

A blurred background image of a modern hospital hallway. Two healthcare professionals, a woman and a man, are walking towards the camera. They are both wearing white lab coats and have stethoscopes around their necks. The woman is on the left, and the man is on the right, holding a tablet. The hallway has large windows on the left and a clean, minimalist design.

HEALTHCARE FRAUD & ABUSE REVIEW 2018

**BASS
BERRY 
SIMS**

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ABOUT BASS, BERRY & SIMS

A LOOK BACK.... A LOOK AHEAD

Perhaps the single most appropriate word to describe the current state of the civil and criminal healthcare fraud enforcement environment is uncertainty. From changes in personnel and policy at the highest levels of government to a myriad of state and federal legislative developments, healthcare providers face an unsettled landscape as they move into the coming year.

To be sure, statistics would suggest that it was business as usual for the government's healthcare fraud enforcement efforts. While civil fraud recoveries by the U.S. Department of Justice (DOJ) dipped to more than \$2.88 billion in the fiscal year ending September 30, 2018 (FY 2018) as compared to \$3.7 billion in FY 2017, recoveries attributable to the healthcare industry were \$2.5 billion in FY 2018 – up from \$2.1 billion in FY 2017. This is the ninth consecutive year where recoveries associated with the healthcare industry exceeded \$2 billion.¹

Whistleblowers filed 645 new *qui tam* lawsuits under the False Claims Act (FCA) in FY 2018, which represented a slight drop-off compared with prior years, but brought the total number of FCA *qui tam* lawsuits filed since 2010 to more than 6,000. For their efforts, whistleblowers recovered more than \$300 million in relator share awards, bringing the total awards to relators to more than \$2.5 billion in the last five years.

In June 2018, DOJ and the U.S. Department of Health and Human Services (HHS) announced the largest ever national healthcare fraud takedown, which resulted in charges against more than 600 individuals responsible for more than \$2 billion in alleged losses. Healthcare providers were charged in 58 federal districts and those charged included 165 doctors, nurses, and other licensed medical professionals. Of particular note was the pursuit of charges against those involved in prescribing and distributing opioids and other narcotics. The takedown also aggressively targeted schemes billing government and commercial payors for medically unnecessary prescription drugs and compounded medications that allegedly were not purchased and/or not distributed to beneficiaries.

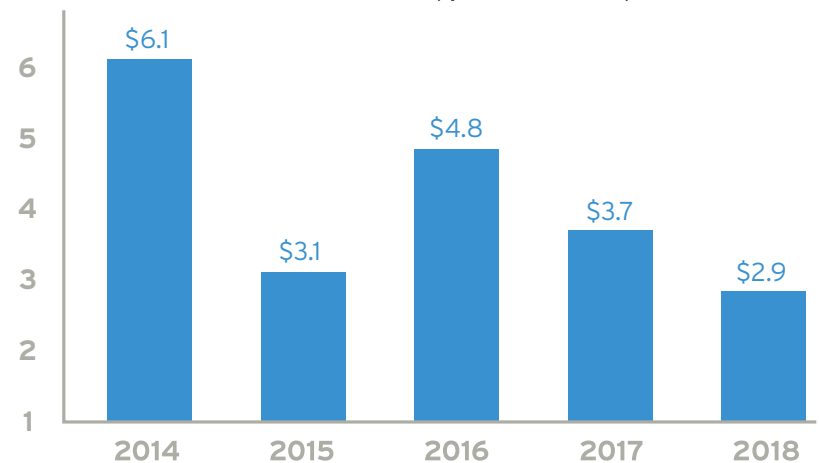
For its part, HHS's Office of Inspector General (HHS-OIG) reported investigative recoveries of more than \$2.9 billion and the pursuit of criminal actions against 764 individuals or organizations and 813 civil actions. HHS-OIG also announced that it had excluded 2,712 individuals and entities from the federal healthcare programs.² With respect to the opioid crisis, HHS-OIG conducted

Recoveries attributable to the healthcare industry were \$2.5 billion in FY 2018 – up from \$2.1 billion in FY 2017.

an analysis of opioid prescribing data in the Medicare Part D program and identified several concerning trends, including: (1) that nearly one in three Medicare beneficiaries received an opioid prescription in 2017; (2) identification of Medicare beneficiaries who appeared to be "doctor shopping;" and (3) identification of almost 300 prescribers who engaged in questionable opioid prescribing practices by ordering opioids for the highest number of Medicare beneficiaries at serious risk of opioid abuse.³ And, in July 2018, HHS-OIG issued a release highlighting key vulnerabilities in the Medicare hospice program and making numerous recommendations for protecting hospice beneficiaries. In a notable admission, HHS-OIG acknowledged that the hospice payment system creates incentives for hospices to minimize services and avoid caring for beneficiaries with the greatest needs.⁴

Regulators and legislators also found other ways to keep the opioid crisis squarely in their sights. In October 2018, DOJ announced the creation of the Appalachian Regional Strike Force to bolster criminal enforcement efforts aimed at healthcare fraud schemes in the Appalachian region and surrounding areas with particular focus on targeting medical professionals and others involved in the illegal prescription and distribution of opioids. Anchored in Nashville, Tennessee, the Strike Force will be made up of prosecutors and data analysts from DOJ's

CIVIL FRAUD RECOVERIES FY 2014-2018 (\$BILLIONS)



1 <https://www.justice.gov/opa/pr/justice-department-recovers-over-28-billion-false-claims-act-cases-fiscal-year-2018>.

2 <https://oig.hhs.gov/reports-and-publications/archives/semiannual/2018/2018-fall-sar.pdf>.

3 *Opioid Use In Part D Remains Concerning*, <https://oig.hhs.gov/oei/reports/oei-02-18-00220.pdf>.

4 *Vulnerabilities in the Hospice Program Affect Quality Care and Program Integrity*, <https://oig.hhs.gov/oei/reports/oei-02-16-00570.pdf>.

For their efforts, whistleblowers recovered more than \$300 million in relator share awards, bringing the total awards to relators to more than \$2.5 billion in the last five years.

in January and ended without confirmation of anyone to replace U.S. Attorney General Jeff Sessions following his resignation in November. The impact of these leadership changes relative to healthcare fraud enforcement efforts is yet to be determined.

The year also began with the issuance of two key DOJ memoranda, referred to as the Granston Memo and the Brand Memo after their respective authors. The Granston Memo sets forth considerations for DOJ attorneys to evaluate in regards to dismissal of declined *qui tam* lawsuits. The Brand Memo prohibits DOJ attorneys from using noncompliance with agency guidance documents in affirmative civil enforcement cases to establish violations of applicable laws, including the FCA. Both memos are likely to have a significant impact on the manner in which FCA cases are litigated and are discussed further in our Issues to Watch.

Finally, the Supreme Court's opinion in ***Universal Health Servs., Inc. v. U.S. ex rel. Escobar*** continued to have a profound impact on the litigation of FCA cases.⁵ *Escobar* upended more than \$1 billion in jury verdicts in FCA *qui tam* lawsuits after courts determined that the relators in those cases had failed to come forward with evidence to satisfy *Escobar*'s materiality requirement. Year-end also saw the intersection of the Granston Memo and *Escobar*, as DOJ filed an amicus brief in connection with the petition for certiorari in ***Gilead Sciences Inc. v. U.S. ex rel. Campie***, which sought review of the Ninth Circuit's reversal of the district court's dismissal of a relator's FCA lawsuit filed in 2011 for failure to plead materiality. While DOJ indicated its support for the Ninth Circuit's interpretation of *Escobar*'s materiality requirement, it also stated that it would seek dismissal of the relator's lawsuit if the case were remanded back to the district court because of its view of the merits of the relator's allegations and the likely burdensome nature of the discovery that would be sought from the government if the case were to proceed. The petition for certiorari filed in ***Campie*** joined at least two other such petitions seeking review of *Escobar*-related appellate decisions by the Supreme Court.

Healthcare Fraud Unit, along with prosecutors from the nine U.S. Attorney's Offices in the region.⁵ And, in that same month, Congress passed sweeping legislation aimed at the opioid crisis, which importantly included an all-payor kickback provision, which prohibits kickbacks in exchange for referrals to recovery homes, clinical treatment facilities, and laboratories.⁶

But for all of the business as usual that statistics, press releases, and reports might suggest, there were plenty of developments warranting a closer look. The year started with new leadership at HHS with the confirmation of Secretary Alex Azar

LARGEST-EVER HEALTHCARE FRAUD TAKEDOWN (JUNE 2018) BY THE NUMBERS

600+

INDIVIDUALS

165

MEDICAL
PROFESSIONALS

\$2

BILLION IN
LOSSES

58

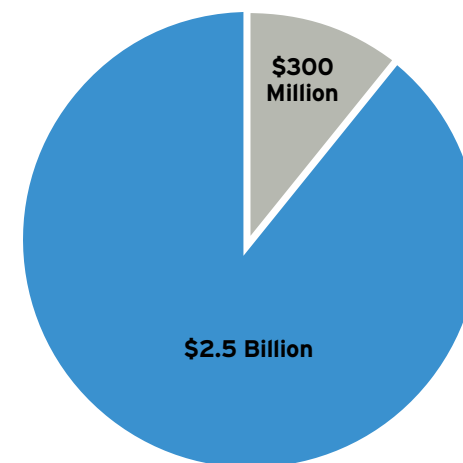
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COURTS

Our firm's annual **Healthcare Fraud & Abuse Review** is intended to 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. Without question, understanding the key developments during the prior year is an important step in implementing necessary safeguards designed to minimize enforcement risks for healthcare providers.

COMPARISON OF RECOVERIES (FY 2018)

HEALTHCARE RECOVERIES V. ALL OTHER RECOVERIES

ALL OTHER RECOVERIES
HEALTHCARE RECOVERIES



⁵ <https://www.justice.gov/opa/pr/justice-department-s-criminal-division-creates-appalachian-regional-prescription-opioid>.

⁶ Substance-Use Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act, H.R. 6, 115th Cong. (2018), <https://www.congress.gov/bill/115th-congress/house-bill/6>.

⁷ 136 S. Ct. 1989 (2016).

NOTEWORTHY SETTLEMENTS

As in recent years, resolutions in healthcare fraud cases accounted for the vast majority of all FCA recoveries in FY 2018. Of the \$2.88 billion in settlements and judgments, recoveries from matters involving the healthcare industry amounted to more than \$2.5 billion (89%). This is the ninth consecutive year that recoveries in federal civil healthcare fraud matters have exceeded \$2 billion.⁸

As has been typical in recent years, newly-filed *qui tam* complaints accounted for the vast majority of the new civil fraud matters initiated in FY 2018. Whistleblowers filed 645 *qui tam* lawsuits in FY 2018 and recoveries from these and earlier filed lawsuits accounted for \$2.11 billion of the \$2.88 billion recovered. Settlements associated with *qui tam* lawsuits where the government intervened or otherwise pursued the allegations comprised more than \$1.86 billion of the recoveries from healthcare companies during FY 2018. But, it is noteworthy that settlements in non-*qui tam* actions involving healthcare providers increased significantly, from \$32 million in FY 2017 to \$568 million in FY 2018.⁹

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

HOSPITALS AND HEALTH SYSTEMS

There were several notable settlements involving hospitals and health systems, including three of the four resolutions that were based on self-disclosures in FY 2018.¹⁰ Most of the settlements involving hospital and health systems related to allegations involving violations of the Stark Law or the Anti-Kickback Statute (AKS). In one such matter, Health Management Associates, LLC (HMA), paid over \$225 million to resolve allegations that it paid illegal remuneration to physicians in return for patient referrals to HMA hospitals, billed government programs for more costly inpatient services that should have been billed as observation or outpatient services, and

Settlements in non-*qui tam* actions involving healthcare providers increased significantly, from \$32 million in FY 2017 to \$568 million in FY 2018.

inflated claims for emergency department facility fees. In addition, an HMA subsidiary paid a \$35 million monetary penalty and pleaded guilty to one count of conspiracy to commit healthcare fraud arising from the alleged scheme to aggressively increase inpatient admissions. HMA's successor company agreed to an amended and extended Corporate Integrity Agreement (CIA) with HHS-OIG as part of the global resolution.¹¹

William Beaumont Hospital, a Michigan-based regional hospital system, agreed to pay \$84.5

million to resolve allegations that it: (1) submitted claims for services referred by physicians with whom it had improper compensation arrangements that violated the Stark Law and AKS; and (2) submitted claims that misrepresented that a CT radiology center qualified as an outpatient department of the hospital. The alleged improper financial arrangements included compensation that exceeded the fair market value of the services actually provided and free or below-market office space and office staff. As part of the settlement, the hospital entered into a five-year CIA with HHS-OIG.¹²

Hospitals and health systems also resolved a number of cases involving allegations that patients were admitted for inpatient services that should have been billed as outpatient or observation services,¹³ and allegations of medically unnecessary¹⁴ or unbundled services or procedures.¹⁵

LONG-TERM CARE PROVIDERS

Settlements involving allegations regarding the medical necessity of hospice, home health, and skilled services continued to dominate the landscape of enforcement actions involving long-term care providers.¹⁶

In the year's largest settlement involving long-term care providers, skilled nursing facility operator Signature HealthCARE, LLC, agreed to pay more than \$30 million to settle allegations that it billed Medicare for medically unnecessary and unskilled rehabilitation therapy services as a result of the following alleged practices: (1) presumptively placing patients in the Ultra High Resource Utilization Group (RUG) level, rather than relying on individualized evaluations to determine the level of care most suitable for each patient's clinical needs; (2) providing the minimum number of minutes required to bill at a given reimbursement level while discouraging

8 <https://www.justice.gov/opa/pr/justice-department-recovers-over-28-billion-false-claims-act-cases-fiscal-year-2018>.

9 <https://www.justice.gov/opa/press-release/file/1020126/download>.

10 See <https://www.justice.gov/opa/pr/ohio-hospital-operator-agrees-pay-united-states-1425-million-settle-alleged-false-claims-act>; <https://www.justice.gov/usao-mdpa/pr/charles-cole-memorial-hospital-agrees-settle-over-billing-allegations>; and <https://www.justice.gov/usao-edva/pr/vcu-health-system-authority-agrees-4-million-settlement>.

11 <https://www.justice.gov/opa/pr/hospital-chain-will-pay-over-260-million-resolve-false-billing-and-kickback-allegations-one>.

12 <https://www.justice.gov/opa/pr/detroit-area-hospital-system-pay-845-million-settle-false-claims-act-allegations-arising>.

13 See, e.g., <https://www.justice.gov/usao-cdca/pr/prime-healthcare-services-and-its-ceo-agree-pay-65-million-settle-medicare-overbilling>; <https://www.justice.gov/opa/pr/banner-health-agrees-pay-over-18-million-settle-false-claims-act-allegations>.

14 <https://www.justice.gov/usao-me/pr/ambulance-provider-and-hospital-agree-pay-1425000-settle-ambulance-transportation-claims>.

15 <https://www.justice.gov/usao-edpa/pr/coordinated-health-and-ceo-pay-125-million-resolve-false-claims-act-liability>.

16 See, e.g., <https://www.justice.gov/usao-md/pr/united-states-reaches-settlement-four-facilities-and-two-medical-companies-resolve>; <https://www.justice.gov/usao-wdky/pr/louisville-skilled-nursing-facility-pay-5191470-settle-false-claims-allegations>; and <https://www.justice.gov/opa/pr/two-consulting-companies-and-nine-affiliated-skilled-nursing-facilities-pay-10-million>.

the provision of additional therapy beyond that minimum threshold; and (3) pressuring therapists and patients to complete the planned minutes of therapy even when patients were sick or declined to participate in therapy. The settlement also resolved allegations that Signature submitted forged pre-admission certifications of patient need for skilled nursing to TennCare, a state Medicaid program. As part of the settlement, Signature entered into a five-year CIA with HHS-OIG.¹⁷

PHARMACEUTICAL AND MEDICAL DEVICE COMPANIES

In FY 2018, the pharmaceutical and medical device industry continued to account for the largest recoveries involving the healthcare industry. These matters involved allegations regarding unlawful marketing, off-label promotion, and AKS violations, among others.

In the largest settlement in the industry, AmerisourceBergen Corporation and certain of its subsidiaries agreed to pay \$625 million to resolve allegations that they improperly harvested “overfill” from the original vials of certain cancer drugs which it repackaged into pre-filled syringes and improperly distributed those syringes which allowed it to create more doses than it bought from the original manufacturers. In 2017, AmerisourceBergen Specialty Group pleaded guilty to related criminal charges and paid \$260 million to resolve criminal liability. The civil

COMPARISON OF TOTAL RECOVERIES: INTERVENED V. DECLINED CASES SETTLEMENTS AND JUDGMENTS (2014-2018)

Year	Intervened Cases	Declined Cases
2014	\$4.39 billion	\$81.38 million
2015	\$1.90 billion	\$512.36 million
2016	\$2.82 billion	\$106.10 million
2017	\$3.01 billion	\$425.77 million
2018	\$1.86 billion	\$250 million

settlement reached in FY 2018 also resolved allegations that the defendants gave kickbacks to physicians in the form of general pharmacy credits to induce the purchase of certain drugs through the company’s pre-filled syringe program. As part of the settlement, the company entered into a five-year CIA with HHS-OIG.¹⁸

Alere Inc., a medical device manufacturer that was acquired by Abbott in 2017, agreed to pay \$33.2 million to resolve allegations that it sold a materially unreliable testing device that was intended to aid clinicians in the diagnosis of drug overdoses, acute coronary syndrome and other serious conditions. The government alleged that Alere, after receiving complaints putting it on notice that certain of its devices produced erroneous results with the potential to create false positives and false negatives, failed to take appropriate corrective actions until U.S. Food and Drug Administration (FDA) inspections initiated a nationwide recall in 2012.¹⁹

A number of settlements involved the improper circumvention of co-payment requirements of Medicare patients. Actelion Pharmaceuticals US, Inc. agreed to pay \$360 million to resolve allegations that it used a foundation as an illegal conduit to pay the co-pay obligations of thousands of Medicare patients taking its pulmonary arterial hypertension drugs, in order to induce those patients to purchase the drugs, knowing its prices otherwise could be a barrier to such purchases.²⁰ Similarly, Pfizer agreed to pay \$23.85 million to resolve FCA allegations that it used a foundation as a conduit to pay the co-pay obligations of Medicare beneficiaries taking three of its drugs. As part of the settlement, Pfizer entered into a five-year CIA with HHS-OIG.²¹

MEDICARE ADVANTAGE

In one of the year’s most substantial recoveries, physician association HealthCare Partners Holdings LLC (HCP), d/b/a DaVita Medical Holdings, LLC, agreed to pay \$270 million to resolve self-disclosed allegations that it engaged in practices that caused Medicare Advantage Organizations (MAOs) to submit incorrect diagnoses codes to CMS in order to obtain inflated Medicare payments. After acquiring HCP in 2012, DaVita disclosed to the government various improper practices that were instituted by HCP. In addition, this settlement resolved whistleblower allegations that HCP engaged in “one-way” chart reviews in which it allegedly reviewed patient records to identify additional diagnoses that enabled managed care plans to obtain additional Medicare revenue, while ignoring inaccurate diagnoses codes that, if deleted, would have decreased reimbursement or required the Medicare Advantage Plans (MA Plans) to repay money to Medicare.

