns to "his supervisors" "on multiple occasions" were insufficient to allege protected activity. The district court compared plaintiff's allegations to those of the plaintiff in ***U.S. ex rel. Grant v. United Airlines, Inc.***, where the plaintiff had "described the contents of an email he sent to the defendant's manager."[173] The Fourth Circuit held that such specific allegations were sufficient to allege protected activity. Unlike in ***Grant***, the plaintiff in ***McClain*** included no such detail. As a result, the district court granted Nutritional Support Services' motion to dismiss the plaintiff's retaliation claim.

Finally, ***Paige v. AM Hospice, Inc.***, provided additional guidance regarding the issue of when internal complaints amount to lawful actions "in furtherance of" an FCA action.[174] There, the district court held that internal complaints *must* "concern false or fraudulent claims for payment submitted to the government." The plaintiff alleged that her internal report revealed that the defendant was "admitting patients who do not qualify for hospice care, and then fraudulently billing Medicare for the admitted patients who d[id] not qualif[y]." The district court held that because the plaintiff characterized her complaints as "involving illegal, unlawful, or false-claims investigations, specifically fraudulent Medicare billings," her actions counted as protected activity and survived the defendant's motion to dismiss.

Employer Notice

As the second element of a *prima facie* FCA retaliation claim, a plaintiff must show that the employer knew about the employee's protected activity. Allegations or evidence of "employer notice" (or the lack thereof) are not only applicable in this context, but also can be relevant to the issue of whether a causal connection exists between the protected activity and the adverse action, as court decisions from the past year reflect.

For example, in ***Katterheinrich v. Al-Razaq Computing Services***, the district court held that because the individual responsible for terminating the employee did not individually have notice of the employee's protected activity, the employee could not establish a causal connection between her protected activity and her termination for purposes of a retaliation

168 31 U.S.C. § 3730(h).
169 31 U.S.C. § 3730(h)(1).
170 963 F.3d 733 (8th Cir. 2020).
171 440 F. Supp. 3d 990 (S.D. Ind. 2020).
172 2020 WL 2464655 (D.S.C. Mar. 16, 2020).
173 912 F.3d 190, 197 (4th Cir. 2018).
174 2020 WL 2543301 (W.D. Tex. May 15, 2020); *see also Paige v. AM Hospice, Inc.*, EP-19-CV-319-PRM, Order Approving and Adopting Report and Recommendation of Magistrate Judge (W. D. Tex. June 23, 2020).

claim.[175] Similarly, in ***Young v. Argos***, the district court found that the plaintiff failed to plead that he was terminated in retaliation for filing a *qui tam* action in part because the complaint "did not identify the decision-maker who fired Plaintiff, whether that individual had knowledge of the *qui tam* action, or how that individual allegedly had such knowledge."[176]

However, in ***Nichols v. Baylor Research Institute***, the district court rejected the defendant's argument that the plaintiff must plead that the individuals to whom she complained about alleged billing issues were involved in the plaintiff's termination or made the decision about her termination.[177] The district court explained that, particularly given the close temporal proximity of the protected activity and the adverse employment decision, it was "plausible to conclude that those who made the adverse employment decision were told of [plaintiff's protected activities], regardless of whether [plaintiff] directly reported her concerns to them or not."

Adverse Employment Action Because of Protected Activity

Plaintiffs asserting FCA retaliation claims must establish that the adverse action at issue resulted from protected activity. Several courts addressed the standard for establishing causation this past year and concluded that a plaintiff must prove that the adverse action was a "but-for" cause of the protected activity, not merely that the protected activity was one motivating factor.

In ***Nesbitt v. Candler Cty.***, the Eleventh Circuit held that a plaintiff must show "but-for" causation between the protected activity and the adverse action, while recognizing that other circuits (Sixth, Seventh, D.C.) have held that the protected activity need only be a "motivating factor" for the adverse action.[178] The Eleventh Circuit reasoned that the FCA's language (*i.e.*, adverse action taken "because of" engagement in protected activity) and the Supreme Court's interpretation of two similar statutes supported its approach.[179]

In ***Lestage v. Coloplast Corp.***, the First Circuit addressed an issue of first impression, holding that the standard for causation in FCA retaliation cases is a "but-for" standard.[180] The defendant allegedly retaliated against the plaintiff on two occasions – first, by placing her on administrative leave after learning that she filed a *qui tam* lawsuit against the defendant, and then by providing her with unfavorable account assignments after she returned from administrative leave and the defendant settled the *qui tam* action. At trial, the jury awarded the plaintiff $765,525. The First Circuit ruled that the district court erroneously instructed the jury that "protected activity" need only be a "substantial motivating factor" for the retaliation. The First Circuit nonetheless upheld the jury verdict because it determined that the evidence was sufficient even under the "but-for" standard.

In ***Bharadwaj v. Mid Dakota Clinic***, the Eighth Circuit held that the causation standard for FCA retaliation claims is more rigorous than other employment-based claims, as "the retaliation [must be] motivated s*olely* by ... protected activity."[181] The Eighth Circuit affirmed the district court's granting of summary judgment in favor of the defendant because the plaintiff-physician lacked any evidence that "his decision to report allegedly fraudulent billing practices of a colleague caused – much less solely caused – [the defendant] to force him" to resign.

The Eighth Circuit also affirmed summary judgment in ***Sherman v. Berkadia Commercial Mortg. LLC***. There, the defendant, a mortgage provider, hired the plaintiff to help ensure that mortgages were compliant with U.S. Department of Housing and Urban Development (HUD) regulations.[182] The plaintiff allegedly believed that the defendant should have disclosed more information to HUD and that management had thwarted the plaintiff's efforts toward more effective compliance. In ruling that the plaintiff failed to prove that his termination was "motivated solely by" these actions, the Eighth Circuit explained that even though the plaintiff "has produced evidence that [defendant's] management did not implement, and were at times critical of, some of [plaintiff's] suggestions regarding compliance with HUD regulations, there [was] also evidence that [plaintiff's] supervisors disapproved of other parts of his job performance," including an inability to work with a manager and accommodating staff who "continually produced work product at a much slower rate than industry average."

175 2020 WL 5847648 (N.D. Ala. Oct. 1, 2020).
176 2020 WL 6275959 (D.S.C. Oct. 26, 2020).
177 2020 WL 1158456 (N.D. Tex. Mar. 10, 2020).
178 945 F.3d 1355 (11th Cir. 2020).
179 *Univ. of Tex. Sw. Med. Ctr. v. Nassar*, 570 U.S. 338 (2013) (anti-retaliation provision of Title VII); *Gross v. FBL Fin. Servs., Inc.*, 557 U.S. 167 (2009) (Age Discrimination in Employment Act of 1967).
180 2020 WL 7238287 (1st Cir. 2020).
181 954 F.3d 1130 (8th Cir. 2020).
182 956 F.3d 526 (8th Cir. 2020).

STARK LAW/ ANTI-KICKBACK STATUTE

The Stark Law and AKS continue to be a significant focus of relators bringing FCA cases with varying results over the past year.

COMPENSATION ARRANGEMENTS

FCA cases alleging that physician compensation arrangements violated the Stark Law and AKS remained prevalent. In ***Benaissa*** (also discussed previously), the Eighth Circuit upheld the district court's dismissal of a former Trinity trauma surgeon's allegations that the regional health system violated the FCA by presenting claims to the government on behalf of physicians compensated in violation of the Stark Law and AKS.[183] The surgeon-relator alleged that the health system paid five physicians in excess of the 90th percentile of compensation in return for referrals, and that such excessive compensation resulted in the performance of medically unnecessary procedures. Subsequently, the relator asserted that Trinity not only submitted claims on behalf of these physicians, but also improperly certified compliance with the Stark Law and AKS in provider agreements and annual cost reports submitted to the government. The Eighth Circuit, however, affirmed the district court's decision to grant the defendants' motion to dismiss for failure to state a claim, finding the surgeon's "general allegations" were insufficient to show that Trinity actually submitted claims for payment to the government.

The Stark Law and AKS continue to be a significant focus of relators bringing FCA cases with varying results over the past year. FCA cases alleging that physician compensation arrangements violated the Stark Law and AKS remained prevalent.

In ***U.S. ex rel. Rasmussen v. Essence Group Holdings Corp.***, the relator alleged that Lester E. Cox Medical Centers (Cox) – an operator of a network of healthcare providers – partnered with Essence to create CoxHealth MedicarePlus, a Medicare Advantage plan.[184] Using data-mining techniques, Essence identified patients in the Medicare Advantage plan who might have additional medical conditions that could be diagnosed and coded, which would increase the patients' risk score (and, in turn, the following year's capitation rate). Essence then attempted to arrange an "Enhanced Encounter" for those patients, which consisted of an examination by the patients' doctors, to determine whether the additional medical conditions existed and could be coded. Cox allegedly paid doctors $100 to conduct each Enhanced Encounter. Among other allegations, the relator claimed that the $100 payments to physicians constituted a "kickback" for purposes of the AKS. The district court disagreed with this characterization and instead found CMS was not billed for the Enhanced Encounters or any associated tests. Under the Medicare Advantage Program, CMS pays the defendants a fixed sum regardless of the medical services provided to the patients. Thus, even if the Enhanced Encounters were medically unnecessary, the district court found this fact could not support a claim under the FCA and granted the defendants' motions to dismiss.

MANAGEMENT SERVICES AGREEMENTS

Management arrangements also attracted the attention of relators with mixed success. In ***Stop Illinois Health Care Fraud, LLC v. Sayeed***, the relator appealed the district court's decision to grant the defendants' motion for a directed verdict.[185] In its complaint and at trial, the relator alleged that Healthcare Consortium of Illinois (HCI), an organization focused on coordinating services to enable low-income seniors to continue living at home, received prohibited remuneration in the form of gift cards and $5,000 monthly payments under a sham management services agreement. In return, the relator alleged that HCI granted a management company and its affiliated home health agency and physician practice access to HCI's patient records to identify, solicit, and obtain patients in need of home healthcare. Noting that some evidence indicated the gift cards were intended to induce referrals, the Seventh Circuit disagreed with the district court's conclusion that the

183 963 F.3d 733 (8th Cir. 2020).

184 2020 WL 4381771 (W.D. Mo. Apr. 29, 2020).

185 957 F.3d 743 (7th Cir. 2020).

management services agreement was not designed to induce prohibited referrals under the AKS. Accordingly, the Seventh Circuit vacated the judgment and remanded the case, urging the district court to more carefully consider whether the arrangement between HCI and the management company granting the company access to HCI's patient records generated referrals in violation of the AKS.

In ***U.S. ex rel. Reilly v. Adventist Health***, the district court dismissed a relator's complaint alleging that San Joaquin Community Hospital, operated by Adventist Health, paid prohibited kickbacks under the AKS through a management services organization (MSO) to a physician provider network, a wholly-owned subsidiary of the hospital, by accepting below FMV payments from the network for management services in exchange for referrals of federal and state prison inmate business.[186] The relator also alleged the physician provider network made monthly payments under the pretext of a consulting arrangement to a directing physician for several California prisons in exchange for triaging prison patients to the hospital. Granting the defendants' motion to dismiss, the district court determined the relators did not plausibly demonstrate the MSO provided any remuneration, such as management services, to the physician provider network for less than FMV or that the network referred inmate patients to the hospital in return. The district court emphasized the contradictory allegations in the relators' complaint, which indicated the MSO provided services to the physician provider network while also alleging that the MSO was a sham entity created for the diversion of funds from the network to the hospital. The district court found that the relator's allegations lacked sufficient supporting details, including the nature and quantity of services furnished by the MSO to the network, the amount the network paid for the management services, the FMV of such services, any examples of a referral directed to the hospital by the network, or a link between any remuneration and referrals. The district court also rejected the kickback allegations involving the California state employee because the relator provided no examples of any referral made by the directing physician during the time at issue, and the services were consistent with contemplated consulting services.

In ***United States v. Medoc Health Services, LLC***, the district court denied the defendants' motion to dismiss various claims under the FCA, alleging that Medoc and its officers solicited and accepted kickbacks from pharmacies.[187] The complaint alleged that Medoc purported to provide management, administrative, and marketing services to pharmacies through its subsidiary MSOs. These MSOs were co-owned by physicians in a position to refer prescriptions to Medoc-associated pharmacies, thus, entitling them to a percentage of the profits earned from their prescriptions. Medoc allegedly rewarded high-volume prescribers with ownership in more lucrative MSOs and would often transfer physicians between MSOs. Medoc officers were also added to the payroll at some of the pharmacies. The defendants claimed these relationships fit within the management services and *bona fide* employee AKS safe harbors. The district court disagreed and found reliance on a safe harbor is not appropriate for a motion to dismiss, as it is an affirmative defense. The district court also found the complaint adequately alleged that the elements of the safe harbor requirements were not met. With respect to the *bona fide* employee safe harbor, Medoc officers allegedly performed no services for the pharmacies, did not submit monthly time reports, and did not report to any executives of the pharmacy, despite receiving pay based on prescription referrals, thus, undermining the existence of a *bona fide* employment relationship. With respect to management services, the complaint alleged that the fees paid (which were calculated at 89% of gross operating income) were in excess of FMV, were not set in advance, and took into account the volume or value of referrals.

PHYSICIAN INDUCEMENTS

Support services and other payments offered by pharmaceutical and medical device companies to physicians also drew scrutiny as potential improper inducements under the AKS.

In ***U.S. ex rel. Suarez v. Abbvie, Inc.***, the relator, a former nurse employed by Abbvie, alleged that Abbvie violated the AKS by providing support services to physicians free of charge through its ambassador program for the drug Humira.[188] As part of the ambassador program, Abbvie used registered nurses to provide support services to physicians who prescribed Humira, such as in-person visits to patient homes, responding to patient questions, and assisting with insurance authorization and enrollment. The relator alleged these free professional services induced physicians to prescribe Humira over other drugs because the physicians would save money and other resources by using ambassadors rather than staff for such services. While the district court granted Abbvie's motion to dismiss allegations related to a nationwide fraud scheme, the district court denied Abbvie's motion to dismiss claims related to conduct in Florida based upon specific allegations involving a Florida physician. The district court noted that: (1) the relator alleged specific facts that the services provided through the ambassador program to a Florida physician exceeded basic product support services; (2) the services conferred independent value on physicians; (3) false claims for such services were submitted to Medicare; and (4) Abbvie acted knowingly under the AKS.

> Support services and other payments offered by pharmaceutical and medical device companies to physicians also drew scrutiny as potential improper inducements under the AKS. Alleged pharmaceutical marketing schemes also continued to be a focus in FCA litigation.

In ***U.S. ex rel. Paul v. Biotronik, Inc.***, the district court found that the relator's conclusory allegations were insufficient to survive a motion to dismiss. In this case, the relator – a former employee of medical device company Biotronik, Inc., who provided technical and clinical support and training to sales representatives, physicians, and others for the medical device company – alleged Biotronik violated the AKS and FCA by providing kickbacks to cardiologists in exchange for their use of Biotronik's products and services.[189] These incentives allegedly included a cruise and various vacations, paying for a cardiologist's

186 2020 WL 2522114 (E.D. Cal. May 18, 2020).
187 2020 WL 3892453 (N.D. Tex. July 2, 2020).
188 2020 WL 7027446 (N.D. Ill. Nov. 30, 2020).
189 2020 WL 1911465 (M.D. Fla. Apr. 20, 2020).

events, paying for a cell phone for the cardiologist's girlfriend, and making "donations" to another cardiologist. The district court found the relator's kickback allegations conclusory and lacking necessary details because the relator did not identify any device or service provided to patients by the cardiologists at issue, the federal healthcare program that paid for any such device or service, or facts regarding when or how the alleged kickbacks were provided to the cardiologists.

In ***U.S. ex rel. STF, LLC v. Vibrant America, LLC***, the relators alleged that a laboratory company violated the AKS and FCA by engaging in two illegal kickback schemes: (1) the "processing fee scheme" where the defendant entered into phlebotomy contracts with physicians' families and staff members that included processing, handling, and collection fees well above FMV for laboratory tests that were often not medically reasonable or necessary and performed by non-phlebotomists; and (2) the "waiver scheme" under which the defendant agreed to cap private pay patients' cost-sharing amounts at $25 and not to send any patients to collections.[190] Relying heavily on special fraud alerts issued by the OIG,[191] the district court denied the defendant's motion to dismiss these two claims. Regarding the processing fee scheme, the district court rejected the defendant's argument that its fees covered a "panoply" of services other than the blood draw and collection, reasoning it was inappropriate on a motion to dismiss for the district court to consider evidence to contradict the relators' allegations. The district court highlighted additional factors that raised the risk of the arrangements, including payments that were made on a per-specimen basis (even where multiple specimens were collected during a single patient encounter); and that the defendant made payments directly to the contracting family and staff members, rather than their practice, leaving the practices to bear the costs of the services while the family and staff reaped the benefits of the arrangement. As for the waiver scheme, the district court found unpersuasive the defendant's argument that the cost-sharing waivers did not violate the AKS because they were given to private, rather than federal healthcare program, beneficiaries. The district court reasoned that the defendant's waivers nevertheless implicated the AKS because "physicians typically wish to minimize the number of laboratories to which they refer for reasons of convenience and administrative efficiency," so the waivers may still be intended to influence the physicians' referral of federal healthcare program business. The district court also declined to require the relator to establish the waivers were not based on financial hardship, emphasizing the relevant inquiry is whether *one purpose* of the remuneration was to induce or reward federal healthcare program referrals.

CO-PAY ASSISTANCE DONATIONS BY PHARMACEUTICAL COMPANY

Allegations related to a drug manufacturer's donations to a co-pay assistance foundation also provided sufficient support to defeat the drug manufacturer's motion to dismiss. In ***United States v. Regeneron Pharmaceuticals, Inc.***, the government asserted that Regeneron made donations to a co-pay assistance foundation to induce physicians to prescribe Regeneron-manufactured drugs.[192] The complaint alleged that Regeneron donated funds intending to cover only the co-pay for Medicare patients who were prescribed its drug, and not its competitor's drug whose co-pays were also funded by the foundation. As a result, Regeneron's funds operated as an inducement to physicians because the physicians saved time and effort explaining and collecting co-payments from patients and an inducement to patients to select its drug over cheaper alternatives without the need to consider the applicable co-pay. The district court denied Regeneron's motion to dismiss, finding that the complaint plausibly asserted a violation of the AKS. While the district court acknowledged donations for a co-pay assistance charity should not generally raise AKS concerns, Regeneron allegedly requested and obtained data from the foundation to ensure its donations roughly equaled the amount of Medicare co-payments for its drug despite its knowledge that such actions were prohibited under OIG guidance.

PHARMACEUTICAL MARKETING PRACTICES

Alleged pharmaceutical marketing schemes also continued to be a focus in FCA litigation. In ***U.S. ex rel. Gohil v. Sanofi U.S. Servs. Inc.***, the relator alleged that his former employer, Aventis, a pharmaceutical company, engaged in certain marketing schemes resulting in prohibited kickbacks to physicians that prescribed the Aventis drug Taxotere in violation of the AKS and FCA.[193] The relator alleged that part of Aventis' kickback scheme included marketing activities such as: (1) implementing an advisory board to expand Taxotere's market presence, which allowed physicians to attend meetings in desirable locations through all-expense paid trips, paid entertainment, and honoraria; (2) requesting physicians for certain "key" accounts to perform speaking engagements to market Taxotere, which included all-expense paid trips, paid entertainment, and honoraria; (3) providing educational grants to certain physicians that prescribe Taxotere; (4) using preceptorships as an opportunity to market products to physicians who prescribed Taxotere at low rates; and (5) *ad hoc* kickbacks, such as gift certificates, meals, and gift baskets to physicians who prescribed certain volumes of products or were speakers in speaker programs. For the claims related to advisory boards, speaker programs, educational grants, and provision of meals and gift baskets, the district denied the defendant's motion for summary judgment, finding that the relator presented sufficient evidence to raise a disputed issue of material fact that the items could be considered remuneration provided to induce prescriptions for Taxotere. The district court, however, granted the defendant's motion for summary judgment on issues related to preceptorships and other *ad hoc* kickbacks because the relator failed to show claims related to these alleged kickbacks were submitted to federal healthcare programs and failed to submit sufficient, specific evidence on other *ad hoc* kickbacks.

VENDOR ARRANGEMENTS

Healthcare vendors also faced FCA claims. In ***U.S. ex rel. Graziosi v. R1 RCM, Inc.***, the defendant operated as a vendor that reviewed medical records and recommended to hospitals inpatient or other admission classifications for their patients.[194] The relator, a

190 2020 WL 4818706 (N.D.Ca. Aug. 19, 2020).
191 *See, e.g.*, https://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/oig_sfa_laboratory_payments_06252014.pdf (hereinafter "2014 Special Fraud Alert"); https://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html.
192 2020 WL 7130004 (D. Mass. Dec. 4, 2020).
193 2020 WL 6682483 (E.D. Pa. Nov. 12, 2020).
194 2020 WL 7025082 (N.D. Ill. Nov. 30, 2020).

former employee of a hospital client, alleged that R1 RCM caused hospitals to submit false claims by recommending the hospital "upgrade" certain admissions from outpatient or observation to inpatient to collect higher Medicare reimbursement. The relator asserted that the fee paid to R1 RCM for its services functioned as a kickback under the AKS, as R1 RCM was being paid to refer or recommend patients to be classified as inpatients where such may not be medically supported. The district court denied the defendant's motions for summary judgment, finding there was sufficient evidence to support the relator's claim that R1 RCM's determinations on inpatient status were motivated by a desire to increase Medicare reimbursement for its hospital clients and continue those arrangements. In reaching this decision, the district court considered, among other factors, the language used in R1 RCM's marketing materials that emphasized the return on investment hospital clients could make for using R1 RCM's services. The district court also denied the relator's motion for partial summary judgment that R1 RCM's solicitations of and receipts from "fees-for-recomendations" contracts with hospitals and hospital systems violated the AKS as a matter of law.

MANAGED CARE/ MEDICARE ADVANTAGE

Medicare Advantage plans face ongoing scrutiny from government agencies focusing on invalid diagnosis codes and risk adjustment scores, among other issues.

FOCUS ON RISK ADJUSTMENT

The number of Medicare beneficiaries electing to enroll in federally-funded Medicare Advantage plans continues to grow. In 2019, the Medicare Advantage Program provided coverage to approximately 23 million beneficiaries at a cost of $264 billion.[195] Medicare Advantage 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, Medicare Advantage plans are compensated on a monthly basis with a fixed capitation payment for each member. The amount of the capitation payment is determined for each payment year through a process called "risk adjustment," which is based on data reflecting the diagnoses documented in a patient's medical record, as well as demographic and other considerations. The codes Medicare Advantage plans submit to CMS to communicate the diagnoses of patients must be supported by the medical record.[196]

195 https://oig.hhs.gov/oei/reports/OEI-03-17-00471.pdf.
196 *See* 42 U.S.C. § 1395w-23.

To protect against over coding of diagnoses, federal law requires that CMS conduct regular Risk Adjustment Data Validation (RADV) audits. Further, all Medicare Advantage plans must agree to "certify (based on best knowledge, information, and belief) that the data it submits" for risk adjustment are "accurate, complete, and truthful."[197] To the extent that an audit identifies that inaccurate codes were submitted, the Medicare Advantage plan is required to propose deletions to correct any overpayment.[198]

Last year, DOJ announced its intention to focus its resources on a growing number of matters related to Medicare's managed care program. DOJ stated that it is concerned some plans or providers will manipulate the risk adjustment process and profit from artificially inflated monthly capitated payments and reimbursements. Some recent and noteworthy cases are set forth on the following pages.

Noteworthy Medicare Advantage and Risk Adjustment Settlements

Kaiser Foundation Health Plan of Washington (formerly Group Health Cooperative) entered into a $6.3 million settlement with DOJ in November 2020 to settle allegations that it submitted invalid diagnoses for Medicare Advantage beneficiaries and received inflated payments from Medicare as a result.[199] The settlement resolves allegations that Group Health Cooperative engaged in "systemic fraud" by knowingly allowing a third-party vendor – who was paid on a contingency fee based on the number of additional diagnosis codes identified – to routinely "upcode" claims, while failing to submit deletes for identified claims that were unsupported in the underlying medical record.

While most cases center on the submission of invalid diagnosis codes, the Independence Blue Cross (IBC) settlement serves as a reminder that liability in connection with the Medicare Advantage Program may extend to representations made to CMS, including at the bid submission stage.[200] In September 2020, IBC agreed to pay $2.25 million to resolve allegations that it incorrectly calculated actual prior costs in the financial bids it submitted to CMS for contract years 2009 and 2010.[201] The incorrect calculations resulted in a higher base amount on IBC's Medicare Advantage plan bids and, ultimately, inflated reimbursement to IBC categorized as overpayments.

Notable Litigation Relating to Medicare Advantage and Risk Adjustment

Litigation concerning purported practices to defraud the government by inflating risk adjustment scores through improper diagnosis code submissions remains ongoing.

In March 2020, the government filed suit against Anthem, Inc., for alleged FCA violations related to improper risk adjustments.[202] The allegations involve Anthem's knowing failure to delete inaccurate diagnosis codes submitted to CMS for risk adjustment purposes. The

197 *See* 42 CFR § 422.504(l).
198 *See* 42 C.F.R. § 422.310.
199 *U.S. ex rel. Ross v. Group Health Cooperative*, 12-CV-0299S (W.D.N.Y.).
200 All MAOs must annually submit "bids" to CMS for each plan they intend to offer to the Medicare Advantage program, which details what an MAO estimates it will cost to provide the regular Medicare benefits. Included within each bid is the cost actually incurred for prior years.
201 *U.S. ex rel. Johnson v. Independence Blue Cross*, 10-cv-1520 (E.D. Pa.).
202 *U.S. v. Anthem, Inc.*, 1:20-cv-2593-ALC (S.D.N.Y.).

DOJ announced its intention to focus its resources on a growing number of matters related to Medicare's managed care program and expressed its concern that some plans or providers will manipulate the risk adjustment process and profit from artificially inflated monthly capitated payments and reimbursements.

government alleged that Anthem conducted a one-sided review of beneficiaries' medical charts with the goal of adding diagnosis codes to submit to CMS to gain revenue, without also identifying and deleting inaccurate codes. The government contends that Anthem generated $100 million or more per year in additional revenue. While the case is pending in the Southern District of New York, Anthem filed a motion to transfer venue to the Southern District of Ohio, arguing that the program at issue in the complaint was run from Anthem's Columbus, Ohio office and Anthem's material witnesses reside there. A motion to dismiss and a motion to strike certain allegations from the complaint remain pending.

In ***U.S. ex rel. Cutler v. Cigna Corp.***, a recently unsealed *qui tam* lawsuit alleges that Cigna-HealthSpring submitted fraudulent claims by misrepresenting the diagnoses of its beneficiaries in violation of the FCA.[203] The relator contends that Cigna-HealthSpring created a program ultimately designed to raise plan members' risk scores to inflate monthly capitated payments by inappropriately capturing diagnoses not supported in the underlying medical record. According to the complaint, Cigna-HealthSpring encouraged nurses to diagnose beneficiaries with exaggerated medical problems, promoted falsification of diagnoses, and reported health conditions not supported by medical documentation or reliable clinical information. While the case is pending in the Southern District of New York, Cigna-HealthSpring has filed a motion to transfer the case to the Middle District of Tennessee.

203 No. 7:17-cv-7515 (S.D.N.Y.).

Other ongoing cases concerning the alleged misrepresentation of diagnosis codes in an effort to increase risk adjustment payments include ***U.S. ex rel. Ormsby v. Sutter Health***[204] and ***U.S. ex rel. Poehling v. UnitedHealth Group, Inc.***[205] In ***Ormsby***, the complaint alleges that Sutter inappropriately inflated risk scores through submission of unsupported diagnosis codes. The complaint additionally alleges that Sutter failed to take adequate steps to address the issue after learning of the unsupported diagnosis codes.

Likewise, in ***Poehling***, UnitedHealth is alleged to have knowingly obtained inflated risk adjustment payments based on untruthful and inaccurate information regarding the health status of its Medicare Advantage beneficiaries. According to the complaint, UnitedHealth allegedly conducted a chart review program designed to identify diagnoses not reported by treating physicians that would increase its risk adjustment payments while ignoring information that showed other diagnoses submitted to Medicare were invalid. The matter is in discovery and scheduled for trial in March 2022.

MEDICARE ADVANTAGE 2014 OVERPAYMENT RULE

An appeal is pending before the D.C. Circuit concerning whether CMS's 2014 Overpayment Rule will remain vacated. The Overpayment Rule required Medicare Advantage plans to return overpayments within 60 days of identifying them. In 2018, the district court vacated the 2014 Overpayment Rule in its entirety, holding that the Rule effectively imposed a 100% accuracy requirement on the data MAOs must report to CMS for risk adjusted payment purposes. The district court further held that the Overpayment Rule violated the statutory mandate of "actuarial equivalence" between CMS payments for healthcare coverage under traditional Medicare and Medicare Advantage plans, the Rule's facilitation of FCA liability for MAOs' failures to engage in "reasonable diligence" exceeded CMS's statutory authority, and the definition of when an overpayment is "identified" was finalized without adequate notice as required by the Administrative Procedure Act.[206] After the district court denied the government's motion for reconsideration,[207] the government appealed the district court's opinion to the D.C. Circuit, and in November 2020, the D.C. Circuit heard oral argument.[208] The outcome of the appeal is pending.

204 No. 15-cv-1-62-LB (N.D. Cal.).
205 No. 2:16-cv-08697-MWF-SS (C.D. Cal.).
206 *UnitedHealthcare Ins. Co. v. Azar*, 330 F. Supp. 3d 173 (D.D.C. 2018).
207 2020 WL 417867 (D.D.C. Jan. 27, 2020).
208 No. 18-5326 (D.C. Cir.).

PHARMACEUTICAL AND MEDICAL DEVICE DEVELOPMENTS

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

SPEAKER PROGRAMS

As discussed previously in our **Issues to Watch**, HHS-OIG issued a Special Fraud Alert regarding the fraud and abuse risks surrounding speaker programs.[209] HHS-OIG stated that it had "significant concerns" about companies offering or paying remuneration in connection with speaker programs and specified that "[p]arties involved in speaker programs may be subject to increased scrutiny." While the Alert focused on liability for the drug and device companies holding and organizing the speaker programs, this scrutiny and liability also applies to healthcare professionals who are paid to speak at such events. All parties involved in these programs must understand that the AKS is a two-way street; both the party offering or giving the inducement and the party asking for or receiving the inducement may be held liable.