OTHER PROVIDERS AND INDIVIDUALS

Multiple settlements in FY 2018 underscored the federal government’s recent enhanced focus on individual actors and their roles in healthcare fraud schemes. In one notable case, the principal owner and CEO of a hospital system agreed to pay \$1.25 million of a \$12.5

¹⁷ <https://www.justice.gov/opa/pr/signature-healthcare-pay-more-30-million-resolve-false-claims-act-allegations-related>.

¹⁸ <https://www.justice.gov/opa/pr/amerisourcebergen-corporation-agrees-pay-625-million-resolve-allegations-it-illegally>.

¹⁹ <https://www.justice.gov/opa/pr/alere-pay-us-332-million-settle-false-claims-act-allegations-relating-unreliable-diagnostic>.

²⁰ <https://www.justice.gov/opa/pr/drug-maker-actelion-agrees-pay-360-million-resolve-false-claims-act-liability-paying>.

²¹ <https://www.justice.gov/opa/pr/drug-maker-pfizer-agrees-pay-2385-million-resolve-false-claims-act-liability-paying-kickbacks>.

million settlement to resolve his role in FCA allegations that the hospital system improperly unbundled reimbursement claims for orthopedic surgeries. The government alleged that the CEO and other executives were informed at least twice about the improper practice, and that the CEO personally engaged in a documentation practice allowing billers to unbundle surgeries using Modifier 59.²²

Two owners of a behavioral health and substance abuse services provider agreed to pay over \$1.3 million to resolve FCA allegations that they billed Medicaid for psychotherapy services which were not provided to patients and were already included in a weekly bundled rate for methadone maintenance services.²³ In another case, a pain management clinic chain and its chiropractor owner agreed to pay \$1.45 million and be excluded from federal healthcare programs for five years to resolve allegations that they violated the FCA by: (1) causing pharmacies to submit claims to federal healthcare programs for medically unnecessary pain killers; (2) upcoding claims for office visits that were not reimbursable at the levels sought; and (3) submitting claims for services provided by two nurse practitioners who were not collaborating with a physician as required by state law. As part of the settlement, a nurse practitioner agreed to pay \$32,000 and surrender her Drug Enforcement Administration (DEA) registration until October 2021 to resolve allegations that she violated the Controlled Substances Act.²⁴

22 <https://www.justice.gov/usao-edpa/pr/coordinated-health-and-ceo-pay-125-million-resolve-false-claims-act-liability>.

23 <https://www.justice.gov/usao-ct/pr/substance-abuse-treatment-providers-pay-more-13-million-settle-false-claims-act>.

24 <https://www.justice.gov/opa/pr/tennessee-chiropractor-pays-more-145-million-resolve-false-claims-act-allegations>.

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.

DOJ PRONOUNCEMENTS

Two internal DOJ memoranda released in 2018 may signal significant shifts in the government's approach to analyzing and pursuing allegations of healthcare fraud. On January 10, 2018, Michael Granston, DOJ's Director of the Commercial Litigation Branch of the Fraud Section, issued an internal memorandum (Granston Memo), which was publically leaked, that set forth considerations regarding whether the government should seek dismissal of a declined *qui tam* FCA case. Just two weeks later, on January 25, 2018, then-Associate Attorney General Rachel Brand issued a memorandum (Brand Memo) prohibiting DOJ litigators from using noncompliance with agency guidance documents in affirmative civil enforcement cases to establish violations of applicable laws, including the FCA.

DOJ's Granston Memo. The FCA provides DOJ with broad authority to dismiss *qui tam* actions, even over a relator's objection.²⁵ The Granston Memo recognized that the government historically has utilized its dismissal authority only "sparingly" in order to avoid "precluding relators from pursuing potentially worthwhile matters."²⁶ In the Granston Memo, however, DOJ litigators were reminded that the dismissal authority "remains an important tool to advance the government's interests, preserve limited resources and avoid adverse precedent." To protect those interests and "[t]o ensure consistency across the Department" with respect to the government exercising its dismissal authority, the Granston Memo provides seven factors that DOJ should consider in determining whether a non-intervened case should be dismissed. In September 2018, DOJ formally incorporated the Granston Memo's policy into its Justice Manual.²⁷

The impact of the Granston Memo has been felt since its issuance.²⁸ One of the most notable examples to date is in an amicus brief filed by the Solicitor General with the Supreme Court in *Campie*.²⁹ In that case, which was initially filed in 2011, the Ninth Circuit reversed the district court's dismissal of the relators' FCA allegations and Gilead filed a petition for writ of certiorari with the Supreme Court in December 2017. In April 2018, the Supreme Court requested that the government file an amicus brief expressing its views on Gilead's petition. On November 30, 2018, the Solicitor General filed its brief supporting the Ninth Circuit's interpretation of *Escobar*

that the relators adequately had pleaded that the regulatory violations at issue were material to the government's payment decision.

Despite staking out that position, the government stunned observers by explaining that if the case were remanded back to the district court in accordance with the Ninth Circuit's opinion, the government would move to dismiss the relators' complaint. The government stated that its decision was based on its investigation of the merits of the relators' allegations, as well as concerns about the burdensome discovery requests that likely would be issued to government agencies in the case to determine the facts relevant to the materiality analysis. Based on those considerations, which were set forth plainly in the Granston Memo, the government concluded that relator's continued pursuit of the FCA claims against Gilead was not in the public interest.

The Granston Memo's significant impact was underscored again in December 2018 when DOJ sought dismissal of 11 different FCA cases brought by the National Health Care Analysis Group (NHCA), a company specializing specifically in generating FCA cases. Each of the cases brought by NHCA alleged that pharmaceutical companies provided patient assistance services that amounted to improper kickbacks to drug prescribers by deploying "nurse educators" who allegedly acted as "undercover sales reps" and by providing the prescribers other remuneration in the form of support services. Noting that the *qui tam* complaints were "essentially cloned," DOJ moved to dismiss them because, similar to its position in *Campie*, it found that the complaints "lack sufficient merit to justify the cost of investigation and prosecution," would force the government to incur "substantial costs in monitoring the litigation and responding to discovery requests," and are "contrary to the public interest." DOJ also noted that the lawsuits "would undermine common industry practices the federal government has determined are, in this particular case, appropriate and beneficial to federal health care programs and their beneficiaries."³⁰

DOJ's Brand Memo. The Brand Memo followed a November 2017 memorandum issued by then-Attorney General Jeff Sessions to all DOJ components, which prohibited DOJ from publishing guidance documents that effectively bind the public without undergoing the notice-and-comment rulemaking process (Sessions Memo). The Brand Memo provided additional instruction to DOJ litigators about limiting the use of agency guidance documents in Affirmative Civil Enforcement (ACE) cases. It confirmed that the principles outlined in the Sessions Memo are relevant to more than just the DOJ's own publication of guidance documents and should

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25 See 31 U.S.C. § 3730(c)(2)(A).

26 <https://assets.documentcloud.org/documents/4358602/Memo-for-Evaluating-Dismissal-Pursuant-to-31-U-S.pdf>.

27 <https://www.justice.gov/opa/pr/departments-justice-announces-rollout-updated-united-states-attorneys-manual>.

28 See, e.g., *U.S. ex rel. Toomer v. TerraPower LLC*, 2018 WL 4934070 (D. Idaho Oct. 10, 2018) (granting government's motion to dismiss the relator's FCA claims).

29 Case No. 17-936 (U.S.).

30 *U.S. ex rel. Health Choice Group, LLC v. Bayer Corp.*, No. 5:17-cv-00126 (E.D. Tex.) (Dkt. Nos. 1, 32, 116).

guide DOJ litigators “in determining the legal relevance of other agencies’ guidance documents” in ACE cases, thus implicating an enormous and far broader swath of sub-regulatory guidance documents beyond those issued by DOJ.

The Brand Memo provided specific limitations about the use of guidance documents in ACE cases. It instructed that DOJ cannot use its enforcement authority to convert guidance documents into binding rules or create binding requirements that do not already exist by statute or regulation. It also prohibited the use of noncompliance with guidance documents as a basis for proving violations of applicable law in ACE cases, specifically including FCA cases. It instructed that a party’s noncompliance with an agency guidance document should not be treated as conclusively or even presumptively establishing a violation of the applicable statute or regulation. The Brand Memo did provide, however, that DOJ attorneys may continue to use guidance documents “for proper purposes,” such as for interpreting statutes or regulations or for proving a party’s knowledge of the statutory or regulatory requirement described in the document. Time will tell whether the Brand Memo will have a lasting, substantial effect on DOJ’s pursuit of certain theories of liability in FCA litigation.

NAVIGATING THE OPIOID CRISIS

In October 2017, the acting HHS Secretary declared a public health emergency in response to the heightened use and abuse of prescription opioids.³¹ Following that lead, state and federal governments have taken numerous actions to curb the impact of the opioid crisis by increasing enforcement efforts and implementing a variety of legislative changes.

To temper the effect of the opioid crisis, the government has created various strike and task forces aimed at identifying fraudulent practices. In October 2018, DOJ announced the Appalachian Regional Prescription Opioid (ARPO) Strike Force with the goal of effectively and efficiently prosecuting criminal conduct associated with improper prescribing and distribution practices by physicians, pharmacists and other medical professionals throughout the Appalachian region and surrounding areas.³² Earlier in 2018, DOJ created a similar task force, the Prescription Interdiction & Litigation (PIL) Task Force, to target what DOJ believes to be manufacturers’ untruthful marketing and actions by distributors that lead to diversion and overprescribing.³³

The heightened focus on opioid-related practices has led to a substantial number of investigations. These investigations, often aided by the government’s various strike and task forces, target key players throughout the distribution chain, from prescribers and pharmacies to manufacturers and distributors and often result in settlements that vary widely in type and magnitude.

Significantly, in June 2018, DOJ “aggressively target[ed]” fraudulent billing schemes focused on allegations of billing for medically unnecessary opioid prescriptions and services often never purchased, distributed or provided, as part of DOJ’s annual healthcare fraud takedown.³⁴ In a case involving a smaller settlement, a not-for-profit hospital paid \$50,000 in May 2018 to settle allegations that it had failed to properly maintain controlled substances records and effective controls against diversion.³⁵ And, in a non-traditional restitution order called “the first of its kind in the nation,” two pharmacists alleged to have dispensed opioids to customers of a well-known “pill mill” were ordered to pay \$5 million in community restitution to two state agencies responsible for providing substance abuse treatment and victims’ assistance services.³⁶

While healthcare providers must be increasingly vigilant to ensure their practices do not contribute to the opioid crisis, they must also take care that their efforts to reduce opioid fraud and abuse do not raise further scrutiny. For instance, urine drug testing is an important tool for identifying drug-seeking patients and ensuring that patients are taking medications as prescribed, but high frequency testing may trigger fraud and abuse allegations.³⁷ In **United States v. Wagoner**, the government alleged that the defendants, who required patients seeking opioid prescriptions to submit to drug screenings, devised a scheme to use a

Current Procedural Terminology (CPT) code modifier to fraudulently bill Indiana Medicaid for multiple urine drug screens using a single patient’s sample. The district court denied the defendants’ motion to dismiss, notwithstanding their argument that the defendants properly used the code to bill for screening multiple drug classes.³⁸

In addition to enforcement and litigation, there have been numerous pieces of legislation introduced and enacted in response to the opioid crisis. Importantly, in October 2018, Congress passed the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act with near-unanimous bipartisan support. Among its most noteworthy provisions, SUPPORT increases access to substance

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31 <https://www.hhs.gov/about/news/2017/10/26/hhs-acting-secretary-declares-public-health-emergency-address-national-opioid-crisis.html>.

32 <https://www.justice.gov/usao-edky/pr/justice-departments-criminal-division-creates-appalachian-regional-prescription-opioid>.

33 <https://www.justice.gov/opa/pr/attorney-general-sessions-announces-new-prescription-interdiction-litigation-task-force>.

34 <https://www.justice.gov/opa/pr/national-health-care-fraud-takedown-results-charges-against-601-individuals-responsible-over>.

35 <https://www.justice.gov/usao-ma/pr/nantucket-hospital-settles-allegations-improper-recordkeeping-and-handling-controlled>.

36 <https://www.justice.gov/usao-ndga/pr/two-pharmacists-sentenced-19-and-20-years-prison-and-ordered-pay-5-million-restitution>.

37 Harry Nelson, *Where Does Your Organization Stand? A Strategic Perspective for Healthcare Organizational Adaptation to the Opioid Crisis*, AHLA, 2018.

38 2018 WL 4539819 (N.D. Ind. Sept. 20, 2018).

abuse treatment for Medicare and Medicaid beneficiaries. For instance, it expands Medicare coverage to include services provided in opioid treatment programs; temporarily expands Medicaid coverage to include medication-assisted treatment; and eliminates certain geographic restrictions for providing telehealth services to Medicare patients. It also contains a new federal all-payor kickback provision, prohibiting kickbacks in exchange for referrals to recovery homes, clinical treatment facilities, and laboratories.³⁹ Due to this broad kickback prohibition and the various provisions expanding coverage to include services by providers not previously subject to federal fraud and abuse laws, we can expect to see a significant uptick in scrutiny of and enforcement actions against these providers.

Pending Legislation. The House and Senate have introduced several other bills in response to the opioid crisis. Next year will likely bring the enactment of some of these and similar pieces of legislation.

- ✦ *Opioid Crisis Response Act of 2018.* In April 2018, the Senate Health, Education, Labor and Pensions Committee introduced this bipartisan bill that includes proposals to issue grants to states and Indian tribes to advance prevention and treatment to mitigate the opioid crisis; to support states to improve their prescription drug monitoring programs and promote data sharing; and to clarify the FDA's authority to require manufacturers to package opioids for set treatment durations.⁴⁰
- ✦ *Opioid Prevention and Patient Safety Act.* In June 2018, the House passed this bill, which would better align the narrow provisions of 42 C.F.R. Part 2 (Confidentiality of Substance Use Disorder Patient Records) with Health Insurance Portability and Accountability Act (HIPAA) to allow sharing substance use disorder records among covered entities and Part 2 programs for treatment, payment and healthcare operations purposes.⁴¹
- ✦ *Preventing Overdoses While in Emergency Rooms Act of 2018.* In June 2018, the House passed this bill, which would require HHS to establish a grant program to enable hospitals to develop protocols for discharging patients treated for drug overdoses and improve integration and coordination of post-discharge care of substance use disorder patients.⁴²

We are likely to continue to see the enactment of opioid-related legislation and increased investigations against key players in the opioid distribution chain. To successfully navigate the changing opioid regulatory and enforcement landscape, providers and other healthcare professionals and entities will need to be alert to changing laws and regularly update compliance plans and policies accordingly, as well as take prompt action when suspected drug diversion occurs.

ESCOBAR UPENDS JURY VERDICTS

The Supreme Court's opinion in *Escobar* continued to garner significant attention from courts considering the question of materiality with respect to FCA claims. And, with many of these cases winding their way through the various federal appellate courts, it may not be long before we see the Supreme Court weigh in again on the FCA's materiality standard. While *Escobar* has had widespread impact relative to motions to dismiss and for summary judgment, perhaps its biggest impact has been in the undoing of more than \$1 billion judgments stemming from jury verdicts against defendants facing FCA claims.

"When the government, at appropriate levels, repeatedly concludes that it has not been defrauded, it is not forgiving a found fraud – rather it is concluding that there was no fraud at all."

U.S. ex rel. Harman v. Trinity Industries, Inc.

In *U.S. ex rel. Harman v. Trinity Industries, Inc.*, the Fifth Circuit vacated a jury verdict against a manufacturer of highway guardrails that allegedly were not manufactured according to government specifications.⁴³ The relator, a competitor of the manufacturer, alleged that changes to the specifications were not approved by the government and had caused various accidents identified by the relator and that the defendant's claims for payment amounted to FCA violations. On the eve of trial, the Federal Highway Administration (FHWA) released an official memorandum stating that the defendant's guardrail system became eligible for federal reimbursement on September 2, 2005, and that

there was "an unbroken chain of eligibility for Federal-aid reimbursement [that] has existed since September 2, 2005, and the [guardrail system] continues to be eligible today." Notwithstanding the FHWA memo, a jury returned a verdict for the relator and the district court entered judgment for more than \$663 million against the defendant.

The Fifth Circuit had little difficulty reversing the district court's judgment and ordering that summary judgment be entered in favor of the defendant "for want of materiality." Relying on the FHWA memo, the Fifth Circuit explained that "continued payment by the federal government after it learns of the alleged fraud substantially increased the burden on the relator in establishing materiality." The FHWA memo followed presentations made by the relator to the government, the FHWA's own investigation of issues raised by the relator, the filing of relator's *qui tam* complaint, and the discovery sought from FHWA, which prompted its memo. Nonetheless, "FHWA paid because it was not persuaded by [relator's] allegations." The Fifth Circuit summed up the implications of *Escobar* on the facts of this case succinctly, explaining that "[w]hen the government, at appropriate levels, repeatedly concludes that it has not been defrauded, it is not forgiving a found fraud—rather it is concluding that there was no fraud at all."