209 https://oig.hhs.gov/fraud/docs/alertsandbulletins/2020/specialfraudalertspeakerprograms.pdf.

While the HHS-OIG's Special Fraud Alert focused on liability for the drug and device companies holding and organizing the speaker programs, this scrutiny and potential liability applies equally to healthcare professionals who are paid to speak at such events.

Enforcement actions and *qui tam* lawsuits have alleged that speaking engagements violated the AKS and/or FCA. Novartis agreed to pay more than $629 million to resolve AKS and FCA claims that it paid more than $100 million in illegal kickbacks to doctors through thousands of sham speaker programs and submitted false claims paid by federal healthcare programs.[210] The government alleged Novartis paid exorbitant speaker fees to doctors who gave no meaningful presentations and provided expensive meals and alcohol to attendees and their guests. The government further alleged Novartis knew that these speaker events were not educational in nature and only served as a means to provide bribes to doctors. Moreover, Novartis purportedly selected and paid high-volume prescribers to speak at these events in order to induce them to continue writing and increase their volume of Novartis prescriptions. In connection with the settlement, Novartis entered into a five-year CIA with HHS-OIG.

In ***Purcell v. Gilead Scis., Inc.***, two former sales directors of Gilead filed an FCA lawsuit alleging that Gilead conditioned payments to physicians for participation in speaker programs and advisory boards on the number of prescriptions they wrote in violation of the AKS.[211] In denying Gilead's motion to dismiss, the district court found that the relators plausibly alleged that the speaker programs and advisory boards were "shams" if the events provided little educational value and the providers were paid even if they failed to offer benefits consistent with their FMVs.

REMUNERATION UNDER AKS

In addition to speaker programs, DOJ brought enforcement actions against medical device makers for the provision of free goods and services to potential referral sources. ResMed, a manufacturer of DME that treats sleep apnea and other chronic respiratory diseases, agreed to pay $37.5 million to settle FCA claims that ResMed paid kickbacks to suppliers, healthcare providers, and other entities.[212] DOJ alleged that ResMed: "(a) provided DME companies with free telephone call center services and other free patient outreach services that enabled these companies to order resupplies for their patients with sleep apnea, (b) provided sleep labs with free and below-cost positive airway pressure masks and diagnostic machines, as well as free installation of these machines, (c) arranged for, and fully guaranteed the

210 https://www.justice.gov/usao-sdny/pr/acting-manhattan-us-attorney-announces-678-million-settlement-fraud-lawsuit-against.
211 439 F. Supp. 3d 388 (E.D. Pa. 2020).
212 https://www.justice.gov/opa/pr/resmed-corp-pay-united-states-375-million-allegedly-causing-false-claims-related-sale.

payments due on, interest-free loans that DME supplies acquired from third-party financial institutions for the purchase of ResMed equipment, and (d) provided non-sleep specialist physicians free home sleep testing devices." As part of the overall settlement, ResMed agreed to enter into a CIA with HHS-OIG, which required, among other things, that ResMed strengthen its internal controls around product pricing and sales and conduct monitoring of its arrangements with referral sources.

Similarly, Merit Medical Systems, Inc. (MMSI) agreed to pay $18 million to settle FCA allegations that it provided millions of dollars in free advertising assistance, practice development, practice support, and unrestricted "educational" grants to induce healthcare providers to purchase and use MMSI's products.[213] In connection with the settlement, MMSI entered into a five-year CIA with HHS-OIG, which requires MMSI to obtain a compliance expert and an independent review organization to analyze its systems and transactions.

Medtronic agreed to pay $8.1 million to resolve allegations that it violated the FCA by paying kickbacks to a neurosurgeon to induce the use of Medtronic's implantable devices used to deliver medication to patients.[214] DOJ alleged that Medtronic paid for more than 100 social events hosted at a restaurant the neurosurgeon owned over a nine-year period. Medtronic also agreed to pay more than $1 million to settle allegations that it underreported payments made to the neurosurgeon in violation of CMS's Open Payments Program.

OFF-LABEL MARKETING

Pharmaceutical and medical device companies continued to face scrutiny related to marketing and off-label uses, a trend that continued from prior years.

At the end of 2019, Carolina Liquid Chemistries, Inc. (CLC) was sentenced to pay $50,000 and placed on two years of probation after pleading guilty to marketing adulterated medical devices. While on probation, CLC is required to develop and submit to the court an effective compliance and ethics program. According to the plea agreement, CLC admitted that it developed and marketed systems for testing human urine for drugs of abuse without first obtaining the necessary U.S. Food and Drug Administration (FDA) approval.[215]

Former owners of Therakos agreed to pay $11.5 million to resolve allegations that it engaged in the off-label promotion and marketing of a blood treatment system in pediatric patients despite lacking FDA approval for pediatric use. The government alleged that Therakos' improper off-label promotion caused the submission of false claims to federal healthcare programs in violation of the FCA. DOJ stated that "[w]hile physicians are free to exercise their independent medical judgment to prescribe medications for uses beyond FDA approved indications, pharmaceutical and device companies cannot interfere with doctors' judgment by allegedly pushing the sale of their drugs or devices for non-FDA approved uses, especially in vulnerable populations."[216]

In contrast, Vanda Pharmaceuticals prevailed on a motion to dismiss a *qui tam* lawsuit alleging that Vanda submitted false claims to federal programs by promoting off-label uses for two of its products. In ***U.S. ex rel. Gardner v. Vanda Pharmaceuticals, Inc.***, the relator alleged that Vanda promoted a drug approved for the treatment of schizophrenia in adults to be prescribed to treat schizophrenia in pediatric patients and bipolar disorder.[217] The relator also alleged that Vanda improperly promoted a circadian regulator approved for treatment for Non-24-Hour Sleep-Wake Disorder for the blind. In dismissing the complaint, the district court held that the relator's allegations did not give rise to a plausible inference that the off-label prescription of the products in question was material to government payment decisions under Medicare or Medicaid.

PATIENT ASSISTANCE PROGRAMS

DOJ continued to scrutinize pharmaceutical companies' relationships with and donations to charitable foundations for PAPs that provide financial assistance to low-income Medicare patients with out-of-pocket costs, including prescription drug copays.

DOJ inked several settlements with pharmaceutical companies to resolve allegations that the companies used charitable foundations as a conduit for kickbacks. Gilead agreed to pay $97 million to settle allegations that it routinely obtained data from a foundation and used the data to correlate its donations to revenue and budgeting for future payments to the foundation to cover the co-pays of Gilead patients.[218] Biogen agreed to pay $22 million to resolve allegations that it coordinated with foundations to transfer Medicare-eligible Biogen patients in its free drug program to foundations to induce these patients' Medicare-reimbursed purchases of its drugs.[219]

Other settlements related to pharmaceutical companies' arrangements with foundations to synchronize the timing of donations with submission of co-pay applications of Medicare patients to ensure that the donations only covered co-pays of the patients on their drugs. Novartis agreed to pay more than $51 million to resolve allegations that it orchestrated the timing of when Novartis made donations to the three foundations and when co-pay applications of Medicare patients were submitted to the foundations so that a disproportionate share of the donations was used to help Medicare patients taking Novartis drugs.[220] Similarly, Sanofi agreed to pay more than $11.8 million to resolve allegations related to the timing of its donations and co-pay application submissions to a foundation.[221]

DOJ filed two civil FCA lawsuits against pharmaceutical companies for their use of foundations. In ***United States v. Regeneron Pharmaceuticals, Inc.***, the complaint alleges that Regeneron paid tens of millions of dollars in kickback payments to foundations only after receiving assurances that its donations would only cover co-pays for its drug and

213 https://www.justice.gov/opa/pr/medical-device-maker-merit-medical-pay-18-million-settle-allegations-improper-payments.
214 https://www.justice.gov/opa/pr/medtronic-pay-over-92-million-settle-allegations-improper-payments-south-dakota-neurosurgeon.
215 https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/carolina-liquid-chemistries-inc-sentenced-pay-50000-developing-and-marketing-drug-tests-without-fda.
216 https://www.justice.gov/usao-edpa/pr/former-owners-therakos-inc-pay-115-million-resolve-false-claims-act-allegations.
217 2020 WL 2542121 (D.D.C. May 19, 2020). The district court permitted the relator to amend the complaint. Vanda filed another motion to dismiss. As of December 2020, the briefing on Vanda's motion is ongoing.
218 https://www.justice.gov/usao-ma/pr/gilead-agrees-pay-97-million-resolve-allegations-it-paid-kickbacks-through-co-pay.
219 https://www.justice.gov/usao-ma/pr/biogen-agrees-pay-22-million-resolve-allegations-it-paid-kickbacks-through-two-co-pay.
220 https://www.justice.gov/opa/pr/novartis-pays-over-642-million-settle-allegations-improper-payments-patients-and-physicians.
221 https://www.justice.gov/usao-ma/pr/sanofi-agrees-pay-1185-million-resolve-allegations-it-paid-kickbacks-through-co-pay.

not competitors' drugs, and that its donations would generate a considerable return on investment.[222] The complaint also alleges that Regeneron's senior executives took extensive measures to conceal the scheme. Denying Regeneron's motion to dismiss, the district court held that the complaint sufficiently alleged that Regeneron paid remuneration to patients through its fund donations "in order to induce physicians to recommend Medicare-subsidized purchases of defendant's drugs and to induce patients to purchase those drugs."[223] The matter is ongoing.

The FCA complaint filed in ***United States v. Teva Pharmaceuticals USA, Inc.***, alleges that Teva made more than $300 million in kickback payments to two foundations from 2007 to 2015 in the form of illegal co-pay subsidies to pay Medicare co-pays for Teva's drug.[224] According to the complaint, Teva used information obtained from its specialty pharmacy vendor to calculate donation amounts needed to cover co-pays of its Medicare patients at each of the foundations and coordinate the timing of its donations and the referral of its Medicare patients to the foundations to ensure that the majority of its donations funded the co-pays of its own patients. The matter is ongoing.

MISBRANDING

Pentax Medical Company agreed to enter into a three-year deferred prosecution agreement and to pay $43 million to resolve criminal charges brought against it for distributing misbranded medical devices in violation of the Federal Food, Drug, and Cosmetic Act (FDCA).[225] Pentax admitted that it used and shipped old cleaning instructions for four of its endoscopes even though the FDA directed it to send its customers revised, approved cleaning instructions for its endoscopes. DOJ said that email evidence showed that Pentax made a deliberate business decision to defy the FDA because it feared the approved instructions would cause Pentax to lose business. Additionally, Pentax admitted that it failed to timely report two incidents where patients suffered bacterial infections after being treated with a particular Pentax endoscope. As part of the Deferred Prosecution Agreement (DPA), Pentax is required to conduct a thorough audit of its current endoscopic instructions and reporting procedures, enhance its compliance training, and annually certify that Pentax took the compliance measures required by the agreement.

GOVERNMENT MAINTAINS FOCUS ON ADDRESSING OPIOID CRISIS

Opioid manufacturer Purdue Pharma agreed to pay $8.3 billion and pleaded guilty to three felony conspiracies to defraud the United States, violate the FDCA, and violate AKS.[226] Purdue admitted to marketing and selling dangerous opioid products to healthcare providers when it had reason to believe those providers were diverting the drugs to drug abusers. The resolution included a condition that Purdue will be reorganized as a public benefit company, the proceeds of which will be directed toward state and local opioid abatement programs. The resolution did not resolve claims by states against Purdue and its owners, the Sackler family.

In 2019, Insys signed a $225 million settlement for criminal and civil claims related to illegal marketing tactics and kickbacks to healthcare providers for its promotion of fentanyl painkiller spray Subsys.[227] In 2020, five former Insys executives were sentenced for their roles in the matter following their racketeering conspiracy convictions. The government charged the executives with conspiring to bribe practitioners to induce medically unnecessary Subsys prescriptions and conspiring to defraud health insurance providers for payment of Subsys for non-cancer patients.[228]

Indivior pleaded guilty to a one-count felony information alleging that the company made false statements to the Massachusetts Medicaid program regarding the safety of an opioid-addiction-treatment drug Suboxone Film around children and admitted to falsely claiming that Suboxone Film had the lowest rate of accidental consumption by children of all buprenorphine drugs in Massachusetts.[229] Indivior's former CEO also pleaded guilty to a misdemeanor information related to the misrepresentations. Indivior agreed to pay $600 million to resolve criminal and civil liability associated with its Suboxone marketing.

As part of the criminal settlement, Indivior was required to disband its Suboxone sales force, prohibited from using HCP-survey data for marketing, sales, and promotional purposes, and ordered to remove HCPs from promotional programs who are at high risk of inappropriate prescribing. Further, Indivior's CEO must annually certify Indivior's compliance with the FDCA or list all non-compliant activity, under penalty of perjury.

The civil settlement resolved allegations that Indivior companies promoted Suboxone to physicians who were prescribing the medication without a legitimate medical purpose, used false and misleading claims suggesting that Suboxone was less susceptible to abuse than other buprenorphine drugs, attempted to improperly control the pricing of Suboxone, and impeded the entry of generic competition into the market. Indivior executed a five-year CIA with HHS-OIG and agreed to pay $10 million under a separate agreement with the Federal Trade Commission that it violated 15 U.S.C. § 53(b) by engaging in unfair methods of competition.[230]

222 https://www.justice.gov/usao-ma/pr/united-states-files-suit-against-drug-manufacturer-regeneron-paying-kickbacks-through-co.
223 2020 WL 7130004 (D. Mass. Dec. 4, 2020).
224 https://www.justice.gov/opa/pr/united-states-files-false-claims-act-complaint-against-drug-maker-teva-pharmaceuticals.
225 https://www.justice.gov/usao-nj/pr/pentax-medical-company-agrees-pay-43-million-resolve-criminal-investigation-concerning.
226 https://www.justice.gov/usao-nj/pr/opioid-manufacturer-purdue-pharma-admits-guilt-fraud-and-kickback-conspiracies.
227 https://www.justice.gov/opa/pr/opioid-manufacturer-insys-therapeutics-agrees-enter-225-million-global-resolution-criminal.
228 https://www.justice.gov/usao-ma/pr/former-national-sales-director-insys-therapeutics-sentenced-racketeering-conspiracy; https://www.justice.gov/usao-ma/pr/former-ceo-insys-therapeutics-sentenced-racketeering-scheme; https://www.justice.gov/usao-ma/pr/former-insys-therapeutics-vice-president-sales-sentenced-racketeering-conspiracy.
229 https://www.justice.gov/opa/pr/indivior-solutions-pleads-guilty-felony-charge-and-indivior-entities-agree-pay-600-million.
230 https://www.ftc.gov/news-events/press-releases/2020/07/indivior-inc-pay-10-million-consumers-settling-ftc-charges.