39 Substance-Use Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act, H.R. 6, 115th Cong. (2018), <https://www.congress.gov/bill/115th-congress/house-bill/6>.

40 Opioid Crisis Response Act of 2018, S. 2680, 115th Cong. (2018), <https://www.congress.gov/bill/115th-congress/senate-bill/2680>.

41 Overdose Prevention and Patient Safety Act, H.R. 6082, 115th Cong. (2018), <https://www.congress.gov/bill/115th-congress/house-bill/6082>.

42 Preventing Overdoses While in Emergency Rooms Act of 2018, H.R. 5176, 115th Cong. (2018), <https://www.congress.gov/bill/115th-congress/house-bill/5176>.

43 872 F.3d 645 (5th Cir. 2017).

In *U.S. ex rel. Ruckh v. Salus Rehabilitation, LLC*, the district court considered post-trial motions seeking to set aside a \$348 million judgment against operators of 53 skilled nursing facilities stemming from allegations that the facilities provided medically unnecessary therapy.⁴⁴ As explained by the district court, “the relator won judgments for almost \$350 million based on the theory ‘that upcoding of RUG levels and failure to maintain care plans made [the defendants’] claims to Medicare and Medicaid false or fraudulent.’” The district court noted that the relator presented no meaningful proof that Medicare or Medicaid would have regarded the disputed practices as material to the decision to pay the defendants and, in fact, would have refused to pay the defendants. To the contrary, the district court acknowledged that the government was aware of the defendants’ disputed actions, aware of the litigation and relator’s allegations, aware of the evidence in the action, and aware of the judgment, but had not ceased paying or even threatened to stop paying the defendants for the services at issue.

As a result of the foregoing, the district court concluded that the relator could not satisfy the materiality requirement as set forth in *Escobar*. The district court explained that “the evidence and the history of this action establish that the federal and state governments regard the disputed practices with leniency or tolerance or indifference or perhaps with resignation to the colossal difficulty of precise, pervasive, ponderous and permanent record-keeping in the pertinent clinical environment.” The district court continued “[t]he evidence shows not a single threat of non-payment, not a single complaint or demand, and not a single resort to an administrative remedy or other sanction for the same practices that result in the enormous verdict at issue.”

Under the circumstances, the district court concluded that the relator failed to carry her burden on proving materiality at trial, which was described as requiring the relator “to show that the federal government and the state government did not know about the record-keeping deficiency but had the governments known, the governments would have refused to pay the operators of fifty-three specialized nursing facilities for services rendered, products delivered and costs incurred.” In fact, the district court went so far as to note that the relator would have to offer proof that would exclude the government’s choosing to resort to “a more moderate, more proportional, more efficacious remedy . . .” The district court then quickly dispatched with all of the evidence cited by the relator in concluding that the relator fell well short of meeting her burden to prove materiality under the parameters set by *Escobar*.

The results in these cases demonstrate that importance that the issue of materiality will continue to have in FCA cases – even where the relator or the government has survived a motion for summary judgment and proceeds to trial. These cases also highlight the need for defendants to pursue discovery aggressively from the government in order to probe whether the government would pay claims for reimbursement notwithstanding the allegedly wrongful conduct at issue.

PRIVATE EQUITY

DOJ’s decision to intervene in an FCA case against not only a compounding pharmacy, but also its private equity firm controlling owner, underscores the potential risks private equity firms face when operating in the highly regulated healthcare space. On February 16, 2018, DOJ filed a complaint in intervention in *Medrano v. Diabetic Care Rx, LLC*, alleging the compounding pharmacy, Patient Care America (PCA), paid illegal kickbacks to marketing firms who targeted military members and their families for prescriptions for compounded drugs the pharmacy then created not to meet individual patient needs, but rather to maximize reimbursement from TRICARE, the federal military healthcare program.⁴⁵ DOJ also named as a defendant the private equity company Riordan, Lewis & Haden Inc. (RLH), which manages and controls PCA through a general partner.

This case may serve as a wake-up call for private equity firms that are actively engaged in the management and control of healthcare companies in which they invest.

According to the government’s theory, it was not a passive investment that brought RLH into the lawsuit. Rather, the government alleged that RLH bought a controlling stake in PCA with an eye toward increasing the pharmacy’s value and selling it for a profit in five years. It then controlled and directed PCA’s operations on behalf of the members of its fund, steering the pharmacy into the business of compounding topical creams for pain management to capitalize on the “extraordinarily high profitability of this therapy.” PCA soon entered into agreements with three marketing companies, which contacted and solicited pharmacy orders from military members and their families and were paid commissions by PCA as independent contractors, outside of the protection of the AKS’s employment safe harbor. The complaint further alleged that the marketers illegally covered patient co-payments as a way to fill additional prescriptions, which were written by telemedicine physicians without establishing legitimate doctor-patient relationships.

The complaint alleged that RLH knowingly participated in the scheme, which led to PCA receiving more than \$68 million in reimbursement from TRICARE. It also pointed out that RLH, which had significant healthcare investing experience, was specifically warned by counsel that the scheme raised kickback concerns, yet it proceeded nonetheless. RLH even went so far as to periodically make commission payments to the marketing firms when PCA had not yet received the corresponding TRICARE reimbursements.⁴⁶

⁴⁴ 304 F.Supp. 3d 1258 (M.D. Fla. 2018).

⁴⁵ No. 15-62617-CIV-BLOOM (S.D. Fla.).

⁴⁶ On November 30, 2018, the magistrate judge recommended that the government’s FCA claims be dismissed with leave to replead as a result of its failure to plead its presentment claim under either the express certification or implied certification theory of liability and knowledge as to certain defendants. *Medrano v. Diabetic Care Rx, LLC*, Report and Recommendation (Dkt. No. 100).

This case may serve as a wake-up call for private equity firms that are actively engaged in the management and control of healthcare companies in which they invest. In the absence of vigilant compliance efforts, and depending on their level of engagement and knowledge, these entities may not be beyond the reach of the government's FCA enforcement efforts.

MEDICARE ADVANTAGE

Several district court decisions have raised significant obstacles to the pursuit of FCA liability against MA Plans. Under Medicare Advantage, also known as Medicare Part C, Medicare beneficiaries can enroll in MA Plans that are paid a capitated, or per-person, monthly payment to provide benefits to their enrolled Medicare beneficiaries. The amount received for each beneficiary is determined by the demographics and health status of the beneficiary based on diagnosis data submitted for the prior year, through a process known as risk adjustment. In general, a beneficiary with more severe diagnoses will have a higher risk score, and, as a result, CMS will make a larger capitated payment to the MA Plan for that beneficiary.

In last year's Review, we discussed how MA Plans have become an area of focus for relators and the government in asserting FCA claims because of the incentive for MA Plans to ensure that they receive higher monthly capitation payments for each member by reporting as many risk adjusting diagnosis codes for each member, coupled with requirements that MA Plans take certain steps to ensure and attest to the truth and accuracy of the member diagnoses submitted to determine capitation payments.

Opinions by district courts in two cases involving UnitedHealth Group (UnitedHealth) highlight some of the key issues in such cases. In *U.S. ex rel. Poehling v. UnitedHealth Group, Inc.*, the district court granted dismissal of the government's claims based on the theory that the defendants' attestations as to the truth and accuracy of the risk adjustment data submitted were false.⁴⁷ The district court held that the government had failed to adequately plead that these attestations were material to the government's payment decision. While the district court granted the government leave to amend its complaint, the government did not do so. The district court, however, denied the motion to dismiss as to the government's claims based on the submission of invalid diagnostic data, and the case is proceeding on these claims.

In *UnitedHealthcare Ins. Co. v. Azar*, the district court granted summary judgment in favor of UnitedHealth in its lawsuit challenging the 60-day repayment rule with respect to MA Plans under the Administrative Procedures Act.⁴⁸ The district court found that the rule violated the "actuarial equivalence" requirement mandated by statute and represented a departure from

prior policy that the government had failed to explain. As a result, the district court's ruling vacated the 60-day repayment rule, as it relates to MA Plans.⁴⁹

A settlement in a related case strongly suggests that claims against vendors who knowingly submit or fail to delete inaccurate diagnosis data to MA Plans may result in FCA liability. In 2017, a parallel case against UnitedHealth was dismissed for failure to plead materiality and other allegations with any particularity.⁵⁰ In 2018, DaVita Medical Holdings, LLC, reached a \$270 million settlement in connection with its acquisition of Healthcare Partners, a defendant in the dismissed litigation.⁵¹ Healthcare Partners had served as a vendor to MA Plans and was alleged to have knowingly submitted unsupported and undocumented diagnosis codes and having failed to delete such codes which caused overpayment to the MA Plans and the retention of those overpayments.⁵²

HHS-OIG DEVELOPMENTS

There have been a number of noteworthy developments concerning HHS-OIG that likely will have a significant impact in the coming year.

Fraud Risk Indicator. On September 27, 2018, HHS-OIG established its new "Fraud Risk Indicator" as a mechanism to increase transparency surrounding HHS-OIG's resolution of its permissive exclusion authority. The Fraud Risk Indicator identifies instances where a healthcare provider or other organization settles an FCA case, but declines to seek a release of administrative liability and enters into a CIA even though HHS-OIG determined that a CIA is warranted. The list of entities that decline a CIA began populating on October 1, 2018, and, per the OIG, these entities are considered higher risk-heightened scrutiny.⁵³ In contrast, per the Fraud Risk Indicator, entities that utilize OIG's self-disclosure protocol present the lowest amount of risk, while entities that settle an FCA matter and contemporaneously execute a CIA present medium/moderate risk.

Advisory Opinion No. 18-14. In Advisory Opinion No. 18-14, HHS-OIG concluded that a pharmaceutical manufacturer's proposal to provide free drugs to hospitals for use in connection with pediatric inpatients suffering from a form of epilepsy could potentially generate prohibited remuneration under the AKS for which HHS-OIG may impose administrative sanctions.⁵⁴ Relying on its longstanding, but apparently never-before-used regulatory authority to "conduct whatever independent investigation [HHS-OIG] believe[s] appropriate" when preparing an advisory opinion, HHS-OIG on its own initiative located and cited to publicly available facts regarding the high cost of the drug, significant historical increases in its list price and availability

47 2018 WL 1363487 (C.D. Cal Feb. 12, 2018).

48 330 F. Supp. 3d 173 (D.D.C. 2018).

49 See also *U.S. ex rel. Gray v. UnitedHealthcare Insurance Co.*, 2018 WL 2933674 (N.D. Ill. June 12, 2018) (dismissing with prejudice a complaint brought against UnitedHealth by a relator who was a member of an MA plan).

50 *U.S. ex rel. Swoben v. Scan Health Plan*, 2017 WL 4564722 (C.D. Cal. Oct. 5, 2017).

51 <https://www.justice.gov/opa/pr/medicare-advantage-provider-pay-270-million-settle-false-claims-act-liabilities>.

52 The government also has intervened in a case alleging FCA liability against a provider of healthcare services to MA Plan beneficiaries on the grounds that they submitted unsupported diagnosis codes that inflated the capitated payments for those beneficiaries. See *U.S. ex rel. Ormsby v. Sutter Health*, No. 15-CV-01062-JD (N.D. Cal.).

53 <https://oig.hhs.gov/compliance/corporate-integrity-agreements/risk.asp>.

54 <https://oig.hhs.gov/fraud/docs/advisoryopinions/2018/AdvOpn18-14.pdf>.

of other possible treatments for the condition at issue.⁵⁵ Ultimately, HHS-OIG found that the proposed arrangement presented more than a minimal risk of fraud and abuse because, among other things: (1) it would relieve hospitals of significant financial obligations associated with purchasing the product; (2) it would not result in any federal healthcare program savings; (3) it could function as a seeding arrangement and lead to unfair competition; and (4) the free drugs were effectively contingent on future purchases given that a course of treatment once initiated could not be discontinued without potential adverse consequences to the patient.

Exclusion Actions. On August 17, 2018, an administrative law judge (ALJ) upheld HHS-OIG's exclusion of BestCare Laboratory Services, LLC and its owner and CEO, Karim Maghareh, Ph.D., from participation in Medicare, Medicaid and other federal healthcare programs for a period of 15 years. The decision is significant because it represents the first time since 2011 that an ALJ has been asked to opine on a sanction imposed by HHS-OIG pursuant to its permissive exclusion authority found at § 1128(b)(7) of the Social Security Act. HHS-OIG based the exclusion on BestCare's and Dr. Maghareh's submission or causing the submission of false claims to Medicare from August 2009 to January 2010 for reimbursement of technician travel costs associated with the collection of lab samples when, in fact, the laboratory had used commercial airline flights to ship samples unaccompanied by trained personnel. Notably, these allegations were originally raised through a *qui tam* complaint, and HHS-OIG pursued the permissive exclusion of BestCare and Dr. Maghareh in parallel with the ongoing FCA litigation.

Modifications to AKS Safe Harbors and Beneficiary Inducement Provisions of the Civil Monetary Penalties Law. On August 24, 2018, HHS-OIG released a Request for Information (RFI) soliciting public comments on potential modifications or the creation of new safe harbors to the AKS and exceptions to the Civil Monetary Penalties Law's beneficiary inducement provisions as part of HHS's Regulatory Sprint to Coordinated Care initiative. The RFI broadly sought feedback on seven areas, ranging from the types of value-based arrangements and associated patient incentives that might be impeded by existing fraud and abuse laws to the establishment of new protections for certain items of value (e.g., cybersecurity-related items or services). The comment period closed on October 26, 2018, with 359 comments received from a combination of hospitals and health systems, physicians, post-acute care and other specialty providers, manufacturers and trade groups. Healthcare organizations are encouraged to monitor developments pertaining to this RFI, including any proposed rule that HHS-OIG may promulgate based on the public input received.

⁵⁵ 42 C.F.R. § 1008.39(d).

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 continue to be a number of legal developments involving the FCA that will greatly impact the government's enforcement efforts.

DEVELOPMENTS FOLLOWING ESCOBAR

Courts across the country have continued to grapple with the Supreme Court's opinion in *Escobar*, in particular, considering the question of materiality with respect to FCA claims. Although the unanimous Supreme Court decision set forth a number of factors that courts may consider when determining whether a statutory, regulatory, or contractual violation is material to payment, courts have come to seemingly irreconcilable conclusions about how those factors should be applied. While many district courts continue to engage in a rigorous materiality analysis as detailed below, circuit courts have taken a more lenient approach. These decisions have potentially sweeping implications for healthcare providers' potential liability under the FCA.

Appellate Courts Continue to Grapple with *Escobar*

By late 2018, at least three *Escobar*-related decisions by federal appellate courts were poised for possible review by the Supreme Court. These cases highlight important considerations for healthcare providers contracting with the government. By lowering the bar for fraud claims on motions to dismiss, these appellate decisions possibly open the door for future relators to file FCA complaints against healthcare providers based on the violation of any myriad number of healthcare regulations that could be deemed a "mechanism for fraud prevention." Further, these decisions potentially allow relators to assume the enforcement authority of federal agencies and threaten to create new obligations for healthcare providers where none have existed before.

Sixth Circuit Developments. In *U.S. ex rel. Prather v. Brookdale Senior Living*, a former utilization review nurse alleged that Brookdale failed to obtain physician signatures on home health certifications as soon as possible after the physician established a plan of care, in violation of Medicare regulations.⁵⁶ The district court twice granted Brookdale's motions to dismiss, first without prejudice to the relator's re-filing and subsequently with prejudice. The district court ruled that the relator failed to adequately plead the presentment of a false claim for payment and that any claim submitted for payment was false under the FCA.

On appeal, a divided Sixth Circuit panel ruled that the relator's allegations satisfied the presentment and falsity elements of an FCA claim. Regarding falsity, the Sixth Circuit held that a claim for home health services was "false" where it was submitted with a physician signature on the certification document that was obtained after the patient was discharged and where the delay was not sufficiently "justified" by the home health agency.

The Supreme Court issued its decision in *Escobar* during the pendency of the appeal. Upon remand, the district court permitted the relator to amend her complaint in light of *Escobar*. Brookdale moved to dismiss the Third Amended Complaint for failure to plead materiality and scienter in accordance with *Escobar*. The district court granted Brookdale's motion to dismiss for a third time. On June 11, 2018, in a 2-1 decision, the same Sixth Circuit panel reversed the district court's most recent dismissal, finding that the relator adequately pleaded the materiality and scienter elements of an FCA claim.

The Sixth Circuit held that a violation of the "timing-and-explanation" requirement for delayed physician signatures on home health certification documents was material to payment under *Escobar*. The Sixth Circuit stated that the relator sufficiently established materiality where the government designated the regulation as a condition of payment and where, by the Sixth

Circuit's own estimation, the regulation could act as a "mechanism for fraud prevention." Notably, the Sixth Circuit held that the relator's failure to plead any facts about whether the government had ever denied claims based on this regulatory violation had "no bearing on the materiality analysis."

Courts across the country have continued to grapple with the Supreme Court's opinion in *Escobar*, in particular, considering the question of materiality with respect to FCA claims.

In a lengthy and sharp dissent, Judge McKeague wrote that "[t]wo years ago, the majority invented a more stringent timing-and-explanation requirement out of whole cloth" and now "decides both that this requirement (created by the court in 2016) was somehow material to the government's decision to pay claims in 2011 and 2012, and that the defendants knew, seven years ago, that it was material—even

though Prather identifies no authority in support of that position." Judge McKeague concluded that without concrete evidence of the government's payment history or any helpful regulatory guidance, the relator must provide additional factual allegations regarding how or why the government likely would have denied claims based on this violation.

Ninth Circuit Developments. The Ninth Circuit also issued an important decision in *U.S. ex rel. Rose v. Stephens Institute*, clarifying the elements of an implied false certification claim and addressing materiality.⁵⁷ Stephens Institute is a private art college in California, which receives federal funding in the form of financial aid to students under Title IV of the Higher Education Act. The *qui tam* lawsuit against the company was filed by former school admissions employees who alleged that the school violated statutory, regulatory and contractual

⁵⁶ 892 F.3d 822 (6th Cir. 2018), cert. pending, No. 18-699 (Nov. 20, 2018).

⁵⁷ 2018 WL 6165627 (9th Cir. 2018).

requirements that prohibit schools receiving Title IV funding from tying incentive payments for admissions employees to the number of students enrolled. The district court denied the school's motion for summary judgment, but certified the issue for interlocutory appeal. On appeal, the Ninth Circuit upheld the district court's ruling.

The Ninth Circuit first addressed the proper test for establishing an implied false certification claim. Prior to *Escobar*, the Ninth Circuit had adopted a broad view of implied certification liability, holding that an implied certification claim could be asserted where the defendant explicitly undertook to comply with a requirement and later submitted claims in violation of that requirement.⁵⁸ In *Escobar*, however, the Supreme Court seemed to construe the theory more narrowly, holding that the implied certification theory can be a basis for FCA liability "at least where" (1) the claim "makes *specific representations* about the goods or services provided," and (2) "the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths."⁵⁹

Arguably, *Escobar* did not rule out other methods for establishing an implied false certification claim, including as described in *U.S. ex rel. Ebeid v. Lungwitz*. In *Rose*, however, the Ninth Circuit explicitly held that after *Escobar*, the only way to establish an implied false certification claim in the Ninth Circuit is to satisfy the two conditions described in *Escobar*. In reaching this conclusion, the Ninth Circuit determined it was bound by two earlier post-*Escobar* Ninth Circuit cases that had looked exclusively to *Escobar* when addressing implied false certification. On the facts alleged, the panel had no trouble finding those requirements met in *Rose*.

The Ninth Circuit also found that materiality was supported by a number of factors. The incentive-compensation ban was "triple conditioned" as an express condition of payment in applicable statutes, regulations, and in the school's agreement with the government. The Ninth Circuit also found that Stephens Institute had not violated the incentive compensation ban in a small way, but offered salary increases up to \$30,000 and an expenses-paid trip to Hawaii to employees who hit their admissions targets. Moreover, the Ninth Circuit was persuaded by evidence that the government took corrective action in 25 of 32 cases in which other schools violated the incentive compensation ban.

The dissent from the majority's opinion on the issue of materiality argued that the evidence of prior corrective actions related only to the government's *general* enforcement of the incentive-compensation ban, not to the types of violations at issue in the case. The dissent would have returned the case to the district court for further discovery into how the government would have responded to the specific alleged violations.

Following issuance of the panel's decision, defendants have indicated they will file a petition for writ of certiorari with the Supreme Court.⁶⁰ Brookdale has also petitioned for writ of certiorari, asking that the Supreme Court review a circuit split regarding whether, in analyzing the FCA's materiality requirement on a motion to dismiss, the relator's or the government's failure to plead facts relating to past government practices concerning the alleged violation can weigh against a finding of materiality.

Failure to Plead Materiality. As noted above, the Sixth Circuit determined in *Prather* that a district court may not consider a relator's failure to plead facts relating to the government's past enforcement of a regulatory provision in the context of a motion to dismiss. Lower courts have taken divergent approaches, however, where a relator fails to plead critical facts regarding the government's decision to pay claims. Most have engaged in a rigorous analysis that requires relators or the government to plead facts beyond conclusory allegations of materiality.

In *U.S. ex rel. Kietzman v. Bethany Circle of King's Daughters of Madison, Indiana, Inc.*, the relator filed a *qui tam* action alleging that a hospital fraudulently overbilled the United States for certain medical services.⁶¹ The complaint alleged multiple schemes with varying degrees of specificity, including allegations of unnecessary scans on cancer patients, purchasing equipment for urologists as kickbacks, failure to provide adequate physician supervision, and up-coding radiology reads. On a motion to dismiss, the district court held that the relator failed to plead material violations of regulations under *Escobar*. The district court held that the complaint included not a single "nonconclusory" allegation of materiality. It explained that, "[n]o facts are alleged as to what types of claims the government usually did or did not pay, nor as to what the government's compliance priorities were, nor as to the degree of severity of the Hospital's alleged breaches of regulation." The district court held that bold conclusions are not enough and dismissed the case.

Similarly, in *U.S. ex rel. Folliard v. Comstor Corp.*, the relator alleged that the defendants sold to the government products that originated in non-designated countries in violation of the Trade Agreement Act.⁶² The district court granted the defendants' motion to dismiss the complaint finding that the relator provided "no factual allegations" relating to past government payment practices in the mine run of cases. Instead, the relator simply regurgitated the regulations at issue. Where the complaint was "silent" as to whether the government took any action whatsoever against the defendants upon finding out about the submission of claims that violated the regulations, the relator has "failed to show" that any alleged false claim was material to the government's decision to pay the claim.⁶³

58 See *U.S. ex rel. Ebeid v. Lungwitz*, 616 F.3d 993 (9th Cir. 2010).

59 136 S. Ct. at 2001 (emphasis supplied).

60 *U.S. ex rel. Brooks v. Stevens-Henager Coll.*, 305 F. Supp. 3d 1279 (D. Utah 2018), also dealt with alleged violations of the incentive compensation band, based on a promissory fraud theory for making false promises to comply when the defendant colleges signed the program participation agreements. The district court noted that compliance with the incentive-compensation ban was "triple conditioned." The district court also noted that Congress attached importance to the ban. The defendant also was alleged to have taken steps to conceal its violations.

61 305 F. Supp. 3d 964 (S.D. Ind. Mar. 30, 2018).

62 308 F. Supp. 3d 56 (D.D.C. Mar. 31, 2018).

63 In *U.S. ex rel. Duffy v. Lawrence Mem'l Hosp.*, 2018 WL 4748345 (D. Kan. Oct. 2, 2018), the relator alleged inaccuracies in patient wait times for certain procedures. The district court dismissed the complaint, finding "no indication" in the plaintiff's materials that the government has refused to pay a claim or reduced compensation to a Medicare participant because of a similar inaccuracy.

On the other side of the spectrum, several courts appear ready to allow suits to proceed to discovery where more facts may be uncovered regarding the government's past payment decisions. In addition to the Sixth Circuit's opinion in *Prather*, in *U.S. v. Select Specialty Hospital–Wilmington, Inc.*, the district court shifted the burden, stating that “nothing in the amended complaint suggests that [the] forgery was immaterial.”⁶⁴ There, a chief nursing officer filed an FCA suit alleging that the hospital where she worked used forged signatures on medical records. The district court held that relator had sufficiently pleaded materiality where she alleged that the government would not have paid the claim and that the government conditions payment on services being “necessary.” This type of analysis appears to rely more on the district court's “common sense” regarding the materiality of potential violations, as opposed to the government's actual behavior in light of a violation. While it may be tempting for courts to fill the gap in this way, doing so runs the risk of turning over enforcement and interpretation of regulatory violations to relators and courts via fraud actions for violations that the applicable government agency never viewed as material to payment.

Subsequent Government Action. Another area of disagreement has been how the government's actions after being made aware of fraud allegations (such as the decision whether to intervene) relate to materiality. The debate stems from *Escobar*'s statement that such actions may be considered when determining materiality.⁶⁵ In *Folliard*, the relator alleged that defendants sold the government Cisco products that originated in non-designated countries, in violation of the Trade Agreement Act.⁶⁶ In dismissing three of the relator's four claims for failure to satisfy the materiality (and scienter) requirement, the district court found it telling that “the government declined to intervene after almost five years of investigation [of the defendants...] has also declined to intervene in similar cases brought by this relator alleging similar fraudulent activity by other companies selling products under GSA contracts to the government.” Further, the district court also noted that the complaint “was filed after the government was fully informed for years about the relator's allegations regarding the defendants' purported role in the fraudulent scheme, is silent as to whether the government took any action whatsoever against the defendants, or took steps to cancel the FSS contracts at issue upon finding out about” the allegedly fraudulent activities.

Likewise, in *U.S. ex rel. Kolchinsky v. Moody's Corp.*, the district court found it significant that when the defendant's alleged fraud was brought to the government's attention, “the Government not only continued to pay Moody's, but also entered into new service contracts.”⁶⁷ In *Kolchinsky*, the relator had alleged that between 2004 and 2007, Moody's artificially inflated credit ratings for residential mortgage-backed securities and collateralized debt obligations

to attract more business. *Kolchinsky* is also notable because the court defended its use of congressional investigations and media reports in determining that the allegations were largely known to the government and were “strong evidence” that the government did not find the defendant's actions material. Ultimately, the court dismissed the relator's complaint.⁶⁸

Likewise, in *U.S. ex rel. Cressman v. Solid Waste Servs., Inc.*,⁶⁹ the district court took a similar approach in granting the defendant's motion for summary judgment in part because the relator had failed to establish that the alleged violation was material to the defendant's contracts. Notably, the district court reasoned that “in the four years since learning of Plaintiff's allegations in this matter, including the regulatory violations asserted and relied upon by Plaintiff, the Department of Justice ha[d] not initiated any proceedings or taken any action against Defendant.” Moreover, similar to the Third Circuit's reasoning in *U.S. ex rel. Petratos v. Genentech*,⁷⁰ the government's declination of intervention was further evidence that it did not consider the violation material.

On the other side of the debate, however, is the Sixth Circuit's decision in *Prather*.⁷¹ There, defendants argued that the government's decision not to intervene illustrated that any alleged violation of the CMS regulations was not material. The Sixth Circuit disagreed, explaining that the government similarly chose not to intervene in *Escobar*, yet the Supreme Court did not mention this factor in its 2016 decision – indicating that it was not a factor to consider in evaluating materiality.

Essence of the Bargain. In last year's Review, we discussed how several courts found materiality satisfied where it was determined that the alleged violation went to “the essence of the bargain” between the defendant and the government. While some courts have continued that trend in 2018, a number of courts have been willing to dismiss FCA actions on a motion to dismiss or at summary judgment on the basis that the alleged violations *do not* go to the essence of the bargain. On their face, however, these decisions do not seem controversial and might indicate a growing comfort with using materiality as a tool to screen unmeritorious FCA actions.

In *U.S. ex rel. Bachert v. Triple Canopy, Inc.*, for example, the relator alleged fraud in connection with the defendant's global contract for providing security services to the State Department where one of the defendant's weapons armorers falsified inspection reports.⁷² The district court granted summary judgment to the defendant, finding that “[e]ven if every weapons inspection by [the armorer] was improper, review of defendant's labor invoices demonstrates that [the armorer's] services accounted for only three-tenths of one percent of the total labor invoice to the government under the Base Contract.” Because reports of a single armorer at

64 2018 WL 1568874 (D. Del. Mar. 30, 2018).

65 136 S. Ct. at 2003-04 (finding that “proof of materiality can include, but is not necessarily limited to” certain factors such as whether “the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position”).

66 308 F. Supp. 3d 56 (D.D.C. Mar. 31, 2018).

67 2018 WL 1322183 (S.D.N.Y. Mar. 13, 2018).

68 Also buttressing the district court's decision was the Statement of Interest filed by the government, stating that its previous prosecution of, and settlement with, Moody's had “no nexus” to the relator's claims. *Id.* at *4.

69 2018 WL 1693349 (E.D. Pa. Apr. 6, 2018).

70 855 F.3d 481 (3d Cir. 2017).

71 892 F.3d 822 (6th Cir. 2018).

72 321 F. Supp. 3d 613 (E.D. Va. 2018).

a single base “are insubstantial in relation to the overall size of the Base Contract, . . . it strains credulity to believe that those inspection reports were a factor in the government’s decision to make payment on the contract.”⁷³

In ***U.S. ex rel. Duffy v. Lawrence Mem’l Hosp.***, the district court dismissed a *qui tam* lawsuit where the relator alleged that the defendant hospital failed to provide anti-fraud training, in violation of certain Medicaid regulations.⁷⁴ In reaching that conclusion, the district court determined that the training did not go to the essence of the bargain between the hospital and the government for the provision of medical services. Notably, the district court reached this conclusion even though the requirements were labeled as conditions of payment.

On the other side of the spectrum, the district court denied the defendant’s motion to dismiss in ***U.S. ex rel. Martino-Fleming v. South Bay Mental Health Center, Inc.***⁷⁵ There, the relator was a former employee of a mental health center who alleged that his employer billed the state Medicaid program even though many staff therapists and supervisors did not meet applicable state licensing requirements. Noting parallels to the factual allegations in *Escobar*, the district court found materiality adequately pleaded because the licensing regulations went “to the heart of the bargain” with the government and because the state Medicaid agency ceased paying the defendants’ claims after learning of the allegations.

Two other cases show that courts are far from uniform in their approach to consideration of the essence of the bargain as it relates to materiality. In ***United States v. Strock***, the district court granted a motion to dismiss FCA claims regarding alleged violations of a Veterans Benefits Act program to support veteran-owned small businesses.⁷⁶ The relator alleged that the civilian owners of the defendant company installed a “figurehead” veteran as an owner of the company to satisfy certain conditions of participation in the funding program. Although the district court acknowledged that the company violated requirements to qualify for the program and although such requirements seemingly were the *sine qua non* of participation in the program, the district court nevertheless found the alleged violations were not material because the requirements were not conditions of payment and there was no allegation that the government had denied other similar claims.

By contrast, the district court found materiality adequately pleaded in ***U.S. ex rel. Millin v. Krause***, where the relator alleged that the defendant misrepresented the individual ownership of a company that submitted claims for farm subsidy payments to the Farm Services Agency.⁷⁷ The district court reasoned that such misrepresentations were material because the ownership requirements were “central to the payment eligibility criteria for farm subsidies” and “the cornerstone to most program eligibility.”

Certification. *Escobar* adopted a two-part test for determining when a plaintiff has pleaded an implied certification claim, but it arguably left open the possibility for additional means by which such claims should be evaluated.⁷⁸ Since that decision, few courts have strayed from its two-part test. As discussed, the Ninth Circuit stuck to that two-part test in ***Rose***.⁷⁹ Likewise, in ***U.S. ex rel. Kelly v. Serco, Inc.***, the district court applied the two-part test and assumed, without discussing, that liability under the FCA’s theory of implied certification is satisfied when the two *Escobar* conditions are met.⁸⁰ The district court determined that the relator had sufficiently pleaded materiality in regards to the alleged forged signatures at issue because “nothing in the amended complaint suggest[ed]” otherwise, and the relator had sufficiently pleaded knowledge because nothing in the complaint suggested that the forged signatures were a mistake or a result of simple negligence.

Implications for Discovery

Under *Escobar*, determining whether compliance with a particular statute, regulation, or contractual provision is material to payment depends not just on how the provision is labeled, but on how the government has enforced the provision in practice. As a result, *Escobar* necessitates substantial discovery from the government regarding its past enforcement and payment practices with respect to the relevant provisions. For intervened cases, this means defendants obtaining party-discovery from the United States. For declined cases, this means relators and defendants seeking discovery through third-party discovery and Touhy requests. Discovery requests in implied certification cases have focused on the government’s knowledge of the allegedly fraudulent scheme, as well as information or documents sufficient to have put the government on notice of any alleged misconduct, such as audits and assessments of a defendant’s performance or claims. Further, some defendants also have had success in seeking discovery from the government regarding its knowledge of conduct by third-parties that is similar to the defendants’ alleged misconduct.

Parties have aggressively pursued discovery from the government related to its knowledge of the alleged misconduct or facts sufficient to put the government on notice of the alleged misconduct.

73 The district court employed similar reasoning in *U.S. ex rel. Daugherty v. Tiversa Holding Corp.*, where it granted the defendant’s motion to dismiss allegations that a single false statement by the defendant could have been material to an eight-year, \$29 million grant from the government to Dartmouth College. 2018 WL 5045336 (S.D.N.Y. Oct. 17, 2018). Even though the defendant’s alleged false statement—that it forged the location in which it had discovered alleged leaked documents to win a cybersecurity monitoring contract from the government—seemed egregious on its face, the district court found the false statement was too attenuated to the overall grant project to have been material.

74 2018 WL 4748345 (D. Kan. Oct. 2, 2018).

75 2018 WL 4539684 (D. Mass. Sept. 21, 2018).

76 2018 WL 647471 (W.D.N.Y. Jan. 31, 2018).

77 2018 WL 1885672 (D.S.D. Apr. 19, 2018).

78 The lack of clarity was noted by at least one district court. In *U.S. ex rel. O’Neill v. Somnia, Inc.*, the district court granted defendants’ motion to dismiss on other grounds, but stated that “precisely what a plaintiff must plead to state an FCA claim based on a theory of implied false certification is subject to some question in the Ninth Circuit” citing *Rose* and that it’s unclear “whether the standard for an implied false certification claim laid out in *Ebeid* remains viable.” 2018 WL 4292234 (E.D. Cal. Sept. 7, 2018) (citing *United States v. Stephens Inst.*, 901 F.3d 1124, 1129–31 (9th Cir. 2018)).

79 See also *U.S. ex rel. Anita Siliingo v. WellPoint et al.*, 904 F.3d 667 (9th Cir. 2018) (similarly applying the strict two-step approach to implied certification).

80 2018 WL 1568874 (D. Del. Mar. 30, 2018).

Government's Knowledge of Defendants' Alleged Fraudulent Scheme. In *Escobar*, the Supreme Court characterized the government's decision to pay "a particular claim in full despite its actual knowledge that certain requirements were violated" as "very strong evidence that those requirements are not material."⁸¹ As a result, parties have aggressively pursued discovery from the government related to its knowledge of the alleged misconduct or facts sufficient to put the government on notice of the alleged misconduct.