APPENDIX
2020 NOTABLE SETTLEMENTS

HOSPITALS AND HEALTH SYSTEMS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
2/11/2020	Tenet Healthcare Corporation; Desert Regional Medical Center	Healthcare company and affiliated hospital agreed to pay $1.41 million to resolve FCA allegations that the hospital billed Medicare for medically unnecessary cardiac monitor implant procedures.[1]	**$1.41 million**
2/14/2020	Cookeville Regional Medical Center Authority	Hospital agreed to pay $4.1 million to resolve FCA allegations that it submitted claims to Medicare and TennCare that resulted from improper financial arrangements between the hospital and a cardiology practice owned by the hospital, in violation of the AKS and Stark Law. As part of the settlement, the hospital entered into a five-year CIA with HHS-OIG.[2]	**$4.1 million**
4/13/2020	Maury Regional Hospital d/b/a Maury Regional Medical Center	Hospital agreed to pay $1,702,903 to resolve self-disclosed FCA allegations that it billed Medicare for various complication and comorbidity codes which were not supported by the medical records.[3]	**$1.702 million**
4/22/2020	Centra Health Inc.; Blue Ridge Ear, Nose, Throat and Plastic Surgery, Inc.	Hospital operator and Ear, Nose, and Throat (ENT) clinic agreed to pay $9,345,845 to resolve FCA allegations self-disclosed by the hospital operator related to improper financial relationships between its hospitals and referring physicians that violated the AKS and Stark Law. As part of its self-disclosure, the hospital operator identified: (1) physician recruitment agreements with physicians who had already relocated; (2) physician compensation arrangements that took into account the value of referrals for in-office laboratory tests; (3) financial arrangements with physicians that were not memorialized in a written and executed contract; and (4) agreements with trauma call coverage physicians and an oncology practice that did not satisfy any exception to the Stark Law.[4]	**$9.345 million**
6/24/2020	Augusta University Medical Center	University medical center agreed to pay $2.625 million to resolve FCA allegations that it billed Medicare and Medicaid for medically unnecessary "Belsey Collis" procedures that also were not covered by federal healthcare programs.[5]	**$2.625 million**
6/25/2020	Piedmont Healthcare, Inc.	Hospital system agreed to pay $16 million to resolve FCA allegations that the hospital: (1) falsely billed for inpatient services that should have been billed on a less costly outpatient or observation basis; and (2) paid a commercially unreasonable and above FMV amount for a catheterization lab partially owned by a physician practice group that the hospital acquired, in violation of the AKS.[6]	**$16 million**

1 https://www.justice.gov/opa/pr/tenet-healthcare-and-affiliated-california-hospital-pay-141-million-settle-false-claims-act.
2 https://www.justice.gov/usao-mdtn/pr/cookeville-hospital-settles-false-claims-act-allegations.
3 https://www.justice.gov/usao-mdtn/pr/maury-regional-medical-center-pay-more-17-million-settle-false-claims-act-allegations.
4 https://www.justice.gov/usao-wdva/pr/centra-health-inc-and-blue-ridge-ear-nose-throat-and-plastic-surgery-inc-agree-pay.
5 https://www.justice.gov/usao-sdga/pr/augusta-university-medical-center-agrees-pay-2625-million-settle-false-claims-act.
6 https://www.justice.gov/usao-ndga/pr/atlanta-hospital-system-pay-16-million-resolve-false-claims-allegations.

HOSPITALS AND HEALTH SYSTEMS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
7/8/2020	Oklahoma Center for Orthopaedic and Multi-Specialty Surgery; USP OKC, Inc.; USP OKC Manager, Inc.; Southwest Orthopaedic Specialists, PLLC; Anthony L. Cruse, D.O.; R.J. Langerman, Jr., D.O.	Specialty hospital, its part-owner and management company, an affiliated physician group, and two physicians agreed to pay $72.3 million to resolve FCA allegations that the hospital provided: (1) physician compensation above FMV; (2) free or below-market value office space and employees; (3) equity buyback provisions and payments; and (4) preferential investment opportunities to the physicians in exchange for patient referrals, in violation of the AKS and Stark Law. As part of the settlement, the specialty hospital entered into a five-year CIA with HHS-OIG.[7]	**$72.3 million**
8/20/2020	Phoenixville Hospital; Phoenixville Hospital Co., LLC	Hospital and its operator company agreed to pay $100,000 to resolve FCA allegations that the hospital caused the submission of false claims for inpatient treatment and/or emergency room visits by allowing its revenue cycle management vendor, Firstsource Solutions, to use an altered form that caused Medicaid to pay claims for patients who should not have been eligible for Medicaid coverage. A related settlement was reached with Firstsource Solutions.[8]	**$100,000**
8/20/2020	UC Health	University hospital system agreed to pay $3.1 million to settle claims that it billed Medicare for transcatheter aortic valve replacements despite not meeting the eligibility requirements for billing Medicare for the services.[9]	**$3.1 million**
9/9/2020	Wheeling Hospital Inc.	Acute care hospital agreed to pay $50 million to resolve FCA allegations that, under the control and direction of its prior management company, it entered into improper compensation arrangements with certain physicians, in violation of the AKS and Stark Law, and submitted claims for services referred to the hospital by those physicians from 2007 to 2020.[10]	**$50 million**
11/2/2020	Memorial Health Services	A nonprofit healthcare organization agreed to pay $31,532,679 to resolve self-disclosed FCA allegations that from 2016 to 2019 it billed Medicaid for prescription drugs at its higher usual and customary (U&C) costs rather than its actual acquisition costs, as required under the 340B Drug Pricing Program.[11]	**$31.532 million**
12/18/2020	Texas Heart Hospital of the Southwest LLP; THHBP Management Company, LLC	Hospital and wholly owned management company agreed to pay $48 million to resolve FCA allegations that the hospital submitted claims for services referred by physicians with whom it had improper compensation arrangements, in violation of the AKS and Stark Law. The hospital allegedly required physician owners to satisfy a yearly 48 patient-contact requirement in order to maintain ownership in the hospital.[12]	**$48 million**

7 https://www.justice.gov/opa/pr/oklahoma-city-hospital-management-company-and-physician-group-pay-723-million-settle-federal.
8 https://www.justice.gov/usao-edpa/pr/phoenixville-hospital-and-firstsource-solutions-agree-pay-325000-resolve-false-claims.
9 https://www.beckershospitalreview.com/legal-regulatory-issues/uc-health-settles-medicare-fraud-allegations.html.
10 https://www.justice.gov/opa/pr/west-virginia-hospital-agrees-pay-50-million-settle-allegations-concerning-improper.
11 https://www.justice.gov/usao-cdca/pr/oc-based-health-care-organization-agrees-pay-over-315-million-settle-claims-it.
12 https://www.justice.gov/opa/pr/texas-heart-hospital-and-wholly-owned-subsidiary-thhbp-management-company-llc-pay-48-million.

HOSPICE AND HOME HEALTH

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
2/27/2020	AseraCare	Hospice provider agreed to pay $1 million to resolve FCA allegations that it submitted claims to Medicare for patients improperly certified as terminally ill and thus, ineligible for the Medicare hospice benefit.[13]	**$1 million**
3/4/2020	STG Healthcare of Atlanta, Inc. (operating as Interim Healthcare of Atlanta); Paschal "Pat" Gilley; Mathew Gilley	Hospice provider and two of its senior executives agreed to pay $1.75 million to resolve FCA allegations that they submitted claims to Medicare and Medicaid for patients ineligible for the hospice benefit and that resulted from referrals from a physician that STG paid to be a "back up" medical director, but who did not serve as a legitimate hospice physician, in violation of the AKS.[14]	**$1.75 million**
7/8/2020	Hope Hospice	Hospice provider agreed to pay $3.2 million to resolve FCA allegations that it submitted claims to Medicare for patients improperly certified or re-certified as terminally ill. The settlement also resolves allegations that the hospice provider submitted claims to Medicare, Medicaid, and TRICARE for general inpatient hospice care in cases where that level of care was not medically necessary. As part of the settlement, the hospice provider entered into a five-year CIA with HHS-OIG.[15]	**$3.2 million**
8/19/2020	Metropolitan Jewish Health System Hospice and Palliative Care	Nonprofit hospice provider agreed to pay $5.225 million to resolve state and federal FCA allegations that it billed Medicare and Medicaid for services at the continuous home care and general inpatient levels of hospice care for patients that did not qualify for these heightened levels of care.[16]	**$5.225 million**
11/24/2020	Doctor's Choice Home Care, Inc.; Timothy Beach; Stuart Christensen	Home health agency and its two former owners agreed to pay $5.15 million to resolve FCA allegations that the agency paid kickbacks disguised as sham medical director agreements and bonuses to family members of referring physicians, in violation of the AKS and Stark Law, respectively. The two founders will each pay $647,000 of the settlement.[17]	**$5.15 million**

13 https://www.businesswire.com/news/home/20200227005767/en/aseracare-successfully-resolves-historic-false-claims-act.
14 https://www.justice.gov/usao-ndga/pr/hospice-pay-175-million-resolve-false-claims-act-allegations.
15 https://www.justice.gov/usao-mdfl/pr/hope-hospice-agrees-pay-32-million-settle-false-claims-act-liability.
16 https://www.justice.gov/usao-edny/pr/new-york-hospice-provider-settles-civil-healthcare-fraud-allegations.
17 https://www.justice.gov/usao-mdfl/pr/home-health-agency-and-former-owners-pay-58-million-settle-false-claims-act-allegations.

SKILLED NURSING FACILITIES AND NURSING HOMES

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
2/19/2020	Guardian Elder Care Holdings Inc.; Guardian LTC Management Inc.; Guardian Elder Care Management Inc.; Guardian Elder Care Management I Inc.; Guardian Rehabilitation Services Inc.	Multi-state operator of more than 50 nursing home facilities agreed to pay $15,466,278 to resolve FCA allegations that several of its facilities overbilled Medicare and the FEHBP for medically unnecessary rehabilitation therapy services. The settlement also resolves self-disclosed allegations that Guardian employed two individuals that were excluded from federal healthcare programs, resulting in Guardian's receipt of payment for ineligible services. As part of the settlement, Guardian entered into a chain-wide, five-year CIA with HHS-OIG.[18]	**$15.466 million**
2/28/2020	Diversicare Health Services, Inc.	Nationwide operator of skilled nursing and rehabilitation facilities agreed to pay $9.5 million to resolve FCA allegations that it billed Medicare for rehabilitation services that were unreasonable, medically unnecessary, and/or unskilled. The settlement also resolves allegations that the company submitted forged pre-admission evaluation certifications of patient need for skilled nursing services to TennCare. As part of the settlement, Diversicare entered into a five-year CIA with HHS-OIG.[19]	**$9.5 million**
4/10/2020	Encore Rehabilitation Services LLC	Nationwide provider of rehabilitation services agreed to pay $4.03 million to resolve FCA allegations that three of its SNFs submitted claims to Medicare for unreasonable, medically unnecessary, and/or unskilled rehabilitation therapy services. The settlement also resolves allegations that the company falsely recorded concurrent or group therapy sessions as individual therapy sessions. Encore entered into a five-year CIA with HHS-OIG as part of the settlement.[20]	**$4.03 million**
4/14/2020	Saber Healthcare Group LLC; Various Related Entities	Multi-state SNF operator agreed to pay $10 million to resolve FCA allegations that seven of its facilities submitted claims to Medicare for rehabilitation services that were unreasonable, medically unnecessary, and/or unskilled. As part of the settlement, Saber entered into a five-year CIA with HHS-OIG.[21]	**$10 million**
7/13/2020	Longwood Management Corporation; Affiliated SNFs	SNF operator and 27 affiliated California SNFs agreed to pay $16.7 million to resolve FCA allegations that they submitted claims to Medicare for medically unnecessary or unreasonable rehabilitation therapy services billed at the highest Resource Utilization Group (RUG) score to maximize reimbursement. As part of the settlement, Longwood entered into a five-year CIA with HHS-OIG.[22]	**$16.7 million**

18 https://www.justice.gov/opa/pr/guardian-elder-care-holdings-and-related-entities-agree-pay-154-million-resolve-false-claims.
19 https://www.justice.gov/usao-mdtn/pr/diversicare-health-services-inc-agrees-pay-95-million-resolve-false-claims-act.
20 https://www.justice.gov/usao-edmi/pr/contract-rehab-provider-pay-4-million-resolve-false-claims-act-allegations-relating.
21 https://www.justice.gov/opa/pr/nursing-home-chain-saber-healthcare-agrees-pay-10-million-settle-false-claims-act-allegations.
22 https://www.justice.gov/opa/pr/twenty-seven-skilled-nursing-facilities-controlled-longwood-management-corporation-pay-167.

PHARMACEUTICAL AND DEVICE

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
1/15/2020	ResMed Corp.	DME manufacturer agreed to pay more than $37.5 million to resolve FCA allegations that it violated the AKS by: (1) providing DME companies with free call center and patient outreach services; (2) providing sleep labs with free and below-cost supplies and free installation; (3) arranging and guaranteeing payments on interest-free loans to DME suppliers for the purchase of ResMed equipment; and (4) providing non-sleep specialist physicians with free home sleep testing devices. As part of the settlement, ResMed entered into a five-year CIA with HHS-OIG.[23]	**$37.5 million**
2/28/2020	Sanofi-Aventis U.S., LLC	Pharmaceutical manufacturer agreed to pay $11.85 million to resolve FCA allegations that it paid kickbacks to Medicare beneficiaries who were prescribed its multiple sclerosis drug in the form of co-pays covered by a purportedly independent charitable foundation. As part of the settlement, Sanofi entered into a CIA with HHS-OIG that extends a separate CIA it entered in 2015 by five years.[24]	**$11.85 million**
3/12/2020	Kohlerman Pharmacy; Charles F. Kohlerman, IV	Pharmacy and pharmacist owner agreed to pay $300,000 to resolve FCA allegations that they submitted claims to Medicare, Medicaid, and FEHBP for the brand name drug Lipitor® when they had actually provided its generic equivalent. Kohlerman pleaded guilty to a related criminal charge and 14 counts of illicitly filling inappropriate narcotics prescriptions, for which he was sentenced to three years in prison with two years' supervised release and was ordered to pay more than $1.7 million in criminal fines and forfeiture.[25]	**$300,000 (civil)** **$1.7 million (criminal)**
4/6/2020	MiMedx Group Inc.	Biopharmaceutical company that manufactures and sells human tissue grafts agreed to pay $6.5 million to resolve FCA allegations that it submitted false commercial pricing disclosures to the U.S. Department of Veterans Affairs (VA), thus enabling MiMedx to charge the VA inflated prices for its human tissue graft products.[26]	**$6.5 million**
7/1/2020	Novartis Pharmaceuticals Corporation	Pharmaceutical manufacturer agreed to pay $51.25 million to resolve FCA allegations that it paid kickbacks to Medicare beneficiaries who were prescribed Novartis' drugs in the form of co-pays covered by three purportedly independent charitable foundations.[27]	**$51.25 million**
7/1/2020	Novartis Pharmaceuticals Corporation	Pharmaceutical manufacturer agreed to pay $591,442,008.92 and forfeit $38,406,717.42 to the United States, and to pay $48,151,273.66 to certain states, to resolve FCA allegations that it paid kickbacks to physicians in the form of speaker fees to induce them to prescribe Novartis' drugs. Novartis entered into a five-year CIA with HHS-OIG as part of this resolution.[28]	**$678 million**

23 https://www.justice.gov/opa/pr/resmed-corp-pay-united-states-375-million-allegedly-causing-false-claims-related-sale.
24 https://www.justice.gov/usao-ma/pr/sanofi-agrees-pay-1185-million-resolve-allegations-it-paid-kickbacks-through-co-pay.
25 https://www.justice.gov/usao-edpa/pr/pharmacist-sentenced-three-years-prison-conspiring-steal-more-45-million-prescription.
26 https://www.justice.gov/opa/pr/mimedx-group-inc-agrees-pay-65-million-resolve-false-claims-act-allegations-false-commercial.
27 https://www.justice.gov/usao-ma/pr/novartis-agrees-pay-over-51-million-resolve-allegations-it-paid-kickbacks-through-co-pay.
28 https://www.justice.gov/usao-sdny/pr/acting-manhattan-us-attorney-announces-678-million-settlement-fraud-lawsuit-against.