At the broadest level, defendants have sought documents or information regarding when certain government officials became aware of the facts or information that serve as the basis for the FCA allegations.⁸² Defendants also typically hone their discovery requests to focus more specifically on the government's knowledge of facts relevant to the particular fraudulent scheme alleged by the government and whether the government continued to pay claims after it became aware of the alleged noncompliance. For example, in FCA cases based on AKS violations, defendants have sought information on the date the government became aware of the allegedly inappropriate relationships.⁸³

Defendants also frequently request information or documents that may have alerted the government to the alleged noncompliance, such as audits and related correspondence. In the healthcare context, defendants frequently request information and documents regarding reviews or audits of the defendants' claims by Medicare contractors.⁸⁴

In at least one case, during discovery negotiations the defendants successfully obtained the underlying documents on which the relevant audit was based, which reflected information regarding the government's decision to pay a claim. In *United States v. DynCorp International LLC*, the defendant sought to compel production of cancelled audit reports and related correspondence and work papers regarding the contract at issue. The audit was ultimately "canceled even though it was nearly complete because the Government determined that the Contracting Officer did not rely upon the [pricing] data submitted by [the defendant] in deciding to award" the contract to the defendant. As the defendant explained, "[t]he fact that the Contracting Officer did not rely upon [the pricing] data submitted by [the defendant] is highly relevant to the Government's FCA claims against [the defendant] as it may preclude showings of falsity and materiality"⁸⁵ While DOJ initially asserted the deliberative process privilege over documents related to the draft audit, it ultimately agreed to produce these documents.⁸⁶

Government's Knowledge of Conduct at Issue in Similar Circumstances. *Escobar* opened the door for discovery into similar conduct beyond the allegations against a specific defendant in a specific case by explaining that "if the Government regularly pays a particular type of

claim in full despite actual knowledge that certain requirements were violated, that is strong evidence that the requirements are not material."⁸⁷ As a result, defendants have sought discovery related to the government's knowledge of circumstances related to conduct similar to the alleged misconduct, even when the requests pertain to other circumstances or parties that are not at issue in a particular case.

In *U.S. ex rel. Dean v. Paramedics Plus LLC*, the government alleged that certain profit-cap agreements between Emergency Medical Services Authority (EMSA), an ambulance service company, and Paramedics Plus, an ambulance owner, for services in Oklahoma violated the federal AKS, and thus, that Paramedics Plus violated the FCA by falsely certifying compliance with the AKS.⁸⁸

During the course of discovery, Paramedics Plus filed a motion to compel the government to respond to a number of discovery requests relating to other situations involving profit caps between a provider and third party, including other providers, third-parties and arrangements not at issue in the case.⁸⁹ First, Paramedics Plus sought information related to claims paid to EMSA after the government learned about a profit-cap arrangement with another ambulance services provider that was not at issue. The government objected to this interrogatory on the grounds that it sought information that was not relevant because it "concerns a different ambulance contractor not a party to the United States' claims" and "an ambulance contract not at issue in the case."

Paramedics Plus also issued interrogatories seeking similar claims data regarding an agreement between itself and two municipal ambulance owners (Pinellas County EMSA and Alameda County EMSA) who had been named in the relator's original complaint, but had previously entered a settlement with the government and were not defendants in the litigated matter. The government objected to the interrogatories on the basis that the information sought was not relevant because it concerned "conduct not at issue in this action from a municipal entity" located outside Oklahoma, where services were provided under the contract at issue.

Finally, Paramedics Plus issued a broad interrogatory seeking information on "any instance" in which a claim for reimbursement was denied because "the medical provider had entered into a profit-cap agreement with a third-party contractor." Again, the government objected, in part, because the "information sought relates to conduct not at issue in this action." The government also responded that it denied reimbursement for claims tainted by potential AKS violations resulting from profit-cap arrangements and offered the settlement with Pinellas EMSA as an example of a denial of payment associated with profit-cap arrangements.

81 136 S. Ct. at 2003.

82 See, e.g., *DynCorp International LLC's First Set of Requests for the Production of Documents to United States at 7, United States v. DynCorp International LLC*, No. 1:16-cv-01473 (D.D.C.) (Dkt. No. 59-3) (requesting documents relating to "the date when facts material to the Complaint of the Government's right of action were known or reasonably should have been known" to various government officials and agencies).

83 See, e.g., *United States' Responses & Objections to Defendant Dent's First Set of Requests for Admission to Plaintiff United States of America at 23-24, United States ex rel. Lutz v. Berkeley Heartlab, Inc.*, No. 9:14-cv-230 (D.S.C.) (Dkt. No. 680-1).

84 See, e.g., *Def. HCR ManorCare, Inc.'s First Request for Production of Documents to United States of America at 16, United States ex rel. Ribik v. Manor Care, Inc.*, No. 1:09-cv-13 (E.D. Va.) (Dkt. No. 207-1) ("All communications between you and a Medicare Contractor regarding any Claims Review, medical review, audit, investigation, or inquiry of Defendants' claims submissions.").

85 See *Def. Dyncorp Int'l LLC's Mem. in Support of Mot. to Compel at 35, No.1:16-cv-01473 (D.D.C.)* (Dkt. No. 59-1).

86 *United States' Opp. to Dyncorp Int'l LLC's Mot. to Compel at 22-23, No.1:16-cv-01473 (D.D.C.)* (Dkt. No. 60).

87 136 S. Ct. at 2003-04.

88 See *Compl. of the United States in Partial Intervention*, No. 4:14-CV-203 (E.D. Tex.) (Dkt. No. 28).

89 2018 WL 620776 (E.D. Tex. Jan. 30, 2018).

The district court held that the information sought by Paramedics Plus was relevant. The government argued that the issue was whether certification of compliance with the AKS was material to the government's decision to pay, not whether the profit-cap arrangements were material to the payment decision. The district court agreed that "the issue at hand is whether certification of compliance with AKS is material," but relying on *Escobar*, it held that "evidence of the government's continued payment after discovery of a profit cap will likely lead to information about whether these specified entities certified compliance." Consequently, the district court ordered the government to respond to the interrogatories. Notably, the district court specifically did not address the government's argument that the interrogatories sought information regarding parties and agreements that were not at issue in the case. The district court's silence on this issue potentially paves the way for defendants to seek wide-ranging discovery regarding the government's payment decisions involving similar conduct, including by third-parties not at issue in the litigation.

Similarly, in *DynCorp*, the defendant had sought documents regarding comparative data from non-State Department contracts that reflected market prices for the labor and lodging at issue. Because the action involved allegations related to the reasonableness of subcontract prices for these services, defendants argued that such information would be relevant not only to materiality, but also to falsity and damages. The government seemingly acknowledged the relevance of such information,⁹⁰ but nevertheless objected to the requests as overly burdensome and disproportionate to the needs of the case. Thus, in cases that have addressed discovery requests that seek information from the government regarding similar conduct involving third parties outside the scope of a particular case, to limit the scope of discovery, the government may need to rely on arguments regarding burden and proportionality, rather than claiming broad categories of responsive information are not relevant to the allegations.

DEVELOPMENTS IN PLEADING STANDARDS

Pleading Details of a Fraudulent Scheme

FCA defendants continued to test the sufficiency of relators' complaints on the grounds that they lacked the requisite level of detail to satisfy Rule 9(b) of the Federal Rules of Civil Procedure. Generally speaking, courts agree that in order to pass muster, FCA complaints must include all of the details one would expect to find in the first paragraph of a newspaper article that is, the "who, what, when, where and how" of the alleged fraud.⁹¹ While meeting this standard may seem simple enough, courts continued to grapple with the nuances and difficulties associated with pleading fraud with the requisite specificity.

As to the "who" component, a number of courts dismissed complaints that impermissibly grouped the defendants together without identifying the conduct attributable to each alleged bad actor.

For instance, in *U.S. ex rel. Hendrickson v. Bank of Am.*, the district court dismissed an FCA complaint where the relator, a former OIG investigator for the Office of Veterans Affairs, failed to distinguish among the 16 individual banks accused of defrauding the government by ignoring Death Notification Entries and unlawfully retaining benefits payments for deceased beneficiaries.⁹² Similarly, the district court in *U.S. ex rel. Schiff v. Norman*, dismissed FCA allegations against two dermatology practices, the owner of the practices and his wife who supervised billing because the relator "lump[ed] together" all of the defendants and failed to specify what fraudulent conduct each was alleged to have committed.⁹³

With respect to the "how" or "what" elements, courts continued to hold that allegations of a fraudulent scheme to defraud the government must be linked to claims actually submitted in furtherance of that scheme.

Carving out an exception to this rule, the Ninth Circuit in *U.S. ex rel. Silingo v. WellPoint, Inc.*, held that a complaint need not distinguish between defendants who had the exact same role in an alleged scheme.⁹⁴ The Ninth Circuit drew an analogy to "chain" and "wheel" conspiracies, explaining that if a fraud scheme resembles a chain conspiracy – where each defendant is responsible for a distinct act within an overall plan – then a complaint must separately identify which defendant was responsible for what distinct part of the plan, but if the scheme resembles a wheel conspiracy – where a single defendant (the "hub") separately agrees with two or more

other members (the "spokes") to carry out similar tasks – then any "parallel actions" of the "spokes" can be addressed by collective allegations. Similarly, the district court in *U.S. ex rel. Gugenheim v. Meridian Senior Living, Inc.*, denied a motion to dismiss against 48 LLC defendants, reasoning that the relevant reimbursement policy had been put into place by their common member-manager.⁹⁵

With respect to the "how" or "what" elements, courts continued to hold that allegations of a fraudulent scheme to defraud the government must be linked to claims actually submitted in furtherance of that scheme. For instance, in *U.S. ex rel. Roycroft v. Geo Group, Inc.*, the relator alleged that a residential drug and alcohol treatment center billed for group counseling services that were not actually provided and falsely certified compliance with statutory and regulatory requirements by failing to disclose that it did not provide enough addiction services each week. While the Sixth Circuit acknowledged the relator detailed a fraudulent billing scheme and even identified representative claims, it affirmed the dismissal of the complaint because it failed to identify what was false about each of the representative claims, so as to connect them to the broader scheme.⁹⁶

90 See, e.g., Def. DynCorp Int'l LLC's Mem. in Support of Mot. to Compel at 19-20, No.1:16-cv-01473 (D.D.C. July 6, 2018) (Dkt. No 59-1) (discussing government's agreement to produce certain documents for comparable contracts); *id.* at 21-22 (including government's response that it would produce or make available certain non-privileged documents responsive to this request).

91 The "first paragraph" standard for pleading fraud was first announced in *DiLeo v. Ernst & Young*, 901 F.2d 624, 627 (7th Cir. 1990).

92 2018 WL 5313932 (N.D. Tex. Oct. 26, 2018).

93 2018 WL 264253 (M.D. Fla. Jan. 2, 2018).

94 904 F.3d 667 (9th Cir. 2018).

95 2018 WL 1463347 (E.D.N.C. Mar. 23, 2018).

96 722 F. App'x. 404 (6th Cir. 2018).

However, at least one district court held that a relator need not always describe the particular statute or regulation violated by the defendant in submitting the claims at issue. In **U.S. ex rel. Morgan v. Champions Fitness, Inc.**, the district court held that where the relator alleged that the submitted claims were “factually false” – in that they were submitted for services not actually provided – rather than “legally false” – in that they were wrongfully certified to be in compliance with a certain statute or regulation – Rule 9(b) did not require the relator to allege that the defendant violated any specific regulation, nor did it require a description of the regulation in the complaint.⁹⁷

Pleading Submission of False Claims

Pleading Actual Claims. As in years past, many courts continued to require FCA plaintiffs to identify false claims that were actually submitted to the government for payment.

In dismissing a relator’s complaint for failure to satisfy Rule 9(b), one district court laid out the level of detail it would expect to see regarding the submission of actual false claims. In **U.S. ex rel. Wollman v. General Hospital Corporation**, the district court held the relator made insufficient allegations of actual claims submitted as part of a fraudulent billing scheme involving overlapping surgeries when she included “no dates, identification numbers, amounts, services, individuals involved, or length of time” for any of the surgeries at issue.⁹⁸

Even in circuits where courts do not require relators to allege the submission of actual claims, they generally impose such a requirement when the scheme alleged by the plaintiff could have led, but did not necessarily lead to the submission of false claims. For instance, the district court in **U.S. ex rel. Campos v. Johns Hopkins Health System Corp.** dismissed a complaint that alleged fraud had resulted from the defendant’s practice of assigning in-state patients a lower waitlist priority code because the relator could not point to a single actually fraudulent claim submitted in furtherance of that scheme.⁹⁹ The district court reasoned that at least some patients’ waitlist codes must have matched their true priority status, since high priority codes were assigned only on the basis of clinical need. Going further, the district court held that the relator was not entitled to use discovery to uncover an actual fraudulent claim.

Alternatives to Pleading Actual Claims. Several courts continued to apply the Fifth Circuit’s so-called “Grubbs standard,” under which a relator is not required to provide a representative false claim that was actually submitted to the government, so long as the relator has provided “reliable indicia” leading to a “strong inference” that such claims were actually submitted.¹⁰⁰

While this standard is less demanding than that required by other circuits, courts continue to require more than speculation, general estimates, or so-called logical conclusions. In

U.S. ex rel. Solis v. Millennium Pharm., Inc., the Ninth Circuit affirmed the dismissal of allegations that a pharmaceutical company fraudulently promoted one of its cardiovascular drugs. Though the relator alleged that Millennium had attempted to get its drug placed on formulary at two hospitals, he failed to identify a single claim submitted pursuant to that scheme, nor did he provide “reliable indicia supporting a strong inference that such claims were submitted.”¹⁰¹

In **U.S. ex rel. Petrowski v. Epic Systems Corp.**, the district court dismissed the relator’s allegations that the defendant’s billing software allowed hospitals to set up their anesthesia billing to improperly include excessive charges, explaining that allegations that the software *could* be used to defraud Medicare were “woefully deficient because [they are] based on pure speculation.”¹⁰² In **U.S. ex rel. Park v. Legacy Heart Care, LLC**, the district court held that the relator’s “estimates” based on his experience working for the defendants that “80%” of patients were Medicare patients and that “80%” of them did not meet the diagnostic criteria, were insufficient to create a “strong inference” that fraudulent claims were actually submitted to the government.¹⁰³ The district court in **U.S. ex rel. Grubea v. Rosicki, Rosicki & Assocs., P.C.**, likewise rejected an FCA claim alleging submission of excessive mortgage servicing charges when the plaintiff could allege only “sixty-odd examples of excessive charges” without any details about what proportion of the defendant’s total claims the given examples represented or whether any of the examples had actually been submitted to the government.¹⁰⁴

First-hand knowledge of a defendant’s billing practices and claims submissions will satisfy the *Grubbs* standard; however, courts have also permitted relators to plead “on information and belief” in cases where the details regarding the submission of claims are “peculiarly within a defendant’s knowledge and control.” For instance, in **U.S. ex rel. Vatan v. QTC Medical Servs.**, the Ninth Circuit reversed the district court’s dismissal of allegations of false claims and certifications when the specifics of the defendant’s contractual requirements with the VA were made on information and belief. The Ninth Circuit noted that under the district court’s ruling, many FCA claims would be barred if the relator alleged insider knowledge of wrongdoing, but lacked “access to corporate documents outlining the precise nature of the company’s obligations.”¹⁰⁵ Similarly, in **U.S. ex rel. Scalamogna v. Steel Valley Ambulance**, the district court allowed a relator’s claims to proceed where she alleged that all billing decisions were made by the owner and CEO of the company, while at all times during her employment she was an EMT and driver.¹⁰⁶

Courts have also permitted individuals intimately connected with the provision of services, but not the submission of claims for those services, to plead on information and belief that claims were submitted. For instance, in **U.S. ex rel. Ailabouni v. Advocate Christ Medical Center**, the district court excused a resident physician who was able to identify false certifications by

97 2018 WL 5114124 (C.D. Ill. Oct. 19, 2018).

98 2018 WL 1586027 (D. Mass. Mar. 30, 2018).

99 2018 WL 1932680 (D. Md. Apr. 24, 2018).

100 See, e.g., *U.S. ex rel. Class v. Bayada Home Health Care, Inc.*, 2018 WL 4566157 (E.D. Penn. Sept. 24, 2018).

101 885 F.3d 623 (9th Cir. 2018).

102 2018 WL 1027147 (M.D. Fla. Feb. 6, 2018).

103 2018 WL 5313884 (N.D. Tex. Oct. 26, 2018).

104 318 F. Supp. 3d 680 (S.D.N.Y. 2018).

105 721 F. App’x. 662 (9th Cir. 2018).

106 2018 WL 3122391 (W.D. Penn. June 26, 2018).

attending physicians about the unavailability of a qualified resident from the requirement of pleading an actual claim. The district court did not require the relator to point to additional information about claims submission because his position “does not appear to include regular access to medical bills.”¹⁰⁷

DEVELOPMENTS REGARDING FALSITY

Objective Falsity in Medical Necessity Cases

In recent years, healthcare providers have increasingly faced civil and criminal enforcement actions premised on the allegation that services billed to government healthcare programs were not medically necessary. As a result, those claims allegedly have constituted fraud in violation of the FCA and/or various criminal statutes.

These actions – whether brought by the government in civil or criminal proceedings or *qui tam* relators in civil FCA cases – pose significant issues for providers. Often, disputing clinical judgments related to care or services provided many years in the past can be particularly challenging when efforts are made by the government or relators to use statistical sampling to establish civil liability and/or damages across a vast universe of claims. Given the risks associated with these cases, it is not surprising that there have been a number of high-dollar civil settlements involving medical necessity allegations against providers, including hospitals, physicians, and providers of hospice, home health, and therapy services. In criminal cases, the government likewise has secured a number of high-profile convictions and guilty pleas in cases challenging billing associated with allegedly unnecessary medical procedures.

In the face of such allegations, providers have made considerable headway in challenging the underlying fraud theory by arguing that claims for reimbursement for medical procedures or services cannot be false or fraudulent if the theory of wrongdoing is based on nothing more than a difference of opinion as to the propriety of the clinical judgment exercised by the provider. In a number of recent opinions, district courts have been receptive to the argument that such fraud claims should be dismissed, particularly where there is no evidence or factual allegations of conduct that could be characterized as resulting in objectively false claims. Two recent appellate decisions, however – one in a criminal action and the other in a civil FCA action – have blunted that argument and, in the process, potentially reinvigorated enforcement actions based on a theory of liability that had appeared to be losing steam.

In ***United States v. Paulus***, the Sixth Circuit reversed the district court’s decision setting aside a guilty verdict against a cardiologist, who was charged with committing healthcare fraud and making false statements by exaggerating the extent of artery blockages so that he could perform and bill for unnecessary procedures.¹⁰⁸

Before the district court, both the government and the cardiologist agreed that interpreting angiograms amounted to a subjective exercise. The government’s proof showed that cardiologists assessing the degree of stenosis in a given angiogram can vary by up to 20%.

The government offered proof, however, that the cardiologist at issue had performed far more angiograms than his colleagues, billed Medicare for more of these procedures than anyone else in the country, and routinely diagnosed his patients with more stenosis or blockage than their angiograms showed to exist. In his defense, the cardiologist put on evidence of significantly higher variations in assessing the degree of stenosis and argued that he could not have been committing fraud when exercising his judgment in interpreting the amount of stenosis shown by angiograms given the inherent subjectivity at play.

Following the jury’s guilty verdict, the district court set aside that verdict and entered a judgment of acquittal because the district court determined that the government had failed to prove fraudulent intent or false statements on the part of the cardiologist. The district court explained that the degree of stenosis “is a subjective medical opinion, incapable of confirmation or contradiction.” According to the district court, evidence at trial showed that interpreting angiograms is a difficult exercise and that cardiologists frequently disagree about the degree of blockage shown. Because the interpretations could not be “subject to proof or disproof,” the district court concluded that they could not be false or fraudulent.

The Sixth Circuit reversed, holding “[t]he degree of stenosis is a fact capable of proof or disproof. A doctor who deliberately inflates the blockage he sees on an angiogram has told a lie; if he does so to bill a more expensive procedure, then he has also committed fraud.” Whether this had occurred with respect to the cardiologist at issue was a question reserved for the jury.

The Sixth Circuit noted that opinions – such as those held by a provider performing allegedly medically unnecessary procedures – may trigger liability for fraud when they are not honestly held or when the speaker knows facts that are fundamentally incompatible with his or her opinions. The Sixth Circuit explained that while a doctor could never be faulted for misreading an angiogram, the government claimed something very different in presenting its case; namely, that the cardiologist “repeatedly and systematically saw one thing on the angiogram and consciously wrote down another, and then used that misinformation to perform and bill unnecessary procedures.” Though the cardiologist argued that he acted in good faith and the government was unfairly second-guessing his medical judgment, the jury reached the opposite conclusion, and there was evidentiary support for that result. The Sixth Circuit also pointed to a plethora of evidence of fraudulent intent – the cardiologist’s huge billing numbers, enormous salary and testimony from injured patients, among other things – as supporting the jury’s conclusion that the cardiologist was fraudulently over-diagnosing his patients and overbilling for unnecessary procedures.

While the Sixth Circuit’s opinion in ***Paulus*** tackled these issues in the context of a criminal prosecution, there is no reason to expect that its reasoning would not apply equally in FCA cases challenging medical necessity. In fact, the Tenth Circuit adopted nearly identical reasoning in an opinion issued shortly after ***Paulus***. In ***U.S. ex rel. Polukoff v. St. Mark’s Hospital***, where a cardiologist was accused of fraudulently billing Medicare for allegedly performing medically unnecessary procedures, the district court dismissed the action, concluding that subjective medical opinions, such as those concerning the reasonableness and necessity of the procedures

¹⁰⁷ 2018 WL 1916670 (N.D. Ill. Apr. 23, 2018).

¹⁰⁸ 894 F.3d 267 (6th Cir. 2018).

at issue, could not be objectively false for purposes of pleading falsity in connection with FCA claims. (Notably, the district court in *Paulus* cited the district court's opinion in *Polukoff*, among other similar cases, in support of its opinion setting aside the jury's guilty verdict.¹⁰⁹)

The Tenth Circuit reversed, holding that it is possible for a medical judgment to be false or fraudulent under the FCA and explaining “that a doctor’s certification for the government that a procedure is ‘reasonable and necessary’ is ‘false’ under the FCA if the procedure was not reasonable and necessary under the government’s definition of the phrase.”¹¹⁰ Noting the potentially far-reaching ramifications of such a broad pronouncement, the Tenth Circuit cited the Supreme Court’s opinion in *Escobar* for the notion that the FCA’s rigorous materiality and scienter requirements should abate concerns about open-ended liability.

According to the Tenth Circuit, because the relator alleged that the cardiologist performed unnecessary procedures and knowingly submitted false certifications to the government that such procedures were necessary, all to obtain federal reimbursement, the relator pleaded sufficient facts to state an FCA claim and survive a motion to dismiss. Similarly, the relator adequately stated false certification claims against two hospitals where the procedures at issue were performed, since there were allegations that both entities submitted claims for hospital charges certified as complying with Medicare requirements.

Following the district courts’ respective opinions in *Paulus* and *Polukoff*, it certainly appeared that the tide might be shifting in favor of providers defending medical necessity cases, particularly given the inherent subjectivity in clinical decisions about the amounts and types of treatment and services patients might need. The appellate courts’ reversals of those opinions, however, appear to have stemmed that tide for the time being. Appeals still pending in a number of cases – including cases such as *U.S. ex rel. Paradies v. Aseracare, Inc.* (appeal pending of entry of summary judgment for provider in case challenging medical necessity of hospice care following trial on question of falsity), and *U.S. ex rel. Ruckh v. CMCII, LLC* (appeal pending of judgment setting aside jury verdict of \$347 million against nursing home chain for failure to establish materiality under *Escobar*) – ultimately may dictate whether civil and criminal healthcare fraud cases challenging the medical necessity of procedures billed to federal healthcare programs truly stand on firmer ground or are merely on momentarily shifting sands.

Express and Implied Certification

Courts continued to closely examine how relators describe and plead theories of falsity. Generally, relators pleading falsity have characterized their allegations as supporting theories of factual or legal falsity. Factual falsity arises when a claim is false because it either contains an incorrect description of the goods provided or is a request for reimbursement for goods that were never provided. By contrast, legal falsity occurs when a submitted claim certifies compliance (either expressly or impliedly) with a material statutory, regulatory or contractual provision.

In *U.S. ex rel. Campos v. Johns Hopkins Health Sys. Corp.*, the district court concluded that a defendant’s express certifications, including certifications that the defendant had complied with “applicable Medicare and/or Medicaid laws, regulations, and program instructions,” and “provided enough information to allow the government to ‘make an informed eligibility and payment decision,’” were not false.¹¹¹ The relator had alleged that Johns Hopkins had prioritized out-of-state patients instead of in-state patients in violation of a government contract, but had importantly failed to “point to a single material term of the [contract] that [the defendant] violated.” Without an underlying contractual violation, none of the defendant’s alleged express certifications was false. Likewise, in *U.S. ex rel. Kietzman v. Bethany Circle of King’s Daughters of Madison, Indiana, Inc.*, the district court rejected a relator’s reliance on an alleged express legal falsity, holding that the complaint never alleged “that, by regulation or contract, the [defendant, a radiology service provider,] specifically and expressly certified to Medicare that it would provide only proper and necessary radiological scans.”¹¹²

In *U.S. ex rel. Piacentile v. Snap Diagnostics, LLC*, the district court concluded that defendants impliedly “represented that [sleep apnea] tests were medically necessary” when they submitted claims for unnecessary sleep apnea testing that, according to Medicare guidance, would only be covered if the testing was medically necessary.¹¹³ The district court in *U.S. ex rel. Folliard v. Comstor Corp.* reached a similar result under the implied false certification theory.¹¹⁴ There, the district court held that defendants sold goods to the United States “with implied false certifications” because those goods violated contractual terms requiring compliance with the Trade Agreement Act and its implementing regulations. In doing so, the district court observed that allegations “that the contractor withheld information about its noncompliance with material contractual requirements” are sufficient to state an implied false certification FCA claim.

In *U.S. ex rel. Marsteller v. Tilton*, the Eleventh Circuit vacated a district court’s conclusion reached prior to *Escobar* that a defendant’s alleged implicit certification of general compliance with the Contractor Code of Business Ethics and Conduct and the Truth in Negotiations Act could not sustain a materially false FCA claim.¹¹⁵ Relators broadly alleged that “defendants’ implicit promise of compliance [with those ethics standards] had influenced the Government’s initial decision to enter into the contracts and its later decision to pay out claims” for the purchase and support of military helicopters. The Eleventh Circuit concluded that the district court should reexamine relators’ false certification claims in light of *Escobar* and allow relators an opportunity to replead those claims.

By contrast, the district court in *U.S. ex rel. Potter v. CASA de Maryland* concluded that defendants’ alleged violations of a certification of compliance “with ‘applicable requirements’ of federal law and regulations” were insufficient to demonstrate falsity.¹¹⁶ While the relator alleged that defendants’ I-9 forms were deficient and that the defendants had “certified ... compliance with *applicable* conditions for federal funding,” the relator needed to allege more; that is, the relator needed to allege “how [defendants’] certifications relate, refer, or are at

109 2017 WL 237615 (D. Utah Jan. 19, 2017).

110 895 F.3d 730 (10th Cir. 2018).

111 2018 WL 1932680 (D. Md. Apr. 24, 2018).

112 305 F. Supp. 3d 964 (S.D. Ind. 2018).

113 2018 WL 2689270 (N.D. Ill. Jun. 5, 2018).

114 308 F. Supp. 3d 56 (D.D.C. 2018).

115 880 F.3d 1302 (11th Cir. 2018).

116 2018 WL 1183659 (D. Md. Mar. 6, 2018).

all connected to properly executed I-9s or even compliance with federal immigration laws.” Because the relator had not alleged “that the scope of compliance” certified to by defendant “incorporate[d] the adequacy of I-9 documentation,” the district court held that the relator had failed to sufficiently allege falsity under *Escobar*.

MEDICAL RECORDS/HITECH

Incentive payments associated with the use of electronic medical record (EMR) systems continue to be an area of scrutiny following a \$155 million settlement announced in *U.S. ex rel. Delaney v. eClinicalWorks LLC* in 2017. That settlement involved allegations that stemmed from the government’s Meaningful Use Program, which incentivizes healthcare providers to make use of EMR technology through monetary incentives for submitting claims for payment that make “meaningful use” of certified EMR technology. To become certified, EMR vendors such as eClinicalWorks must submit their software for testing. When the provider then submits claims for payment using such technology, the provider must certify that they made “meaningful use” of *certified* technology. In the case of eClinicalWorks, the complaint alleged the eClinicalWorks purposefully manipulated the test results, thereby causing providers who used the software to unknowingly submit false claims when the providers certified that eClinicalWorks software used was properly certified.¹¹⁷

The eClinicalWorks matter did not end, however, with the 2017 settlement. As part of the settlement agreement, eClinicalWorks entered a five-year CIA. On July 18, 2018, CMS announced that eClinicalWorks had “paid a stipulated penalty of \$132,500 for failure to comply with its obligation to report Patient Safety Issues as Reportable Events,” as required by the CIA.¹¹⁸ The company has also faced class action claims brought by customers, some of whom have had to forfeit their meaningful use incentive payments and could not collect future payments,¹¹⁹ and the estate of a cancer patient, which alleged the patient died because the medical records failed to display accurately and prevented him from reliably determining when his cancer symptoms appeared.¹²⁰

While other meaningful use investigations have yet to be resolved, the issue remains a focus for regulators. Estimating that CMS has inappropriately paid at least \$729 million in EHR incentive payments to providers who did not meet meaningful use requirements, last year CMS reiterated a prior recommendation from June 2017 to “include stronger program integrity safeguards to modifications of EHR meaningful use requirements to allow for more consistent verification of reporting of required measures.”¹²¹ And, at least one healthcare provider has disclosed that it has received a Civil Investigation Demand (CID) regarding its adoption of EHR technology and the meaningful use program.¹²² Consequently, we anticipate seeing additional enforcement activity related to meaningful use over the next few years.

Relators have struggled, however, to pin liability on software providers in cases alleging fraudulent documentation or billing schemes. In *U.S. ex rel. Petrowski v. Epic Systems Corp.*, the relator’s second amended complaint alleged Epic’s EMR software incorrectly billed anesthesia charges and resulted in double-billing. The district court held that the complaint failed “the most basic test for Rule 9(b) particularity” because it did not identify any representations by Epic that caused the submission of false claims, much less provide any supporting details about the representation or relevant claims. In dismissing the complaint with prejudice, the court concluded the allegations were based on “pure speculation” that “Epic’s software *could* be used in such a way that would allow its hospital customers to generate bills that cause the Medicare program to double pay for certain aspects of professional anesthesia services.”¹²³

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In *U.S. ex rel. Olcott v. Southwest Home Health Care, Inc.*, the district court similarly granted a software provider’s motion to dismiss a relator’s complaint with prejudice.¹²⁴ The relator alleged that Southwest and its medical director submitted false claims by creating false medical records and submitting claims for care that was not provided or submitted multiple bills for the same care. The relator claimed Southwest began submitting false claims prior to purchasing billing software from Kinnser Software and, after purchasing Kinnser’s software, continued to do so with the “knowledge and consent of Kinnser or at the direction of Kinnser.” The district court concluded that the relator had failed to allege that Kinnser caused the submission of a false claim because the complaint alleged “Southwest and [the medical director] would have been submitting fraudulent claims to Medicare even if Southwest had not purchased Kinnser’s software.” Furthermore, the complaint lacked any allegation that Kinnser’s representative to Southwest directed any part of the fraudulent conduct or that Kinnser was aware of the representative’s knowledge or role in the fraudulent conduct and the complaint failed to identify any patient whose records were fraudulently changed by Kinnser’s representative or at her direction. As a result, the district court dismissed the complaint because it failed to state a plausible claim under the FCA.

117 <https://www.justice.gov/opa/pr/electronic-health-records-vendor-pay-155-million-settle-false-claims-act-allegations>.

118 <https://oig.hhs.gov/fraud/enforcement/ciae/stipulated-penalties.asp>.

119 See *Tot v. eClinical Works LLC*, No. 1:18-cv-11658 (D. Mass. Aug. 6, 2018) (Dkt. No. 1).

120 See *Carrollton Family Clinic, LLC v. eClinicalWorks, LLC*, No. 1:17-cv-12530 (D. Mass. Dec. 21, 2017) (Dkt. No. 1).

121 <https://oig.hhs.gov/reports-and-publications/compendium/files/compendium2018.pdf>.

122 <https://www.sec.gov/Archives/edgar/data/1108109/000119312518229648/d497838d10q.htm>.

123 2018 WL 1027147 (M.D. Fla. Feb. 6, 2018).

124 2018 WL 4568635 (N.D. Okla. Sept. 24, 2018).

DEVELOPMENTS REGARDING KNOWLEDGE AND SCIENTER

To prevail in FCA cases, relators or the government must prove the defendant acted with the requisite level of knowledge in connection with the underlying conduct that allegedly resulted in the submission of false claims. That requirement may be satisfied if it is shown the defendant acted with actual knowledge, deliberate indifference, or reckless disregard.

In recent years, courts have taken a critical look at whether particular circumstances would allow a showing of knowledge as a matter of law in a number of cases. Last year, however, fewer cases tackled the issue of knowledge with respect to FCA claims than in prior years. But, one district court case did consider whether a relator adequately pleaded knowledge with respect to five separate fraud schemes. In *U.S. ex rel. Riedel v. Boston Heart Diagnostics Corp.*, the relator alleged that Boston Heart, a laboratory specializing in lipid testing, violated the FCA by engaging in illegal kickback schemes and performing and billing the government for medically unnecessary tests ordered through its test panels.¹²⁵ The wide-ranging kickback schemes allegedly involved: (1) waiving patient co-payments and deductibles for physicians who would send all of their lipid-related business to Boston Heart; (2) paying physicians inflated packaging fees, in excess of the actual cost to ship specimens to Boston Heart; (3) performing and billing the government for lab tests ordered by physicians who were Boston Heart shareholders in violation of the Stark Law; and (4) paying “outrageous” consulting fees to referring physicians.

The district court thoroughly examined the question of knowledge with respect to each of the alleged schemes. As to Boston Heart’s alleged kickback schemes, the relator – who was a former board member of Boston Heart – alleged that he had sent three letters to Boston Heart’s Board of Directors warning it of the potential liability issues related to the schemes at issue, but received no response. The district court characterized those letters as evidence of *relator*’s knowledge and not Boston Heart and, therefore, found those letters did not support the conclusion that the relator sufficiently pleaded knowledge.

The relator also offered factual allegations regarding each of the specific fraud schemes. As to the co-payment and deductible waivers, the relator alleged that Boston Heart changed its practice of waiving co-payments and deductibles after DOJ intervened in FCA litigation against Berkeley Heart Laboratories involving the same alleged conduct and settled FCA allegations with two other Boston Heart competitors. According to the relator, Boston Heart implemented a new practice with respect to co-payments and waivers that relied on a fee schedule and that this conduct

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constituted an effort to avoid detection of its waiver practice by DOJ. The district court found these allegations sufficient to plead knowledge.

The relator also alleged that Boston Heart had knowledge that its inflated packaging fees paid to physicians would induce the physicians to increase referrals to Boston Heart. This knowledge was reflected by Boston Heart’s actions in response to an OIG Special Fraud Alert that the labs’ payments of packaging fees could constitute illegal remuneration in violation of the AKS. Boston Heart allegedly changed its conduct by using third parties to make the payments to physicians’ staff and families, rather than payment directly to physicians. The relator also alleged that Boston Heart’s CEO and two board members were involved in the decision to pay packaging fees to physicians. These allegations sufficiently pleaded knowledge according to the district court.

The relator failed to sufficiently plead knowledge with respect to the remaining two schemes involving physician self-referrals in violation of the Stark Law and the alleged performance of medically unnecessary testing. As to the former scheme, the district court concluded that the relator failed to allege that Boston Heart knew it received referrals from physicians who were Boston Heart shareholders apart from the letters sent by relator to the board. As to the latter scheme involving medically unnecessary testing, the district court concluded that the relator failed to allege facts that Boston Heart knew the additional tests were medically unnecessary.