PHARMACEUTICAL AND DEVICE

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
7/28/2020	Pacira Pharmaceuticals Inc.	Pharmaceutical manufacturer agreed to pay $3.5 million to resolve FCA allegations that it engaged in an unlawful kickback scheme wherein it paid bogus research grants to physicians to induce prescriptions for Pacira's drug, in violation of the AKS.[29]	**$3.5 million**
8/24/2020	DUSA Pharmaceuticals Inc.	Pharmaceutical manufacturer agreed to pay $20.75 million to resolve FCA allegations that it caused physicians to submit false claims to Medicare and FEHBP by promoting an administration process for its drug Levulan Kerastick that contradicted FDA product instructions and was unsupported by sufficient clinical evidence. DUSA allegedly encouraged physicians to use demonstrably less effective short incubation periods through use of paid physician speaker programs and paid physician peer-to-peer discussions, among other means. As part of the settlement, DUSA and its parent company, Sun Pharmaceutical Industries Inc., entered into a five-year CIA with HHS-OIG.[30]	**$20.75 million**
9/23/2020	Gilead Sciences, Inc.	Pharmaceutical company agreed to pay $97 million to resolve FCA allegations that it illegally used a charitable foundation as a conduit to pay kickbacks to Medicare beneficiaries who were prescribed its pulmonary arterial hypertension drug, Letairis, in violation of the AKS.[31]	**$97 million**
10/14/2020	Merit Medical Systems, Inc.	Medical device manufacturer agreed to pay $18 million to resolve state and federal FCA allegations that it submitted claims to Medicare, Medicaid, and TRICARE that were tainted by illegal kickbacks in the form of practice development and support, advertising assistance, and unrestricted educational grants provided to healthcare providers to induce them to use the company's devices. As part of the settlement, Merit entered into a five-year CIA with HHS-OIG.[32]	**$18 million**

29 https://www.justice.gov/usao-nj/pr/pharmaceutical-company-agrees-pay-35-million-resolve-allegations-violating-false-claims.
30 https://www.justice.gov/usao-wdwa/pr/dusa-pharmaceuticals-pay-us-2075-million-settle-false-claims-act-allegations-relating.
31 https://www.justice.gov/opa/pr/gilead-agrees-pay-97-million-resolve-alleged-false-claims-act-liability-paying-kickbacks.
32 https://www.justice.gov/usao-nj/pr/medical-device-maker-pay-18-million-settle-allegations-improper-payments-physicians.

PHARMACEUTICAL AND DEVICE

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
10/21/2020	Purdue Pharma LP; Individual Members of the Sackler Family	Pharmaceutical manufacturer agreed to pay more than $8.3 billion to resolve criminal and civil investigations into its role in the national opioid crisis. The civil settlement resolves allegations that, among other conduct, the company violated the FCA by paying kickbacks to physicians in the form of speaker fees to induce them to prescribe more of Purdue's opioid products. The company also pleaded guilty to one count of conspiracy to defraud the United States and to violate the FDCA and two counts of conspiracy to violate the AKS. The $5.544 billion in criminal fines and forfeiture comprise the largest penalties ever levied against a pharmaceutical manufacturer. The company also agreed to emerge from its pending bankruptcy proceeding as a public benefit company focused on opioid abatement and overdose prevention. Purdue also agreed to a civil settlement of $2.8 billion. Separately, individual members of the Sackler family agreed to a civil settlement of $225 million to resolve allegations related to family members' conduct, including directing a marketing program that aimed to increase market share by targeting suspicious prescribers and transferring assets into Sackler family holding companies and trusts that were made to hinder future creditors.[33]	**$2.8 billion (civil)** **$5.544 billion (criminal)**
10/29/2020	Medtronic USA Inc.	Medical device manufacturer agreed to pay more than $8.1 million to resolve FCA allegations that it paid for social events at a restaurant owned by a neurosurgeon in exchange for the surgeon's use of its intrathecal infusion pumps, in violation of the AKS. Medtronic also agreed to pay $1.11 million to resolve allegations that it violated the Open Payments Program by failing to accurately report its payments to the neurosurgeon.[34]	**$9.21 million**
11/12/2020	Indivior Solutions	Pharmaceutical manufacturer agreed to pay $300 million to resolve civil FCA liability and was sentenced to pay $289 million to resolve criminal liability related to its unlawful marketing of Suboxone, including knowingly marketing to physicians who were prescribing Suboxone where there was no legitimate medical purpose. As part of its guilty plea, Indivior admitted to making false statements to MassHealth regarding the safety of Suboxone Film. Indivior's former CEO and medical director have also entered guilty pleas in connection to these allegations. As part of the resolution, Indivior entered into a five-year CIA with HHS-OIG.[35]	**$300 million (civil)** **$289 million (criminal)**
11/19/2020	Medical Device Business Services, Inc.; The Gores Group	Former owners of medical device company Therakos, Inc., agreed to pay $11.5 million to resolve allegations that Therakos marketed and promoted its extracorporeal photopheresis systems to treat pediatric patients for uses not approved by the FDA causing false claims to be submitted to Medicaid, TRICARE, and FEHBP.[36]	**$11.5 million**

33 https://www.justice.gov/usao-me/pr/justice-department-announces-global-resolution-criminal-and-civil-investigations-opioid.
34 https://www.justice.gov/opa/pr/medtronic-pay-over-92-million-settle-allegations-improper-payments-south-dakota-neurosurgeon.
35 https://www.justice.gov/opa/pr/indivior-solutions-pleads-guilty-felony-charge-and-indivior-entities-agree-pay-600-million; https://www.justice.gov/opa/pr/indivior-solutions-sentenced-pay-289-million-criminal-penalties-unlawful-marketing-opioid.
36 https://www.justice.gov/usao-edpa/pr/former-owners-therakos-inc-pay-115-million-resolve-false-claims-act-allegations.

PHARMACEUTICAL AND DEVICE

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
12/16/2020	Seashore Drugs, Inc.; John D. Waggett; Billy W. King II	Pharmacy, its owner, and its pharmacist-in-charge entered a consent judgment to pay $1.05 million to resolve FCA allegations related to ignoring "red flags" and filling medically unnecessary opioid prescriptions. As part of the resolution, Waggett is permanently prohibited from dispensing opioids or other controlled substances; King is prohibited from dispensing Schedule II controlled substances, including most opioids, for 180 days and will submit to Drug Enforcement Administration (DEA) monitoring for three years thereafter; and Waggett and King are permanently prohibited from owning or operating any entity that administers, dispenses, or distributes controlled substances.[37]	**$1.05 million**
12/17/2020	Biogen, Inc.; Advanced Care Scripts	Pharmaceutical company agreed to pay $22 million to resolve FCA allegations that it illegally used foundations as a conduit to pay the co-pays of Medicare patients taking Biogen's multiple sclerosis drugs, in violation of the AKS. Specialty pharmacy Advanced Care Scripts agreed to pay $1.4 million for its role in the allegations.[38]	**$23.4 million**
12/21/2020	Apria Healthcare Group, Inc.; Apria Healthcare LLC	Durable medical equipment provider agreed to pay $40.5 million to resolve FCA allegations that it submitted claims to federal healthcare programs that: (1) sought reimbursement for the rental of non-invasive ventilators to beneficiaries who were not using the ventilators, such that the devices were not medically necessary; or (2) involved the improper waiver of patient co-insurance patients, among other improper practices. As part of the settlement, the company also entered into a five-year CIA with HHS-OIG.[39]	**$40.5 million**

37 https://www.justice.gov/opa/pr/federal-court-orders-north-carolina-pharmacy-pharmacy-owner-and-pharmacist-charge-pay-more-1.
38 https://www.justice.gov/usao-ma/pr/biogen-agrees-pay-22-million-resolve-allegations-it-paid-kickbacks-through-two-co-pay.
39 https://www.justice.gov/usao-sdny/pr/acting-manhattan-us-attorney-announces-405-million-settlement-durable-medical-equipment.

LABORATORY, PATHOLOGY, RADIOLOGY, AND DIAGNOSTICS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
4/15/2020	Logan Laboratories, Inc.; Tampa Pain Relief Centers, Inc.; Michael T. Doyle; Christopher Utz Toepke	Laboratory, pain clinic, and two executives agreed to pay $41 million to resolve FCA allegations that they billed Medicare, Medicaid, and TRICARE for presumptive and definitive urine drug testing that was not medically necessary. As part of the settlement, the laboratory entered into a three-year integrity agreement (IA) with HHS-OIG.[40]	**$41 million**
4/27/2020	Genova Diagnostics Inc.	Clinical testing laboratory agreed to pay up to $43 million to resolve allegations that it: (1) submitted inappropriate claims to Medicare, TRICARE, and FEHBP for medically unnecessary tests; (2) employed improper billing techniques; and (3) compensated three phlebotomy vendors in violation of the Stark Law. As part of the settlement, the company entered into a five-year CIA with HHS-OIG.[41]	**$43 million**
5/7/2020	Seattle Pain Center; Northwest Analytics; Dr. Frank Danger Li	Pain clinic chain, affiliated laboratory, and physician owner agreed to pay $2.85 million to resolve FCA allegations that the pain clinics conducted medically unnecessary urine drug testing pursuant to a company policy requiring full panel testing for patients on each provider visit.[42]	**$2.85 million**
7/1/2020	Agendia, Inc.	Molecular diagnostics testing company agreed to pay $8.25 million to resolve FCA allegations that it conspired with hospitals to delay ordering its breast cancer genetic assay test to avoid application of Medicare's 14-Day Rule, which prevents a lab company from separately billing Medicare for tests ordered within 14 days of a patient's inpatient or outpatient discharge.[43]	**$8.25 million**
7/20/2020	Sterling Healthcare Opco, LLC d/b/a Cordant Health Solutions	Drug testing lab company agreed to pay $11,942,913 to resolve FCA allegations that it paid kickbacks to Northwestern Physicians Laboratories, LLC and Genesis Marketing Group in exchange for the referral of urine drug tests to its labs, in violation of the AKS. As part of the resolution, the company entered into a five-year CIA with HHS-OIG.[44]	**$11.942 million**
7/23/2020	Progenity, Inc. f/k/a Ascendant MDx	Biotechnology and laboratory company agreed to pay $49 million to resolve state and federal FCA allegations that it: (1) fraudulently billed Medicaid, TRICARE, the VA, and FEHBP for improperly coded claims for non-covered, non-invasive prenatal testing; and (2) provided illegal incentives to physicians and patients to use its laboratory services, in violation of the AKS. Progenity also entered into a five-year CIA with HHS-OIG as part of the resolution.[45]	**$49 million**

40 https://www.justice.gov/usao-edpa/pr/florida-based-laboratory-pain-clinic-and-two-former-executives-agree-pay-41-million.
41 https://www.justice.gov/usao-wdnc/pr/testing-laboratory-agrees-pay-43-million-resolve-allegations-medically-unnecessary.
42 https://www.justice.gov/usao-wdwa/pr/doj-settles-false-claims-act-allegations-seattle-physician-his-pain-clinics-and-his.
43 https://www.justice.gov/usao-wdky/pr/california-genetic-testing-company-agrees-pay-825-million-resolve-false-claims.
44 https://www.justice.gov/usao-wdwa/pr/doj-settles-false-claims-act-allegations-against-drug-testing-lab-operations-tacoma-and.
45 https://www.justice.gov/usao-sdca/pr/san-diego-laboratory-admits-fraudulent-tricare-billing-agrees-pay-49-million.

LABORATORY, PATHOLOGY, RADIOLOGY, AND DIAGNOSTICS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
8/12/2020	Physician's Mobile X-Ray	Mobile imaging company agreed to pay $49,759 to resolve FCA allegations that it improperly billed Medicare for the transportation component of x-ray services by failing to apportion such charges when services were provided to more than one patient at the same location during the same visit.[46]	**$49,759**
9/9/2020	William M. Kelly, M.D., Inc.; Omega Imaging Inc.	Two companies that jointly operate radiology facilities agreed to pay $5 million to resolve FCA allegations that they billed Medicare and TRICARE for CT scans and MRIs that lacked appropriate physician supervision and were performed in non-accredited radiology facilities. As part of the settlement, the companies entered into a three-year IA with HHS-OIG.[47]	**$5 million**
9/22/2020	Bio-Reference Laboratories, Inc.	Biotechnology company that provides molecular and diagnostic testing agreed to pay $11,500,960 to resolve FCA allegations that it billed Medicare and TRICARE for: (1) testing conducted on hospital inpatients that should have been paid by the hospitals themselves; and (2) claims tainted by kickbacks paid to physicians in the form of a percentage of the cost of the physicians' electronic medical records software, in violation of the AKS.[48]	**$11.5 million**
9/25/2020	Advanced Imaging of Port Charlotte, LLC	Radiology center agreed to pay $501,000 to resolve FCA allegations that it improperly billed Medicare and TRICARE for dye-contrast scans that were administered without the required direct physician supervision and for services performed by physicians who were not properly credentialed by Medicare.[49]	**$501,000**
10/2/2020	Phamatech, Inc.; Tuan Pham	Medical technology company and its CEO and founder agreed to pay $3,043,484 to resolve FCA allegations that they billed Medicare for lab tests that were medically unnecessary and tainted by kickbacks in the form of per-specimen fees that the company paid to a referring medical practice group.[50]	**$3.043 million**
10/23/2020	Great Lakes Medical Laboratory, Inc.	Medical reference laboratory agreed to pay $1,200,737.64 to resolve FCA allegations that it improperly billed Medicare and various United Mine Workers funds for services that were: (1) included in bills submitted for other laboratory services; (2) not actually ordered by the referring physician; and (3) never performed. As part of the settlement, Great Lakes Medical entered into a three-year IA with HHS-OIG.[51]	**$1.2 million**

46 https://www.justice.gov/usao-mdpa/pr/mobile-x-ray-company-pay-49759-settle-false-claims-liability.
47 https://www.justice.gov/opa/pr/william-m-kelly-md-inc-and-omega-imaging-inc-agree-pay-5-million-resolve-alleged-false-claims.
48 https://www.justice.gov/usao-sdny/pr/acting-manhattan-us-attorney-announces-115-million-settlement-biotech-testing-company.
49 https://www.justice.gov/usao-mdfl/pr/radiology-center-pays-501000-resolve-healthcare-fraud-allegations-allegations.
50 https://www.justice.gov/usao-sdca/pr/san-diego-laboratory-phamatech-agrees-pay-3-million-settle-fraudulent-medicare-billing.
51 https://www.justice.gov/usao-sdwv/pr/united-states-attorney-mike-stuart-announces-healthcare-fraud-settlement-over-12.