REVERSE FALSE CLAIMS

Under the “reverse false claim” provision of the FCA, 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 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.

Contingent Payment Obligations

As we noted in last year’s Review, courts consistently emphasized that “obligation[s]” that are *contingent* on future acts or events do not support liability under the FCA’s reverse false claims provision, which requires there be an “established duty” before reverse false claims liability may arise. Several noteworthy decisions this year have continued to emphasize this distinction.

In *U.S. ex rel. Grubea v. Rosicki, Rosicki & Assocs., P.C.*, the district court held that the relator plausibly alleged a reverse false claims violation where the defendant loan servicer’s claims allegedly caused Fannie Mae and Freddie Mac to reimburse hundreds of thousands of dollars in inflated foreclosure expenses, thereby causing a reduction in the amount of money these entities paid the Treasury Department under their Stock Purchase Agreement (SPA).¹²⁶ The SPA gave the Treasury the right to receive quarterly dividends from Fannie Mae “when, as and if declared by [Fannie Mae]’s Board of Directors, in its sole discretion.” Thus, the defendant argued Fannie Mae did not have an “obligation” within the meaning of the FCA,

¹²⁵ 332 F. Supp. 3d 48 (D.D.C. 2018).

¹²⁶ 318 F. Supp. 3d 680 (S.D.N.Y. 2018).

because its receipt of dividends was “dependent on a future discretionary act.” The district court rejected this argument, noting that even if Fannie Mae’s Board of Directors were to elect not to declare a dividend for a given quarter, “the payment obligation to the government would not disappear,” because another clause in the SPA provided that dividends “shall accrue and shall be added to the Liquidation Preference [retained by the government],” whether or not dividends were declared. The district court also rejected the defendant’s argument that the relator had not pleaded a reasonably close nexus between defendants’ conduct and funds owed to the government.

By contrast, in *U.S. ex rel. Tracy v. Emigration Improvement District*, the district court held that the relator had not sufficiently alleged an “obligation” for purposes of establishing FCA liability.¹²⁷ At the outset, the district court rejected as a legal conclusion the relator’s allegation that the defendant had defaulted on a loan with the government and was therefore required to pay or transmit money or property to the government. The district court then found it appropriate under the circumstances to consult the terms of the operative loan agreement referenced in the relator’s complaint and found the terms directly contradicted the existence of an “obligation” actionable under the FCA. Under the operative agreement, an event of default occurred only if the defendant failed to perform within 30 days after the government’s written notification of the defendant’s failure to perform and, if there was an event of default, the government “may” require defendant to pay an interest penalty. Because the relator had not alleged that the defendant was notified in writing that it had failed to perform a covenant or requirement in the loan, the district court held that the relator had not alleged an event of default, and the obligation to pay an interest penalty was not triggered. Citing Tenth Circuit precedent, the district court re-emphasized that potential obligations are not actionable under the FCA’s reverse false claims provision.¹²⁸

Relationship to Traditional FCA Violations

Courts also continued to emphasize that a defendant’s failure to report or return money obtained through traditional violations of the FCA, standing alone, will not support liability for “reverse” false claims.

For example, in *U.S. ex rel. Martino-Fleming v. South Bay Mental Health Center, Inc.*, the relator alleged that the defendant, a provider of mental health services, improperly billed the government for services provided by employees who lacked appropriate qualifications and adequate supervision, in violation of applicable regulatory requirements.¹²⁹ The relator’s reverse false claim theory rested on these same allegations, along with the fact that the defendant failed to “return the overpayments once it was aware of the regulatory violations.” The district court

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dismissed the reverse false claims count, explaining that the defendant could not be liable on that theory because the relator did not “adequately allege that [the defendant] took any action independent of the main FCA theories” asserted by the relator.

The district court reached the same conclusion in *Riedel*, dismissing a reverse false claims cause of action that failed to plead “any monetary obligation owed ... to the government independent of [the defendant’s] allegedly fraudulent activity.”¹³⁰ The relator asserted traditional FCA claims based on several types of kickback schemes, while also alleging that the defendant’s failure to return to the government payments fraudulently obtained through the kickback schemes supported reverse FCA liability. The district court explained that “[a] reverse false claim may not rest ... on the argument that an

obligation arose out of the defendant’s concealment of their allegedly fraudulent activity, because by this logic, just about any traditional false statement or presentment action would give rise to a reverse false claim action.”¹³¹

On the other hand, in *U.S. ex rel. Patzer v. Sikorsky Aircraft Corp.*, the district court declined to dismiss the government’s reverse FCA cause of action even though it involved the same “sums of money ... allegedly obtained through submission of direct false claims.”¹³² The district court noted that, in its view, “the FCA does not prevent the government from pursuing direct and reverse false claims relating to the same money,” so long as the two types of claims are premised on separate false statements to the government. Because, in this case, the defendant made additional false statements to the government *after* fraudulently obtaining government funds, the district court determined that those false statements could separately support reverse FCA liability.

Retention of Overpayments

Finally, of particular importance to healthcare providers is the potential for reverse false claims liability to apply to an overpayment retained for more than 60 days after it is identified or for more than 60 days after it should have been identified through the exercise of reasonable diligence.¹³³

¹²⁷ 2018 WL 3111687 (D. Utah June 22, 2018) (citing *U.S. ex rel. Barrick v. Parker-Migliorini Int’l, LLC*, 2017 WL 6614466, at *7 (10th Cir. 2017)).

¹²⁸ See also *Carlisle v. Daewon Kangup Co., Ltd.*, 2018 WL 2336757 (M.D. Ala. May 23, 2018) (no reverse FCA liability because the alleged obligation was “contingent on the exercise of administrative discretion”); *United States v. CVS Pharmacy, Inc.*, 2018 WL 654289 (C.D. Cal. Jan. 31, 2018) (dismissing reverse FCA claim premised on “a failure to pay penalties that, to be enforced, would require exercise of Government discretion”).

¹²⁹ 2018 WL 4539684 (D. Mass. Sept. 21, 2018).

¹³⁰ 332 F. Supp. 3d 48 (D.D.C. 2018) (alterations and internal quotation marks omitted).

¹³¹ See also *U.S. ex rel. Gelbman v. City of N.Y.*, 2018 WL 476157 (S.D.N.Y. Sept. 30, 2018) (“Relator’s reverse false claim allegations—which essentially boil down to various providers allegedly receiving payment on false claims and thus retaining Government funds to which they were not entitled—are not an adequate basis on which to allege a reverse false claim.”); *U.S. ex rel. Myers v. America’s Disabled Homebound, Inc.*, 2018 WL 1427171 (N.D. Ill. Mar. 22, 2018) (dismissing reverse FCA claim that court deemed “redundant” to the relator’s traditional FCA allegations).

¹³² 2018 WL 3518518 (E.D. Wisc. July 20, 2018).

¹³³ See 42 U.S.C. 1320a-7k(d); 42 C.F.R. § 401.305.

In *U.S. ex rel. Hernandez-Gil v. Dental Dreams, LLC*, the relator alleged that the defendant, a dental practice, violated the reverse false claims provision of the FCA where its management had been informed of false billing practices, but refused to allow an investigation or audit into those practices “because it would cost too much money.”¹³⁴ The district court denied defendant’s summary judgment motion, noting that a reasonable jury could infer that the defendant “knew it received overpayments and took no steps to investigate, quantify, report, or return the overpayments.” This case highlights the need for providers to undertake a reasonable investigation anytime they are notified of credible information about potential overpayments, as the failure to do so may result in reverse FCA liability even when no overpayments have been specifically identified.

PUBLIC DISCLOSURE BAR

The FCA’s public disclosure bar prevents a relator from filing a *qui tam* complaint based on information previously disclosed to the public, thereby dissuading parasitic lawsuits based on publicly available information. Courts have continued to address allegations of conduct that occurred both before and after the Patient Protection and Affordable Care Act’s (PPACA) amendments to the FCA in 2010, and sometimes those amendments have been dispositive as to whether allegations were barred on public disclosure grounds. Where prior public disclosures did occur, courts must determine whether the disclosures were substantially similar to the FCA allegations and, if so, then determine whether the relator is nonetheless an “original source” of the allegations.

Which Version of the Public Disclosure Bar Applies?

Although less frequent as we move further away in time from PPACA’s amendments to the FCA’s public disclosure bar, cases have continued to involve conduct bridging PPACA’s enactment in March 2010. Courts addressing that scenario have continued the trend of bifurcating the public disclosure analysis to address pre-PPACA conduct under the older version of the statute and post-PPACA conduct under the current version.¹³⁵ In *U.S. ex rel. Monsour v. Performance Accounts Receivable, LLC*, applying different versions of the statute resulted in barring pre-amendment claims, but allowing post-amendment claims to proceed. The relators filed their complaint in 2016, alleging that beginning in 2005, numerous hospitals and affiliated vendors and consultants engaged in a cost-padding scheme to obtain higher payments under Medicare’s cost-based “Critical Access Hospitals” program. In 2013, the hospital where the relators worked had sued several of the defendants in a state court action, asserting fraud and civil conspiracy claims for defrauding the hospital and Medicare through essentially the same scheme. That

action qualified as a public disclosure under the pre-PPACA version of the public disclosure bar, but not under the post-PPACA version, because it was a state court action and because the United States was not a party. As a result, the district court dismissed the relators’ pre-amendment claims, but allowed their post-amendment claims to proceed.¹³⁶

What Qualifies as a Public Disclosure?

Before comparing previous public disclosures to *qui tam* allegations to determine whether they are sufficiently similar such that the relator’s allegations are barred from proceeding, courts have to address the threshold issue of what sources of information qualify as public disclosures for purposes of the public disclosure bar.

In *U.S. ex rel. Hong v. Newport Sensors, Inc.*, the Ninth Circuit held that the district court did not abuse its discretion in taking judicial notice of seven documents that defendants used to demonstrate public disclosure. The relator challenged the accuracy of one disclosure, a faculty profile on a university’s website, but the Ninth Circuit noted that the relator “d[id] not dispute the authenticity of the website itself, nor does he dispute [the defendant]’s suggestion that the profile was publicly available on the site.” Judicial notice was appropriate because the disclosures were submitted not “for the truth of the information” contained within them, but “merely to show the information was publicly available.”¹³⁷

With respect to consideration of prior legal proceedings as public disclosures, the post-PPACA version of the statute bars allegations that were disclosed “in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party.” Multiple courts have addressed whether the government must intervene in a prior *qui tam* lawsuit for the lawsuit to constitute a public disclosure for purposes of the bar. The district court in *U.S. ex rel. Gilbert v. Virginia College, LLC*, held that a non-intervened case can constitute a public disclosure. The district court recognized that the Supreme Court held within the context of determining the length of an appeal period that the United States is not a “party” in a *qui tam* lawsuit if it did not intervene.¹³⁸ The district court held, however, that the public disclosure bar applied nonetheless because relators in declined *qui tam* actions act as “agents” of the government, reasoning that “[the government] remains the real party of interest and has certain rights over the litigation” whether or not it intervenes, and “[i]f Congress had intended to allow a relator who is not an original source to proceed with a lawsuit alleging substantially the same violations as a previous relator’s complaint simply because the Government failed to intervene in the previous lawsuit, it would have said so.”

¹³⁴ 307 F. Supp. 3d 1224 (D.N.M. 2018).

¹³⁵ See, e.g., *U.S. ex rel. Daugherty v. Tiversa Holding Corp.*, 2018 WL 5045336 (S.D.N.Y. Oct. 17, 2018) (“Neither the Second Circuit nor the Supreme Court has addressed whether the 2010 amendment to the FCA is retroactive. Relevant precedent, however, dictates that it is not. . . . Thus, the pre-2010 version of the public disclosure bar applies to fraudulent claims paid by the Government before March 23, 2010, and the current version applies to claims paid after that date, or presented after that date and never paid.”).

¹³⁶ 2018 WL 4682343 (S.D. Miss. Sept. 28, 2018).

¹³⁷ 728 F. App’x. 660 (9th Cir. 2018).

¹³⁸ 305 F. Supp. 3d 1315 (S.D. Ala. Mar. 29, 2018) (citing *U.S. ex rel. Eisenstein v. City of New York*, 556 U.S. 928 (2009), in which the Supreme Court held that the relator was not entitled to the lengthier time period available to the government to file a notice of appeal under the Federal Rules of Appellate procedure because the government declined to intervene in the lawsuit and “[t]he United States . . . is a ‘party’ to a privately filed FCA action only if it intervenes in accordance with the procedures established by federal law.”).

By contrast, the district court in ***U.S. ex rel. Forney v. Medtronic, Inc.***, rejected the defendant's agency argument and held that the public disclosure bar does not apply where the United States declined to intervene. The district court reasoned that relators do not act as agents of the government because the government does not authorize relators to act in its place as a representative, does not exercise control over relators, and is not owed fiduciary duties by a relator.¹³⁹

When Are Disclosures Sufficient to Bar FCA Allegations?

Where prior public disclosures similar to *qui tam* allegations were made before the FCA action was filed, courts continued the trend of generally viewing the determination of whether those disclosures were "substantially similar" to the FCA allegations as a relatively lenient standard. As long as the previous disclosures reasonably identified the type of alleged conduct at issue and implicated the defendant named in the case, courts often found the public disclosure bar to be triggered and allowed to the original source analysis to determine whether the relator's allegations could proceed.

In ***U.S. ex rel. Folliard v. Comstor Corp.***, the district court applied the now familiar formula of the "transaction test" to assess whether FCA allegations were previously publicly disclosed: an allegation of fraud (Z) consists of two "essential elements," a misrepresented state of facts (X) and a true state of facts (Y), such that $X + Y = Z$.¹⁴⁰ If either X and Y, or Z, are in the public domain before the relator files an FCA action, then the allegations previously were publicly disclosed. The relator alleged that the defendants submitted false claims and false statements to the government under contracts involving the sale of Cisco information technology products to the federal government. The relator previously "use[d] almost identical language" to bring the same claims against two separate certified partner resellers of Cisco products. The district court acknowledged that while "the alleged manner of execution of the fraud scheme allegedly was also used by the defendants named in the other cases," the public disclosure bar was not implicated to bar the present claims because "none of the *qui tam* complaints previously filed . . . suggested 'other' entities complicit in the alleged fraud scheme or, more importantly, alleged that the instant defendants were involved in the alleged fraud."

Under Third Circuit precedent, the district court in ***Forney*** applied the same $X + Y = Z$ formula. The relator alleged that the defendant medical device company paid kickbacks to healthcare providers in the form of various free services related to their products, including free device checks and interrogations – including covering the cost of credentialing specialists to perform them – and free practice management consulting. The district court examined each alleged fraud theory separately when comparing it to the publicly disclosed allegations in two previous *qui tam* actions against Medtronic, holding that the prior matters "disclosed all of Relator Forney's remaining allegations of fraud except for her credentialing allegation."¹⁴¹ As a result, the district court found that the previous public disclosures were substantially similar to some, but not all, of the relator's *qui tam* allegations.

Although the district court in ***Monsour*** applied different versions of the statute to the relator's pre- and post-amendment claims, the district court held that the "transaction test" was the appropriate test to measure the similarity of the disclosures and the allegations under both versions of the public disclosure bar. For pre-2010 claims, the district court applied the Fifth Circuit's test "for determining whether public disclosures contain sufficient indicia of an FCA violation to bar a subsequently filed FCA complaint."¹⁴² Under that approach, both elements for an inference of fraud – a misrepresented set of facts and the true set of facts – "must be revealed in the public domain." Recognizing that the Fifth Circuit had not yet adopted that test for post-amendment claims, the district court nevertheless reasoned that because the pre-2010 version barred actions "based upon" public disclosures and the post-2010 bar applies if "substantially the same allegations or transactions" were publicly disclosed, that change in language was not significant. The Fifth Circuit previously had concluded that *qui tam* allegations were barred under the pre-2010 version if the disclosures "provide specific details about the fraudulent scheme and the types of actions involved in it sufficient to set the government on the trail of fraud," a similar standard to the post-2010 "substantially similar" test.

In ***U.S. ex rel. Patriarca v. Siemens Healthcare Diagnostics, Inc.***, the district court emphasized the Second Circuit's "broad view" of the public disclosure bar, noting that prior disclosures will bar a later claim "if they were sufficient to set the government squarely upon the trail of the alleged fraud." The relator alleged that Siemens' diagnostic tests improperly deviated from relevant benchmark testing guidelines. The district court found that those deviations were previously publicly disclosed in scholarly articles and publications. The district court rejected the relator's challenging of the validity of those studies, questioning their relevance, and distinguishing his own parallel studies to show his complaint was not substantially similar to the prior disclosures. The district court reasoned that the relator had not "provided any novel information" and that "information critical to Relator's allegation of a differential between the Siemens and [other] tests . . . was squarely publicly disclosed."¹⁴³

In ***U.S. ex rel. Solis v. Millennium Pharmaceuticals, Inc.***, the relator alleged that his former employers violated the FCA through three schemes involving off-label promotion and providing kickbacks to providers prescribing the drug Integrilin. The Ninth Circuit affirmed dismissal of the complaint on public disclosure grounds. The district court held that the relator's claims regarding the first scheme were substantially similar to a prior lawsuit filed in state court by an unrelated plaintiff in 2006 alleging that the defendant promoted Integrilin for dangerous combination use with other drugs. The Ninth Circuit rejected the relator's argument that the prior lawsuit was not substantially similar because it alleged only negligence rather than fraud. The Ninth Circuit observed that "[t]he absence of any explicit allegation of wrongdoing in the prior public disclosure is simply no moment so long as the material transactions giving rise to the defendant's alleged unlawful . . . schemes were publicly disclosed." The Ninth Circuit held that the relator's claims regarding the other two schemes were substantially similar to five complaints filed in federal court by unrelated plaintiffs in 2007. It rejected the relator's argument

¹³⁹ 327 F. Supp. 3d 831 (E.D. Pa. 2018). However, the district court also held that the government becomes a party to the entire case even when it only partially intervenes. *Id.* at 845.