BEHAVIORAL HEALTH AND SUBSTANCE ABUSE TREATMENT

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
1/6/2020	Tree of Life, Inc.; Ada Vidal; Victor Vidal	Behavioral health clinic and its owners agreed to pay $1.65 million to resolve FCA allegations that they billed Medicaid for outpatient mental health services that were: (1) falsely inflated; (2) provided by unqualified individuals; or (3) never provided. As part of the resolution, the owners are permanently excluded from participating in federal healthcare programs.[52]	**$1.65 million**
1/7/2020	Behavioral Consulting of Tampa Bay	Autism service provider agreed to pay $675,000 to resolve FCA allegations that it submitted claims to TRICARE that: (1) misrepresented the services provided; (2) misrepresented the rendering provider; (3) were not supported by the medical record; and/or (4) were not provided.[53]	**$675,000**
1/24/2020	Children's Behavioral Therapy LLC; Channa Sontag, LPC	Behavioral health practice and its licensed professional counselor owner agreed to pay $39,471 to resolve FCA allegations that they repeatedly billed Medicaid for 60-minute individual psychotherapy sessions when the services were provided for less time. Sontag agreed to a five-year suspension from participating in Connecticut Medicaid as part of the settlement.[54]	**$39,471**
2/4/2020	The Center of Attention, LLC: No One Left Behind; Selina Christian	Behavioral health clinic and its owner agreed to pay $200,000 to resolve FCA allegations that they submitted claims to Connecticut Medicaid for psychotherapy services that were never provided and for non-psychotherapy services that were not eligible for reimbursement. As part of the resolution, the center and its owner are suspended from participating in the Connecticut Medical Assistance Program for five years.[55]	**$200,000**
3/27/2020	Progressions Behavioral Health Services, Inc.; Sharmon James	Behavioral health clinic and a formerly-employed therapist agreed to pay $27,500 to resolve FCA allegations that they submitted claims to Medicaid for outpatient sessions that never occurred and for which the therapist forged documentation.[56]	**$27,500**
5/5/2020	Connecticut Counseling Centers	Outpatient substance abuse and mental health treatment provider agreed to pay $295,000 to resolve FCA allegations that it billed Medicaid for bundled services that included on-site drug testing, when the drug tests were performed by an outside laboratory that separately billed for the testing.[57]	**$295,000**
7/10/2020	Turning Point Care Center, LLC	A behavioral health facility agreed to pay $5 million to resolve FCA allegations that it provided free or discounted transportation services to Medicare and Medicaid beneficiaries to induce them to seek treatment with the facility, in violation of the AKS.[58]	**$5 million**

52 https://www.justice.gov/usao-edpa/pr/united-states-obtains-165-million-resolution-fraudulent-medicaid-billing-against.
53 https://www.justice.gov/usao-mdfl/pr/tampa-bay-autism-service-provider-agrees-pay-675000-resolve-civil-healthcare-fraud.
54 https://www.justice.gov/usao-ct/pr/waterbury-licensed-professional-counselor-pays-39k-settle-false-claims-allegations.
55 https://portal.ct.gov/ag/press-releases/2020-press-releases/tong--gifford-announce-200000-settlement-with-east-hartford-behavioral-health-providers.
56 https://www.justice.gov/usao-edpa/pr/progressions-behavioral-health-services-inc-and-one-its-former-mental-health-therapists.
57 https://www.justice.gov/usao-ct/pr/connecticut-substance-abuse-treatment-provider-pays-295k-settle-improper-billing.
58 https://www.justice.gov/opa/pr/universal-health-services-inc-and-related-entities-pay-122-million-settle-false-claims-act.

BEHAVIORAL HEALTH AND SUBSTANCE ABUSE TREATMENT

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
7/10/2020	Universal Health Services, Inc.; UHS of Delaware, Inc.;	Psychiatric hospital and behavioral health facility operator agreed to pay $117 million to resolve FCA allegations that its hospitals and facilities: (1) admitted federal healthcare beneficiaries who were not eligible for inpatient or residential treatment; (2) failed to discharge appropriately admitted patients when inpatient care was no longer necessary; (3) billed for services not rendered; (4) billed for excessive and improper lengths of stay; (5) failed to provide adequate staffing or training and supervision of staff; and (6) improperly used physical and chemical restraints and seclusion. As part of the settlement, the companies entered into a five-year CIA with HHS-OIG.[59]	**$117 million**
7/23/2020	Recovery Network of Programs, Inc.	Substance abuse and mental health services provider agreed to pay $354,367 to resolve FCA allegations that it billed Medicaid for bundled services that included on-site drug testing, when the drug tests were performed by an outside laboratory that separately billed for the testing.[60]	**$354,367**
9/10/2020	Victoria Transcultural Clinical Center, VTCC, LLC	Behavioral therapy and mental health services provider agreed to pay $263,280 to resolve FCA allegations that it improperly billed Medicaid by inflating bills for services rendered, billing for services not rendered, and failing to take steps to repay overpayments within 60 days after identifying these claims.[61]	**$263,280**
9/25/2020	East Tennessee Recovery; Dr. Chambless Johnston	Addiction recovery specialist and his clinic agreed to pay $530,000 to resolve FCA allegations that they improperly billed Medicare and Medicaid for: (1) services provided by unlicensed or unsupervised providers; (2) upcoded E&M office visits; and (3) case management services that were either not included in the practice's contract or that were improperly rendered in a group setting.[62]	**$530,000**

59 https://www.justice.gov/opa/pr/universal-health-services-inc-and-related-entities-pay-122-million-settle-false-claims-act.
60 https://www.justice.gov/usao-ct/pr/connecticut-substance-abuse-treatment-provider-pays-over-354k-settle-improper-billing.
61 https://www.justice.gov/usao-edva/pr/virginia-mental-health-agency-agrees-pay-263280-settle-civil-false-claims-act-lawsuit.
62 https://www.justice.gov/usao-edtn/pr/addiction-recovery-physician-pays-530000-resolve-false-claims-act-allegations-billing.

BEHAVIORAL HEALTH AND SUBSTANCE ABUSE TREATMENT

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
10/1/2020	Hector B. Chukwuemeka Okwuosa; My Father My Son Rehabilitation and Counseling Center LLC	A drug and alcohol counselor and his now-dissolved practice agreed to pay $230,000 to resolve FCA allegations that they billed Medicare for services that were provided by an individual that was not a licensed behavioral health counselor.[63]	**$230,000**
10/22/2020	Preferred Family Healthcare, Inc. (PFH)	Behavioral health nonprofit organization agreed to pay $6.5 million to resolve state and federal FCA allegations that it: (1) improperly billed Medicaid instead of Medicare for services provided to a certain class of Medicare beneficiaries; and (2) billed Medicaid for counseling services that were never rendered or were overbilled. As part of the settlement, PFH entered into a five-year CIA with HHS-OIG.[64]	**$6.5 million**

63 https://www.justice.gov/usao-ct/pr/connecticut-licensed-alcohol-and-drug-counselor-pays-230k-settle-false-claims-allegations.
64 https://arkansasag.gov/media-center/news-releases/rutledge-announces-settlements-with-preferred-family-health-totaling-6.5-million.

SPECIALTY CARE AND OTHER PROVIDER ENTITIES

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
1/15/2020	L.M.G., Inc. d/b/a TMJ & Orofacial Pain Treatment Centers of Wisconsin	Clinic operator specializing in temporomandibular joint disorder treatment agreed to pay $1 million to resolve FCA allegations that it billed Medicare and TRICARE for oral appliances as if the appliances were fabricated by the clinic's dentists when in fact they were fabricated and purchased from an outside laboratory and used billing codes applicable to expensive prosthetic devices fabricated by surgeons instead of those applicable to appliances fabricated by an outside laboratory.[65]	**$1 million**
1/23/2020	Arch Health Partners, Inc.	Physician contracting company for regional health system agreed to pay $2,910,370 to resolve self-disclosed FCA allegations that the hospital improperly billed Medicare by falsely inflating the level of E&M services performed and for services referred by physicians with whom the company had improper compensation arrangements, in violation of the AKS and Stark Law.[66]	**$2.91 million**
1/24/2020	Comprehensive Pain Management Institute; Leon Margolin, M.D.	Pain clinic and its owner agreed to pay $650,000 to resolve FCA allegations that they billed Medicare for nerve conduction studies and substance abuse assessments that were not medically necessary or were not performed as billed.[67]	**$650,000**
2/4/2020	Southeastern Retina Associates	Ophthalmology practice agreed to pay $1.5 million to resolve FCA allegations that it billed Medicare and Medicaid for exams that were not separately billable from other procedures performed on the same day and other exams at higher levels than appropriate. As part of the settlement, the practice entered into a five-year CIA with HHS-OIG. [68]	**$1.5 million**
2/27/2020	Trina Health-Wichita NW, LLC; Jack West	Healthcare clinic and company principal agreed to pay $775,000 to resolve FCA allegations that they improperly billed Medicare and TRICARE for non-covered insulin infusion treatments that they billed as covered "artificial pancreas treatments" for diabetes.[69]	**$775,000**
3/11/2020	Millennium Physicians Association PLLC	A physician group agreed to pay $1,248,964 to resolve: (1) FCA allegations that they improperly billed Medicare for sleep studies that were conducted without properly certified technicians present; and (2) self-reported FCA allegations that they improperly billed for tests performed at unaccredited facilities.[70]	**$1.248 million**

65 https://www.justice.gov/usao-edwi/pr/tmj-orofacial-pain-treatment-centers-wisconsin-agree-pay-1-million-resolve-false-claims.
66 https://www.justice.gov/usao-sdca/pr/san-diego-s-arch-health-pays-29-million-resolve-false-claims-act-allegations.
67 https://www.justice.gov/opa/pr/columbus-pain-clinic-and-owner-agree-pay-650000-resolve-allegations-unnecessary-procedures.
68 https://www.justice.gov/usao-edtn/pr/u-s-settles-false-claims-act-allegations-against-southeastern-retina-associates.
69 https://www.justice.gov/usao-ks/pr/kansas-clinic-agrees-pay-775000-resolve-false-claims-act-allegations.
70 https://www.justice.gov/usao-sdtx/pr/physicians-group-pays-over-1m-resolve-false-billing-claims.

SPECIALTY CARE AND OTHER PROVIDER ENTITIES

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
3/13/2020	Village Dermatology and Cosmetic Surgery, L.L.C.; Dr. Thi Thien Nguyen Tran	Dermatology clinic and its owner agreed to pay $1.744 million to resolve FCA allegations that they improperly billed Medicare for adjacent tissue transfers, when in fact, the procedures performed were less costly complex wound repairs. As part of the settlement, the physician and clinic entered into a three-year IA with HHS-OIG.[71]	**$1.744 million**
3/16/2020	Mulberry Medical Associates, P.C.	Internal medicine practice agreed to pay $425,000 to resolve FCA allegations that it improperly billed Medicaid, Medicare, and FEHBP for non-FDA-approved pharmaceutical products used to treat osteoarthritis and osteoporosis.[72]	**$425,000**
3/31/2020	Your Eyes of New Britain, Inc.; Carol Sanderson	Optician group and its owner agreed to pay $263,488.50 to resolve FCA allegations that they improperly billed Medicaid when dispensing new glasses by billing for both an initial fitting and a repair, when the repair services provided were actually final adjustments that were included in the claims for the initial fittings.[73]	**$263,488**
4/17/2020	Washington Cardiovascular Institute; Advanced Vascular Resources; Washington Vascular Institute; Mubashar Choudry, M.D.	Cardiologist and three related medical practices agreed to pay $750,000 to resolve FCA allegations that they billed Medicare and TRICARE for services referred by physicians from whom they failed to charge FMV for testing used to detect peripheral arterial disease, in violation of the AKS and Stark Law.[74]	**$750,000**
5/1/2020	Center for Pain Management, S.C.; Nosheen Hasan, M.D.	Pain management clinic operator and its owner agreed to pay at least $1.35 million, with five years of future contingent payments based on specified criteria, to resolve FCA allegations that they ordered medically unnecessary urine drug tests in exchange for kickbacks from a drug testing laboratory, in violation of the AKS. The clinic operator and its owner also entered into a three-year IA with HHS-OIG as part of the resolution.[75]	**$1.35 million**
5/4/2020	Lexington Foot and Ankle Center, PSC; Dr. Michael Allen	Podiatry clinic and its founder and CEO agreed to pay $750,000 to resolve FCA allegations that they submitted claims to Medicare and FEHBP for nail debridement services which were: (1) not medically necessary; (2) not appropriately assessed; or (3) less involved procedures were actually performed. The clinic and physician also entered into a five-year IA with HHS-OIG.[76]	**$750,000**

71 https://www.justice.gov/usao-mdfl/pr/villages-dermatologist-agrees-pay-more-17-million-settle-false-claims-act-liability.
72 https://www.justice.gov/usao-mdal/pr/medical-practice-pay-425000-settle-false-claims-act-allegations.
73 https://www.justice.gov/usao-ct/pr/new-britain-optician-group-pays-more-263k-resolve-false-claims-allegations.
74 https://www.justice.gov/usao-md/pr/maryland-cardiologist-and-related-medical-practices-pay-united-states-750000-alleged.
75 https://www.justice.gov/usao-edwi/pr/milwaukee-pain-management-clinic-and-physician-agree-pay-least-135-million-resolve.
76 https://www.justice.gov/usao-edky/pr/lexington-foot-and-ankle-center-agrees-pay-750000-resolve-allegations-violations-false.

SPECIALTY CARE AND OTHER PROVIDER ENTITIES

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
5/20/2020	Premier Medical Associates	Medical practice agreed to pay $750,000 to resolve FCA allegations that it billed federal healthcare programs for higher and more expensive levels of medical services than were actually performed and also billed for certain claims using "modifier 25," indicating that a separate E&M service was performed, even when there was no such separate service.[77]	**$750,000**
5/20/2020	Rinova The Wellness Group, PC	Pain clinic operator agreed to pay $482,224 to resolve FCA allegations that it obtained new Medicare payment numbers to submit claims and evade a Medicare payment suspension applicable to the prior operator, while the prior operator was still under investigation and the clinics continued to operate with the same employees, clinics, locations, and patients.[78]	**$482,224**
6/5/2020	Alaska Neurology Center LLC; Franklin Ellenson, M.D.	Neurology center and its owner agreed to pay $2 million to resolve FCA allegations that they improperly billed federal healthcare programs for: (1) services performed by unqualified assistants; (2) services that were performed on different dates than were represented on the claims; (3) physical therapy when the service was actually non-reimbursable massage therapy; (4) claims using multiple, unbundled codes instead of the correct single code; (5) claims with incorrect provider names; and (6) claims re-submitted with false service or diagnosis information, and without consulting a medical provider, after an original claim was rejected. The center and physician concurrently entered into a three-year IA with HHS-OIG.[79]	**$2 million**
6/5/2020	Sioux Center Chiropractic Wellness Center, P.C.; Tyler Armstrong; Tiffany Armstrong	Chiropractic clinic and its two chiropractor operators agreed to pay $30,418 to resolve FCA allegations that they billed Medicaid for the treatment of conditions for which payment is not allowed, including constipation and ear infections.[80]	**$30,418**
6/26/2020	Associated Pain Specialists, P.C.	Pain management clinic agreed to pay $400,000 to resolve FCA allegations that it billed Medicare and TennCare for medically unnecessary vital assessment tests, when less costly or alternative tests were available, and the results were not used in subsequent treatment. The clinic entered into a three-year IA with HHS-OIG as part of the resolution.[81]	**$400,000**
6/30/2020	Ophthalmic Consultants, P.A.; Dr. Robert K. Snyder	Ophthalmology practice and physician agreed to pay $4.8 million to resolve FCA allegations that they billed federal healthcare programs for single-use macular degeneration drugs then used them to treat multiple patients, thereby obtaining excessive reimbursement. The practice and Dr. Snyder entered into a three-year IA with HHS-OIG as part of the resolution.[82]	**$4.8 million**

77 https://www.justice.gov/usao-mdfl/pr/premier-medical-associates-agree-pay-750000-resolve-claims-false-billing.
78 https://www.justice.gov/usao-mdtn/pr/franklin-tennessee-based-rinova-settles-allegations-fraudulent-operations-former-pain.
79 https://www.justice.gov/usao-ak/pr/alaska-neurology-center-llc-and-its-owner-pay-2-million-settle-false-claims-act.
80 https://www.justice.gov/usao-ndia/pr/sioux-center-chiropractic-clinic-pay-30418-resolve-allegations-related-claims-submitted.
81 https://www.justice.gov/usao-edtn/pr/associated-pain-specialists-pc-knoxville-enters-settlement-resolving-false-claims-act.
82 https://www.justice.gov/usao-mdfl/pr/sarasota-based-ophthalmic-consultants-agrees-pay-48-million-resolve-claims-multi-dosing.

SPECIALTY CARE AND OTHER PROVIDER ENTITIES

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
7/1/2020	Advanced Cardiovascular Care Center P.A.; Dr. Annie T. Varughese; Babu Varughese	Cardiology clinic, its physician owner, and its administrator agreed to pay $400,000 to resolve FCA allegations that they improperly billed Medicare for medically unnecessary cardiology services and services that lacked appropriate documentation regarding supervision of services.[83]	**$400,000**
7/6/2020	Bibi Tasleyma Sattar, D.O.; Oakmont Wellness Center, PA	Osteopathic physician and her practice agreed to pay $210,000 to resolve FCA allegations that they improperly billed federal healthcare programs for laboratory services that were provided at a laboratory with whom the practice had an improper referral relationship, in violation of the AKS.[84]	**$210,000**
7/7/2020	Florida Cancer Specialists & Research Institute, LLC	Oncology group agreed to pay $2,341,508.91 to resolve FCA allegations that it improperly billed the VA for claims related to physician-administered drugs.[85]	**$2.341 million**
8/21/2020	Heller Family Medicine, LLC; Dr. Jennifer Heller, D.C.	Chiropractor and her practice agreed to pay more than $5 million to resolve FCA allegations that they billed Medicare for surgical procedures when non-covered acupuncture services were actually provided.[86]	**$5 million**
9/10/2020	Shreveport Prosthetics, Inc.	Prosthetics provider agreed to pay $1.6 million to resolve FCA allegations that it improperly billed Medicare through another supplier during a time when its own supplier number was deactivated and routinely waived coinsurance payments, thus overcharging for billed services. The provider entered into a three-year IA with HHS-OIG as part of the resolution.[87]	**$1.6 million**
9/21/2020	Sagi M. Kuznits; Pnina Kuznits; Neurosurgical Care LLC	Neurosurgery practice, neurosurgeon, and practice director agreed to pay $1,017,375.03 to resolve FCA allegations that they billed Medicare, TRICARE, and FEHBP for surgical procedures when non-covered acupuncture services were actually provided. The settlement also resolves allegations that they submitted claims to Medicare for memory-loss testing using multiple billing codes instead of the correct code for the single test.[88]	**$1.017 million**

83 https://www.justice.gov/usao-sdtx/pr/houston-area-cardiologist-settles-allegations.
84 https://www.justice.gov/usao-edtx/pr/north-texas-doctor-pay-210000-settle-false-claims-act-allegations-accepting-illegal.
85 https://www.justice.gov/usao-mdfl/pr/cancer-treatment-center-repays-more-234-million-resolve-civil-claims-pertaining.
86 https://www.justice.gov/usao-sdga/pr/government-obtains-more-5-million-judgments-resolve-healthcare-fraud-allegations.
87 https://www.justice.gov/usao-wdla/pr/shreveport-prosthetics-inc-agrees-pay-16-million-resolve-false-claims-act-allegations.
88 https://www.justice.gov/usao-edpa/pr/neurosurgeon-medical-practice-director-pay-over-1-million-resolve-false-claims-act.

SPECIALTY CARE AND OTHER PROVIDER ENTITIES

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
10/1/2020	Advanced Pain Management Holdings Inc. (APMH); APM Wisconsin MSO; Advanced Pain Management LLC; Advanced Pain Management S.C.	Chain of pain management clinics agreed to pay $885,452 to resolve FCA allegations that they billed for services tainted by kickbacks, in violation of the AKS. The alleged improper remuneration included incentive stock that was allegedly given as a reward for past and anticipated referrals to APMH's ambulatory service centers and medical director compensation that was tied to the volume of procedures performed at APMH's ambulatory service centers. The settlement also resolves self-disclosed allegations of medically unnecessary confirmatory urine drug tests.[89]	**$885,452**
10/1/2020	Columbia Dental, P.C.; Columbia Oral Maxillofacial Imaging, L.L.C.; Abbas Mohammadi, DDS	Dentist and oral surgeon and two of his dental clinics agreed to pay $300,000 to resolve FCA allegations that they billed Medicaid for: (1) dental restoration services that were not medically necessary or were not provided; and (2) x-ray services performed by individuals who were not appropriately certified.[90]	**$300,000**
10/2/2020	Williamsburg Physical Therapy, P.C.; Euro Physical Therapy, P.C.; First Plus Services, Inc.; Alex Klurfeld; Diana Klurfeld	Two physical therapy clinics, an affiliated administrative company, and two owners agreed to pay $4 million to resolve FCA allegations that they improperly billed federal healthcare programs: (1) for services provided or supervised by individuals other than the licensed physical therapist identified on the claims; and (2) for services improperly backdated after treatment authorizations had expired. The clinics, administrative company, and owners entered into a three-year IA with HHS-OIG as part of the resolution.[91]	**$4 million**
10/30/2020	Memphis Primary Care Specialists; Lunceford Family Health Center; Getwell Family Medicine; Shoaib Qureshi, M.D.; Imran Mirza, M.D.	Chain of family medicine practices and their owners agreed to pay $341,690 to resolve allegations that they improperly billed Medicare for services rendered by nurse practitioners at the higher reimbursement rate for physician services.[92]	**$341,690**
11/12/2020	Eranga Cardiology, P.A.; Dr. Eranga Haththotuwa	Cardiology practice and cardiologist owner agreed to pay $500,000 to resolve FCA allegations that they improperly billed Medicare and Medicaid for claims requiring interpretive reports when the reports were never actually generated.[93]	**$500,000**

89 https://www.justice.gov/opa/pr/wisconsin-pain-management-companies-settle-false-claims-act-allegations.
90 https://www.justice.gov/usao-ct/pr/manchester-dentist-dental-clinics-and-dental-imaging-facility-pay-300k-settle-false.
91 https://www.justice.gov/usao-edny/pr/new-york-physical-therapy-providers-settle-civil-healthcare-fraud-allegations.
92 https://www.justice.gov/opa/pr/memphis-physicians-agree-pay-more-340000-alleged-overbilling.
93 https://www.justice.gov/usao-de/pr/eranga-cardiology-pay-500000-resolve-health-care-fraud-allegations.

INDIVIDUAL PROVIDERS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
1/2/2020	Dr. Mark D. Smith; Dr. Fane Robinson	Two ophthalmologists agreed to pay $948,768.18 to resolve FCA allegations that they submitted claims for care that was provided by another physician in their practice who was not credentialed to provide care to Medicare patients and submitted claims that misidentified the treating physician.[94]	**$948,768**
1/7/2020	Dr. Jayam Krishna Iyer	A pain management physician agreed to pay $102,126.98 to resolve FCA allegations that she issued medically unnecessary prescriptions for opioids. The physician pleaded guilty to related healthcare fraud charges in 2018.[95]	**$102,126**
1/16/2020	Dr. Joseph X. Latella	A physician agreed to pay $316,438.96 to resolve allegations that he billed Medicare for visits to patients at nursing homes as if he had spent more time with the patients than he actually did, causing Medicare to reimburse at a higher rate. The physician also pleaded guilty to related criminal charges and was sentenced to two months in prison and ordered to pay a fine of $117,199.32.[96]	**$316,438 (civil)** **$117,199 (criminal)**
1/21/2020	Dr. Rajendra Bhayani	An otolaryngologist agreed to pay $1.109 million to resolve FCA allegations that he and his practice paid improper remuneration to medical management companies in adult homes in exchange for exclusive access to the residents for allergy testing and other services, in violation of the AKS. These services were not always medically necessary and were performed by a nurse practitioner rather than the physician. The physician and his practice concurrently entered into a three-year IA with HHS-OIG.[97]	**$1.109 million**
1/24/2020	Dr. Chang-Wen Chen; Chang-Wen Chen, M.D., P.C.	A family physician and his practice agreed to pay $285,000 to resolve FCA allegations that they billed for services as if they were provided by a physician when in fact they were provided by an unsupervised nurse practitioner.[98]	**$285,000**
2/12/2020	Dr. William Choi	A neurosurgeon and three spinal equipment companies he owned paid $2.35 million to resolve FCA allegations that they secretly controlled and profited from companies that distributed spinal implant equipment purchased by hospitals where he performed surgeries and used in surgeries he performed, in violation of the AKS.[99]	**$2.35 million**

94 https://www.justice.gov/usao-sdca/pr/san-diego-eye-doctors-pay-950000-settle-medicare-billing-fraud-allegations.
95 https://www.justice.gov/usao-mdfl/pr/former-clearwater-anesthesiologist-agrees-pay-102126-resolve-civil-healthcare-fraud.
96 https://www.justice.gov/usao-ndia/pr/northern-iowa-doctor-sentenced-federal-prison-making-false-statements-and-will-pay-more.
97 https://www.justice.gov/usao-edny/pr/medical-doctor-settles-civil-fraud-allegations-adult-homes-investigation.
98 https://www.justice.gov/usao-edtn/pr/family-physician-pays-285000-settle-false-claims-act-allegations-billing-services.
99 https://www.justice.gov/usao-co/pr/colorado-neurosurgeon-and-related-companies-pay-235-million-resolve-allegations-illegal.

INDIVIDUAL PROVIDERS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
2/19/2020	Dr. Nathaniel Chan; Advanced Dental Arts	A dentist and his practice agreed to pay $135,000 to resolve allegations that they gave monetary rewards and raffle prizes to patients that attended more appointments and referred patients to the practice, in violation of Massachusetts' anti-kickback law.[100]	**$135,000**
3/2/2020	Dr. Crispin Abarientos; Dr. Antonieta Abarientos	Two physicians agreed to pay $4,927,903 to resolve FCA allegations that their practice submitted claims to Medicaid for a rheumatoid arthritis drug provided to Medicare and state employee health plan patients instead of Medicaid patients, while simultaneously billing Medicare and state employee health plans for the same drug and keeping the profits. One of the physicians previously pleaded guilty in a related criminal case and was sentenced to 37 months in prison.[101]	**$4.927 million**
3/17/2020	Dr. Andrew M. Berkowitz	A physician agreed to pay $2.8 million in civil damages, penalties, and forfeiture to resolve FCA and Controlled Substances Act allegations that his business: (1) dispensed controlled substances without regard for medical necessity; (2) submitted claims for the drugs and for services that were not actually provided; and (3) prescribed oxycodone to "pill-seeking" patients in exchange for submitting excessive claims to patients' insurance for medically unnecessary prescription drugs and for services not rendered. He also consented to exclusion from Medicare and Medicaid for 20 years, permanent exclusion from prescribing controlled substances, and pleaded guilty to related criminal charges, for which he will pay an additional $3.5 million in restitution.[102]	**$2.8 million (civil)** **$3.5 million (criminal)**
3/20/2020	Dr. Parveen Khanna	A physician agreed to pay $850,000 to resolve allegations that she received kickbacks from a pharmaceutical company in exchange for prescribing its fentanyl drug Subsys. The amount of the settlement was based on the physician's ability to pay. The physician entered into a three-year IA with HHS-OIG as part of the resolution.[103]	**$850,000**
4/1/2020	Stephen Ryan Honeycutt	A physician assistant agreed to pay $620,508.36 to resolve FCA allegations that he received kickbacks disguised as medical director fees from a compounding pharmacy in exchange for prescribing and recommending the pharmacy's pain creams.[104]	**$620,508**
4/6/2020	Dr. Mehran Heydarpour	A physician agreed to pay $175,000 to resolve allegations under both the FCA and the Controlled Substances Act for prescribing opioid pain medications without a legitimate medical purpose and billing Medicare for patient visits that did not occur. He also agreed to never again register with the DEA to be authorized to prescribe controlled substances.[105]	**$175,000**

100 https://www.mass.gov/news/canton-doctor-settles-allegations-of-illegal-patient-kickback-schemes.
101 https://www.justice.gov/usao-ct/pr/two-connecticut-physicians-pay-over-49-million-settle-false-claims-act-allegations.
102 https://www.justice.gov/usao-edpa/pr/doctor-who-pleaded-guilty-health-care-fraud-goodie-bags-agrees-resolve-civil-fraud-and.
103 https://www.justice.gov/usao-mdfl/pr/jacksonville-area-doctor-pays-850000-settle-allegations-she-received-illegal-kickbacks.
104 https://www.justice.gov/usao-ndok/pr/physician-assistant-agrees-pay-620-500-allegedly-engaging-illegal-kickback-scheme-0.
105 https://www.justice.gov/usao-edwi/pr/wisconsin-physician-agrees-pay-financial-penalties-resolve-allegations-he-prescribed.

INDIVIDUAL PROVIDERS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
4/6/2020	David Podell	A chiropractor agreed to pay $2 million to resolve FCA allegations that he billed Medicare for medically unnecessary osteoarthritis injections and custom knee braces and received kickbacks from the manufacturer of the knee braces.[106]	**$2 million**
4/15/2020	Dr. Ebenezer Quainoo	A physician agreed to pay $436,000 to resolve FCA allegations that he billed Medicare for medically unnecessary nervous function tests and muscle injections.[107]	**$436,000**
4/21/2020	Dr. Pramod Pilania	A psychiatrist agreed to pay $91,109 to resolve FCA allegations that, on several occasions, he claimed to have seen more than 120 patients in a single day where the visits were required to be at least 15 minutes each and did not record beginning and end times for those visits as required.[108]	**$91,109**
4/24/2020	Dr. Jeffrey R. Carlson	An orthopedic surgeon agreed to pay $1.75 million to resolve FCA allegations that he received kickbacks in the form of sham consulting payments and free meals from a spinal device manufacturer. The surgeon admitted that he estimated consulting time based on how often he used the company's devices and could not document the consulting hours.[109]	**$1.75 million**
4/28/2020	Dr. Ibrahim Oudeh; Teresa Sloan-Oudeh	A doctor, his wife, and their medical practice agreed to pay $5.5 million and relinquish $3.3 million in assets to resolve FCA allegations that they: (1) billed Medicare for "an astronomical" number of medically unnecessary diagnostic tests and did not appropriately reimburse the physicians who interpreted the tests; (2) submitted office visit claims at a higher level of care than actually provided; and (3) certified studies that the doctor was not qualified to interpret.[110]	**$8.8 million**
5/14/2020	Dr. Maaz Abbasi	A physician agreed to pay $450,000 to resolve FCA allegations that he received kickbacks from a home health company in exchange for certifying patients for home health services without knowledge of the patients' conditions and that he forged another physician's name on the certifications and plans of care. The physician also agreed to a three-year exclusion from federal healthcare programs.[111]	**$450,000**
6/30/2020	Dr. Jaime Robledo	An anesthesiologist paid $100,000 to resolve allegations that he falsely billed Medicare for implantation of neurostimulator electrodes, a surgical procedure, when he actually only applied a device for electro-acupuncture, which is not covered by Medicare.[112]	**$100,000**

106 https://www.justice.gov/usao-mn/pr/new-jersey-chiropractor-agrees-pay-2-million-resolve-allegations-unnecessary-knee.
107 https://www.justice.gov/usao-md/pr/baltimore-doctor-pay-436000-united-states-resolve-false-claims-act-allegations-relating.
108 https://www.justice.gov/usao-edpa/pr/psychiatrist-affiliated-philadelphia-and-lehigh-valley-area-health-clinics-who-claimed.
109 https://www.justice.gov/usao-ma/pr/surgeon-agrees-pay-175-million-resolve-allegations-he-accepted-kickbacks-spinefrontier.
110 https://www.justice.gov/usao-ednc/pr/prominent-physician-dunn-north-carolina-agrees-pay-88-million-resolve-allegedly.
111 https://www.justice.gov/usao-sdtx/pr/missouri-city-physician-pays-nearly-half-million-resolve-illegal-kickback-and-fraud.
112 https://www.justice.gov/usao-sdtx/pr/katy-anesthesiologist-pays-settle-allegations-arising-electro-acupuncture-device.

INDIVIDUAL PROVIDERS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
7/6/2020	Dr. William J. Cruz; Medscan, P.S.C.	A physician and his practice agreed to pay $1 million in a civil consent judgment to resolve FCA allegations that they submitted claims to Medicare while the doctor's Medicare billing privileges were revoked. They also entered into a three-year IA with HHS-OIG.[113]	**$1 million**
7/10/2020	Sarah Malstrom	A physician assistant agreed to pay $25,000 to resolve allegations that she received kickbacks such as food, meals, gift cards, gifts, and speaking and consulting fees from a pharmaceutical company to prescribe the company's dermatology drugs.[114]	**$25,000**
8/7/2020	Dr. Ean James	A dentist agreed to pay $148, 632.23 to resolve allegations that he billed Medicaid for anesthesia and sedation services after his annual conscious sedation permit had lapsed.[115]	**$148,632**
8/21/2020	Dr. Ghanshyam Bhambhani	A cardiologist agreed to pay $2 million to resolve civil FCA claims and admitted he: (1) paid kickbacks disguised as rent payments to other physicians for patient referrals; and (2) falsified records to justify performing cardiac procedures. The physician agreed to cooperate in the government's ongoing investigation. In 2018, he pleaded guilty to conspiracy to pay healthcare kickbacks, surrendered his medical license, was sentenced to 34 months in prison with three years' supervised release, and ordered to pay $217,364.83 in restitution and $1.08 million in criminal forfeiture.[116]	**$2 million**
8/25/2020	Dr. Syed Nasir	A pain management doctor agreed to pay $530,000 to resolve allegations that he falsely billed Medicare for implantation of neurostimulator electrodes, a surgical procedure, when he actually only applied a device for electro-acupuncture, which is not covered by Medicare.[117]	**$530,000**
9/9/2020	Michael Smith; Codey Brown; Dr. Harrison Frank	The owner and two managers of a now-defunct group of family medicine, immediate care, and pain management practices agreed to pay $900,000 to resolve FCA allegations that the group submitted claims to Medicare and Medicaid for medically unnecessary diagnostic tests and procedures.[118]	**$900,000**

113 https://www.justice.gov/usao-pr/pr/government-reaches-one-million-dollar-settlement-healthcare-fraud-matter.
114 https://www.justice.gov/usao-edpa/pr/physician-assistant-pay-25000-resolve-allegations-receiving-kickbacks-pharmaceutical.
115 https://www.justice.gov/usao-ct/pr/connecticut-dentist-pays-over-148k-settle-improper-billing-allegations.
116 https://www.justice.gov/usao-edny/pr/former-queens-cardiologist-settles-civil-fraud-allegations.
117 https://www.justice.gov/usao-sdtx/pr/pain-doctor-pays-settle-allegations-deceptive-medicare-billing.
118 https://www.justice.gov/usao-wdnc/pr/owner-and-two-managers-health-care-practice-agree-pay-900000-resolve-allegations-0.

INDIVIDUAL PROVIDERS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
9/18/2020	Dr. Thomas J. Whalen	A physician agreed to pay $1,257,499 to resolve FCA allegations that he billed federal healthcare programs for FDA-approved drugs when in fact he administered unapproved, foreign, cheaper versions of the drugs. The settlement also resolved allegations that he prescribed controlled substances without a legitimate medical purpose in violation of the Controlled Substances Act. The physician permanently surrendered his DEA controlled substances registration, surrendered his medical license, and will be excluded from federal healthcare programs. He also pleaded guilty to related criminal charges and was sentenced to one day in prison, 12 months of home confinement, three years of supervised release, and a $25,000 fine.[119]	**$1.257 million**
9/29/2020	Dr. David Mora	An optometrist agreed to pay $3,234,900.50 to resolve allegations that he billed Medicare for medically unnecessary tests and procedures. The doctor and his clinic also entered into a three-year IA with HHS-OIG.[120]	**$3.234 million**
11/9/2020	Dr. Nava K. Nawaz	A physician agreed to pay $850,000 to resolve allegations that she used her laboratory company to submit false travel reimbursement claims for specimen collection and testing. As a part of the settlement, she agreed not to own or operate a laboratory for 18 months.[121]	**$850,000**
11/9/2020	Dr. Dominick Piacente	A family physician agreed to pay $150,000 to resolve FCA allegations that he paid kickbacks to medical management companies in adult homes in exchange for allowing him to receive payments from Medicare for services he did not actually provide.[122]	**$150,000**

119 https://www.justice.gov/usao-edpa/pr/chester-county-doctor-agrees-pay-over-12-million-settle-allegations-fraudulent-billing.
120 https://www.justice.gov/usao-sdtx/pr/laredo-eye-doctor-pays-over-3m-resolve-fraud-claims.
121 https://www.justice.gov/usao-mdpa/pr/mechanicsburg-physician-pay-850000-resolve-potential-liability-under-false-claims-act.
122 https://www.justice.gov/usao-edny/pr/medical-doctor-settles-civil-fraud-allegations-adult-homes-investigation-0.

OTHER

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
1/27/2020	Practice Fusion Inc.	Electronic health records software company agreed to pay $145 million to resolve civil and criminal allegations that the company solicited and received kickbacks from pharmaceutical companies in exchange for implementing alerts in its EHR system designed to influence healthcare providers to increase the use of the pharmaceutical companies' products. The civil settlement also covers allegations that the software did not meet all requirements that it purported to meet, thus, the company knowingly caused users to falsely certify compliance with Medicare incentive payment requirements.[123]	**$118.6 million (civil)** **$26 million (criminal)**
8/20/2020	Firstsource Solutions, Ltd.; Firstsource Solutions USA, LLC; Medassist, Inc.	Revenue cycle management vendor agreed to pay $225,000 to resolve FCA allegations that it submitted or caused the submission of false claims to Medicaid for inpatient treatment and/or emergency room visits billed by its client, Phoenixville Hospital. The hospital and its operator separately resolved related allegations.[124]	**$225,000**
9/3/2020	Keystone Health Plan East, Inc.; QCC Insurance Company, Inc.	Two subsidiaries of MAO Independence Blue Cross, Inc., agreed to pay $2.25 million to resolve FCA allegations that they incorrectly calculated actual prior costs in bids submitted to CMS, resulting in CMS paying inflated reimbursement to the company.[125]	**$2.25 million**
11/16/2020	Kaiser Foundation Health Plan of Washington f/k/a Group Health Cooperative	MAO agreed to pay $6.375 million to resolve FCA allegations that the MAO submitted invalid diagnoses for Medicare Advantage beneficiaries to receive inflated payments from Medicare.[126]	**$6.375 million**

123 https://www.justice.gov/opa/pr/electronic-health-records-vendor-pay-145-million-resolve-criminal-and-civil-investigations-0.
124 https://www.justice.gov/usao-edpa/pr/phoenixville-hospital-and-firstsource-solutions-agree-pay-325000-resolve-false-claims.
125 https://www.justice.gov/usao-edpa/pr/pennsylvania-medicare-advantage-plan-provider-agrees-pay-225m-resolve-allegations.
126 https://www.justice.gov/opa/pr/medicare-advantage-provider-pay-63-million-settle-false-claims-act-allegations.

ABOUT BASS, BERRY & SIMS

The Bass, Berry & Sims Healthcare Fraud & Abuse Task Force represents healthcare providers in responding to inquiries and investigations by the U.S. Department of Justice, the U.S. Department of Health and Human Services – Office of Inspector General, various states' Attorneys General offices, and other federal and state agencies.

We have a proven track record of successfully representing healthcare providers in False Claims Act investigations and litigation throughout the United States, including securing dismissals in numerous False Claims Act lawsuits, and representing healthcare providers in criminal and civil enforcement proceedings brought by the government. 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 projects.

Our team includes former members of the U.S. Department of Justice and the U.S. Department of Health and Human Services – Office of Inspector General with significant experience handling healthcare fraud matters. Our attorneys are frequent speakers on healthcare fraud and abuse topics, and two of our members serve as Adjunct Professors of Law at Vanderbilt Law School teaching Healthcare Fraud and Abuse. For more information, please visit our website at **www.bassberry.com/healthcare-fraud.**

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Taylor Chenery centers 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 for healthcare companies and providers, advising them on compliance-related issues.

MATTHEW M. CURLEY

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Matthew Curley represents healthcare providers in connection with civil and criminal investigations by federal and state regulators and in related FCA litigation. 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, teaching Healthcare Fraud and Abuse.

WALLACE W. DIETZ

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Wallace Dietz is chair of the firm's Compliance & Government Investigations Practice Group. His practice includes representing healthcare companies facing whistleblower lawsuits under the FCA or other regulatory violations and conducting internal and government investigations. Wally has notable successes negotiating with DOJ, FTC, various state regulators, and other government agencies.

JOHN C. EASON

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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

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Lindsey Brown Fetzer focuses her practice on white collar and corporate compliance matters, including healthcare fraud and abuse issues. Lindsey has represented clients in foreign and domestic matters involving DOJ, the SEC, and other primary enforcement agencies.

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Lauren Gaffney represents healthcare clients concerning regulatory compliance and healthcare fraud matters and has advised clients concerning internal investigations and self-disclosures. She also counsels clients in connection with responding to audits and appeals by government contractors.

JEFF H. GIBSON

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

ANNA M. GRIZZLE

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

STEWART W. KAMEEN

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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.

JOHN E. KELLY

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John Kelly is the Managing Partner of the firm's Washington, D.C. office, a former DOJ healthcare fraud prosecutor, and an experienced trial lawyer who represents healthcare providers, payors, pharmaceutical manufacturers, medical device companies, and executives in investigations and enforcement actions concerning the FCA, AKS, Stark Law, FDCA, and FCPA. John held a number of leadership positions at DOJ, including Assistant Chief for Healthcare Fraud, Criminal Division, Fraud Section; Lead Prosecutor, Medicare Fraud Strike Force; and Chief of Staff and Deputy Director of EOUSA.

LISA S. RIVERA

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Lisa Rivera 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.

BRIAN D. ROARK

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Brian Roark leads the firm's Healthcare Fraud 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 and Abuse.

GLENN B. ROSE

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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.

DANIELLE M. SLOANE

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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

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Julia Tamulis provides guidance on government investigations of healthcare providers concerning potential fraud and abuse matters, including under the AKS, Stark Law, and FCA. She assists healthcare companies with internal compliance reviews and investigations 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.

ANGELA L. BERGMAN

Angela Bergman represents clients in internal and government investigations, administrative actions, and litigation related to compliance and alleged FCA violations, including home health and hospital billing practices, medical necessity issues, and other fraud and abuse matters.

NICHOLAS A. DEUSCHLE

Nicholas Deuschle represents healthcare companies in fraud and abuse investigations, enforcement actions, litigation, and criminal prosecutions stemming from government and whistleblower claims brought under the FCA, AKS, Stark Law, and other healthcare statutes.

MARGARET DODSON

Margaret Dodson represents healthcare providers involved in litigation and investigations involving various state and federal statutes, including the FCA, Stark Law, and AKS. She also helps clients respond to government investigations by DOJ, HHS-OIG, U.S. Attorneys' Offices, and the SEC.

SCOTT D. GALLISDORFER

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.

MALEAKA N. GUICE

Maleaka Guice provides healthcare regulatory counsel as it relates to compliance, operational, and transactional matters. She works with a range of the firm's healthcare clients, including hospitals, health systems, and hospice and home health providers.

DANIELLE DUDDING IRVINE

Danielle Dudding Irvine defends healthcare providers and pharmaceutical companies in connection with alleged violations of the FCA, AKS, Stark Law, and other healthcare statutes. She also counsels clients in connection with internal compliance investigations.

BRIAN IRVING

Brian Irving represents clients in civil litigation and government investigations, focusing on healthcare fraud matters brought under the FCA. He helps healthcare providers respond to government inquiries brought by DOJ, HHS-OIG, and U.S. Attorneys' Offices.

SARA K. MORGAN

Sara Morgan represents healthcare clients related to various federal and state compliance issues including the FCA, Stark Law, and AKS. She works with clients in defense of allegations of healthcare fraud and abuse.

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.

JACQUELYN PAPISH

Jacquelyn Papish represents healthcare clients in a range of high-stakes litigation matters. She also defends clients against government investigations involving compliance with the FCA and AKS.

DAWN PEREZ-SLAVINSKI

Dawn Perez-Slavinski uses insight previously gained while working at HHS-OGC to advise healthcare clients on complex regulatory issues implicated by day-to-day operations, healthcare transactions, and internal and government investigations. Dawn's practice focuses on evaluating and mitigating legal risks and exposure that arise in the context of healthcare program participation, billing, and reimbursement requirements.

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, and FCA. Additionally, Brianna assists clients in responding to and appealing commercial and government payor audits.

MOLLY K. RUBERG

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.

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.

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.

PAGE MINTON SMITH

Page Minton Smith provides healthcare regulatory counsel as it relates to compliance, operational, fraud and abuse, and transactional matters. She also assists clients with internal investigations and in responding to potential legal and regulatory violations and government investigations.

HANNAH E. WEBBER

Hannah Webber represents 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 inquires. She has experience representing providers in the not-for-profit and academic medicine spaces.

ABBY YI

Abby Yi represents companies in connection with internal and government investigations concerning white collar and corporate compliance matters. In addition, she regularly works with healthcare companies on healthcare fraud and abuse issues related to alleged violations under the FCA, AKS, and Stark Law.

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