¹⁴⁰ 308 F. Supp. 3d 56 (D.D.C. Mar. 31, 2018). The district court also noted in a footnote that, to the extent the defendants intended to argue that the relator's prior *qui tam* actions resulted in an "industry-wide" public disclosure, that argument would fail because the relator's prior suit had not implicated all or even a significant percentage of industry actors. *Id.* at 77 n. 12.

¹⁴¹ 327 F. Supp. 3d 831 (E.D. Pa. 2018).

¹⁴² 2018 WL 4682343 (quoting *U.S. ex rel. Solomon v. Lockheed Martin Corp.*, 878 F.3d 139, 144 (5th Cir. 2017)).

¹⁴³ 295 F. Supp. 3d 186 (E.D.N.Y. 2018).

that the prior complaints were not sufficient public disclosures because they discussed “many ‘subject drugs’ as a group,” of which Integrilin was only one. The Ninth Circuit noted that the use of a defined term to avoid repeating the name of multiple drugs – one of which was Integrilin – hundreds of times, did not make the similarity any less substantial.¹⁴⁴

When is a Relator an Original Source?

Application of the public disclosure bar’s original source requirement suggests that the post-PPACA version of the requirement often is considered broader and an easier standard for relators to satisfy than the pre-PPACA requirement. Whether the pre-amendment or post-amendment version applies is dispositive more often in the original source analysis than in determining whether previous public disclosures were sufficient to bar subsequent *qui tam* allegations, and, even where the version of the statute was not dispositive, at least one court nonetheless underscored the significance of the amendment with respect to the original source requirement.

In ***Patriarca***, the allegations spanned PPACA’s 2010 amendments to the public disclosure bar. The district court recognized that the 2010 amendment changed the “rigorousness” of the original source requirement by broadening the definition of an original source post-2010. The district court acknowledged that the Second Circuit had not decided which definition of “original source” should apply when a relator’s allegations include both pre- and post-2010 conduct. That was not a dispositive determination, however, because the district court held that the “[r]elator is not an original source under even the more generous post-amendment statute.” In a case involving Siemens’ alleged deviation from benchmark guidelines in its diagnostic tests, the district court found that the relator’s “parallel” studies were not significantly “independent” of the previously disclosed studies, nor were his studies’ findings “sufficiently or qualitatively different from the core information” already publicly disclosed. The district court emphasized the notion that, “just as combining publicly available information with specialized expertise is not sufficient to overcome the first step of the public disclosure bar, neither does conducting an analysis based on such expertise qualify a relator as an original source.”¹⁴⁵

The district court in ***U.S. ex rel. Banigan v. PharMerica, Inc.***, applied the pre-amendment version of the original source requirement to find that two management-level employees did not qualify as original sources. Under the pre-amendment version, the district court held that the relators’ knowledge was independent, but it was not direct. The district court defined direct knowledge as that which is acquired through the relators’ own efforts without an intervening agency and explained that the relators’ knowledge “must be something more than secondhand information or collateral research and investigations.”¹⁴⁶ In this case, the relators heard about the alleged scheme, which involved offering financial incentives to long-term care pharmacies to prescribe its drug, from other employees who planned to retain the information without disclosing it so that they would have the leverage to blackmail the company if they deemed

it necessary. After an independent investigation, the relators found evidence of the scheme, corroborating what the other employees had said, and brought the *qui tam* suit based on that information. The district court held that relators did not have “direct” knowledge because they did not uncover the scheme in the regular course of their job duties, but instead as part of “collateral research and investigations.”

In ***Gilbert***, although the district court ultimately held that the relator was not an original source, it rejected the defendants’ argument that allegations based on information and belief were secondhand and, therefore, not “independent” for purposes of the original source analysis. The district court explained that the post-PPACA version of the requirement eliminates the word “direct” from the type of knowledge that is required; thus, independent, secondhand knowledge may suffice as long as it “materially adds” to the previously disclosed information. Nonetheless, the district court held that, although the relator provided previously undisclosed “background information and details” about the alleged fraudulent scheme, she did not allege any new or distinct violations, and, thus, she did not “materially add” to the previous public disclosures or qualify as an original source.¹⁴⁷

In ***United States v. CVS Pharmacy, Inc.***, the relator alleged that CVS defrauded the government by dispensing inexpensive, over-the-counter drugs, but billing the government for more expensive drugs. Although the district court recognized that the relator’s allegations represented “a continuation of the same type of practices alleged” in a previous lawsuit, it also noted that the relator alleged that the fraudulent scheme included additional drugs that were not referenced in the previous action and that the scheme continued after the prior suit settled. Thus, although the relator’s allegations were substantially similar to the previous public disclosures, the district court held that the relator’s additional allegations as to the scope and timeframe of the alleged fraudulent scheme “materially add[ed]” to the previously disclosed allegations and the relator therefore qualified as an original source.¹⁴⁸

Both the pre- and post-PPACA versions of the original source provision require that the relator “voluntarily” disclose to the government the information on which the allegations are based. The district court in ***U.S. ex rel. Hendrickson v. Bank of Am.*** held that a relator cannot qualify as an original source when his job requires him to uncover and report the very types of fraud alleged in the *qui tam* complaint. The relator in that case was an OIG investigator for the U.S. Department of Veterans Affairs (VA) who asserted FCA claims against banks that processed payments for recipients of lifetime federal benefits, alleging that the banks ignored death notification entries and falsely certified the date on which they learned of the recipients’ deaths. The district court held that under Fifth Circuit precedent, the relator did not provide his information about the alleged fraud “voluntarily” because he was hired by the OIG specifically to investigate and disclose fraud.¹⁴⁹

144 885 F.3d 623 (9th Cir. 2018).

145 295 F. Supp. 3d 186 (E.D.N.Y. 2018) (quoting *U.S. ex rel. JDJ & Assocs. LLP v. Natixis*, 2017 WL 4357797, at *11 (S.D.N.Y. Sep. 29, 2017)).

146 2018 WL 2012684 (D. Mass. Apr. 30, 2018) (quoting *In re Pharm. Indus. Average Wholesale Price Litig.*, 2010 WL 1375298, at *2-3 (D. Mass. Mar. 25, 2010)).

147 305 F. Supp. 3d at 1326.

148 2018 WL 654289 (C.D. Cal. Jan. 31, 2018).

149 2018 WL 5313932 (N.D. Tex. Oct. 26, 2018) (citing *Little v. Shell Expl. & Prod. Co.*, 690 F.3d 282, 294 (5th Cir. 2012)). The court additionally found that relator did not have direct and independent knowledge of allegedly fraudulent post-death benefit payments from agencies other than the VA because he did not work at any other agency. *Id.*

Can Outsiders Serve as Relators?

In what could become a growing trend, the data analytics firm Integra Med Analytics filed multiple *qui tam* actions this past year as an outside relator. In one such case to watch, ***U.S. ex rel. Integra Med Analytics, LLC v. Providence Health & Servs.***, the defendants have moved to dismiss the analytics firm's *qui tam* complaint on public disclosure grounds. The defendants have argued that to develop its allegations, Integra cobbled together public information from multiple public sources, including: (1) data obtained from CMS, which the defendants argue constitutes a "federal report" under Supreme Court precedent related to Freedom of Information Act (FOIA) requests; (2) publicly available OIG reports; and (3) public comments from an online forum and information from other public websites. The defendants have argued that the "relator [is] an outsider who pieced together bits of publicly disclosed information to speculate the existence and mechanisms of fraud." The defendants also have argued that the relator is not an original source because it has no independent knowledge of the facts alleged and its "proprietary analysis" of CMS's data does not materially add to what the government already knew. The defendants have argued that under Ninth Circuit precedent, identifying the legal consequences of information already in the public domain does not constitute discovery of fraud.

In response, the relator has argued that CMS data is not publicly available, but is released to a limited number of parties and in accordance with strict privacy requirements. The relator also has argued that it is an original source of the relevant information because it conducted "sophisticated quantitative, statistical, and econometric analyses" that demonstrate a "new and undisclosed relationship" between any facts that previously were publicly disclosed.¹⁵⁰ The defendants' motions to dismiss are scheduled for hearing in early 2019. Whether the district court allows Integra's allegations to proceed may provide some insight into the viability of data analysts without inside information acting as *qui tam* relators.¹⁵¹

STATUTE OF LIMITATIONS

The determination of whether the FCA's statute of limitations applies to bar either a relator's or the government's FCA claims can have a significant impact on the scope of liability and damages for a defendant. When the FCA's statute of limitations applies, however, can be a complicated analysis.

The FCA's statute of limitations provision, found at 31 U.S.C. § 3731(b), states that a civil action may not be brought under the FCA:

1. more than 6 years after the date on which the violation of section 3729 is committed, or
2. more than 3 years after the date when facts material to the right of action are known or should have been known by the official of the United States charged with responsibility to act in the circumstances, but in no event more than 10 years after the date on which the violation is committed, whichever occurs last.

In what could become a growing trend, the data analytics firm Integra Med Analytics filed multiple *qui tam* actions this past year as an outside relator.

are entitled to the ten-year statute of limitations found in § 3731(b)(2), but that the limitations period begins on the date the *government* should have known of facts material to the right of action. The third approach provides that the private party stands in the shoes of the government where the government has declined to intervene and that the limitations period begins to run on the date that the *relator* knew or should have known the facts relevant to the right of action.¹⁵²

In ***U.S. ex rel. Millin v. Krause***, the district court considered which provision of the FCA's statute of limitations applies when the government declines to intervene in an action filed by a relator.¹⁵³ The district court concluded that it agreed with the approach outlined by the Ninth Circuit in *Hyatt*, in that the equitable tolling codified for the government at § 3731(b)(2) should similarly be available to a private plaintiff such that both § 3731(b)(1) and (b)(2) apply to any civil FCA actions whether pursued by a relator or the government. In reaching this conclusion, the district court explained that the private plaintiff filing an FCA claim stands in for the government's interest and that the limitations period should begin to run on the date the relator knew or should have known the facts relevant to the right of action. By allowing for the extended limitations period in § 3731(b)(2) to apply to claims brought by a relator and potentially tying the running of the limitations period to that relator's knowledge, the district court adopted the most expansive view of the FCA limitations period.

In ***U.S. ex rel. Hunt v. Cochise Consultancy, Inc.***, the Eleventh Circuit deepened a circuit split among federal appellate courts by reversing the district court's conclusion that § 3731(b)(2) is inapplicable where the government has declined to intervene and decided for the first time that the FCA's three-year limitations period applies to a relator's *qui tam* claims in such a scenario.¹⁵⁴ In reaching that conclusion, the Eleventh Circuit also explained that the FCA's three-year limitations period was triggered by the *government's* knowledge of the alleged fraud and not the relator's knowledge, and therefore, the relator's knowledge of the alleged fraud was irrelevant to the analysis. To that end, the Eleventh Circuit departed from the view espoused by the Ninth Circuit in *Hyatt*, in which the Ninth Circuit concluded that § 3731(b)(2) would be triggered by the *relator's* knowledge. The Eleventh Circuit's approach likewise conflicts with the holding of the

150 No. 2:17-cv-01694-PSG-SS (C.D. Cal.) (Dkt. Nos. 56-1, 57, 61-62).

151 See also *U.S. ex rel. Integra Med Analytics LLC v. Baylor Scott & White Health*, No. 5:17-cv-00886 (W.D. Tex.).

152 See, e.g., *U.S. ex rel. Sanders v. N. Am. Bus. Indus., Inc.*, 546 F.3d 288 (4th Cir. 2008) (first approach); *U.S. ex rel. Pogue v. Diabetes Treatment Ctrs. of Am.*, 474 F. Supp. 2d 75 (D.D.C. 2007) (second approach); *U.S. ex rel. Hyatt v. Northrop Corp.*, 91 F.3d 1211 (9th Cir. 1996) (third approach).

153 2018 WL 1885672 (D.S.D. Apr. 19, 2018).

154 887 F.3d 1081 (11th Cir. 2018).

Fourth Circuit in *Sanders*, which held that under the FCA's plain text, § 3731(b)(2) applies only to the government and not to relators. The Eleventh Circuit's decision was significant because it potentially revived the relator's otherwise time-barred claims, as the relator had not filed his action within the six-year limitations period of § 3731(b)(1).

On November 16, 2018, the Supreme Court announced that the petition for writ of certiorari filed in *Hunt* had been granted.¹⁵⁵ As a result, the Supreme Court should bring some much needed clarity to an issue of statutory interpretation concerning the FCA that has plagued a number of courts in recent years.

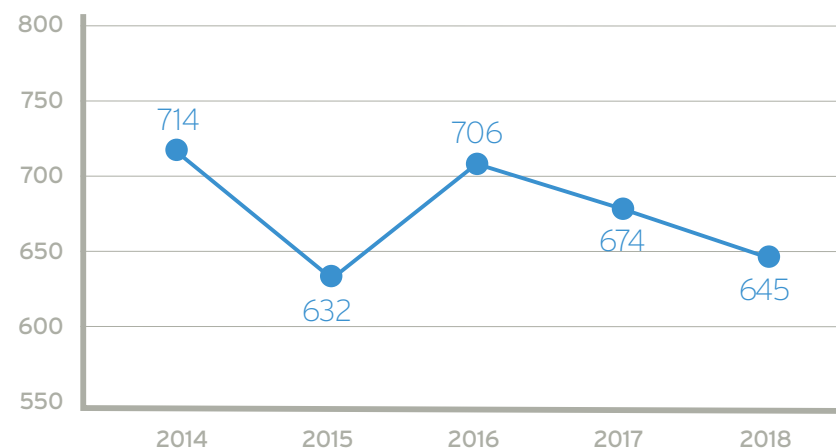
DEVELOPMENTS REGARDING DAMAGES AND PENALTIES

After cases in recent years tackling legal issues associated with FCA damages and penalties, there were relatively few cases examining those issues last year.

In *United States v. Christenson*, the district court considered whether an award of treble damages and per claim penalties under the FCA violated the Eighth Amendment's Excessive Fines Clause.¹⁵⁶ That provision provides that a punitive sanction – such as the FCA's treble damages and per claim penalties – is unconstitutional in violation of the Eighth Amendment if the sanction is disproportional to the gravity of the underlying offense. As the district court explained, proportionality is determined by numerous factors, including the "reprehensibility of the defendant's conduct, the relationship between the penalty and the harm to the victim, and legislative intent."

The defendant, who served as a postmaster, had summary judgment on civil FCA claims entered against him following his criminal conviction for defrauding the postal service. The district court determined that the government was defrauded in the amount of \$8,970.01 based on 61 false claims certified by the defendant, trebled that amount and awarded \$335,000 in civil penalties for a total damages award of \$353,441.42, which was approximately 39 times the actual damages suffered by the postal service. Nonetheless, the district court had little difficulty in determining that the award in favor of the government against the defendant did not violate the Eighth Amendment's Excessive Fines Clause because each of the defendant's FCA violations, upon which the award of damages and penalties was based, was the result of intentional misconduct on the part of the defendant.

NUMBER OF NEW QUI TAM LAWSUITS FILED BY YEAR (FY 2014-2018)



DEVELOPMENTS REGARDING RELATORS

First-to-File Bar and Government Action

First-to-File Bar. The FCA's first-to-file bar prohibits any person other than the government from "bring[ing] a related action based on the facts underlying" an already pending FCA action.¹⁵⁷ Over the past year, courts have continued to examine the contours of that prohibition with a particular focus on whether the legal sufficiency of the already pending, first-filed FCA complaint or dismissal of the first-filed FCA action affects the application of the first-to-file bar in the second-filed action.

The most significant decision addressing those issues was the Second Circuit's ruling in *U.S. ex rel. Wood v. Allergan Inc.*,¹⁵⁸ which addressed two aspects of the first-to-file bar. The Second Circuit first held that the first-to-file bar prohibits the filing of a second "related" action even if the first-filed complaint is legally infirm under Rule 9(b), which requires that fraud be pleaded with particularity. According to the Second Circuit, "[n]othing in the language of [the first-to-file bar] incorporates the particularity requirement of Rule 9(b), which militates against reading such a requirement into the statute." Equally important for the Second Circuit were the different purposes served by the first-to-file bar and Rule 9(b), with Rule 9(b) "protect[ing]

¹⁵⁵ https://www.supremecourt.gov/orders/courtorders/111618zr_daei.pdf.

¹⁵⁶ 2018 WL 2944470 (D.S.D. June 11, 2018).

¹⁵⁷ 31 U.S.C. § 3730(b)(5).

¹⁵⁸ 899 F.3d 163 (2d Cir. 2018).

defendants in fraud cases from ‘frivolous accusations’” and the first-to-file bar “reward[ing] a qui tam relator for putting the Government on notice of a potential fraud without the dilution of ‘copycat actions that provide no additional material information.’” Finally, the Second Circuit observed that requiring the first-filed complaint to satisfy Rule 9(b) would necessarily oblige the district court in the second-filed action “to evaluate the sufficiency of a complaint pending before another court, creating a precarious dynamic.”

The Second Circuit in **Wood** also held that a violation of the first-to-file bar in the second-filed action could not be “cured” by changes in the first-filed action. The relator in **Wood** argued that, even if a first-filed relation action was “pending” when he initially filed his complaint, his second-filed complaint could go forward by being amended once the first-filed “related” action was no longer pending. The Second Circuit disagreed. In doing so, the Second Circuit joined the D.C. Circuit, concluding that the relator’s action “was incurably flawed from the moment he filed it.” According to the Second Circuit, because the first-to-file bar prevents a relator from “bring[ing]” a second related action, an amendment to the second-filed complaint does nothing to alter the bringing of the second action.

Since **Wood**, several district courts have held that the legal sufficiency of the first-filed complaint need not be determined for the first-to-file bar to apply. In **U.S. ex rel. Phillips v. Stephen L. LaFrance Holdings, Inc.**, the district court rejected a relator’s contention that a second-filed action could not be dismissed under the first-to-file bar until a court ruled on motions to dismiss in the first-filed action.¹⁵⁹ The district court reasoned that “the Supreme Court does not require that another district court certify that the relator plaintiff in the earlier-filed case has stated a claim upon which relief can be granted, and an earlier-filed case must simply ‘remain undecided’ or be ‘awaiting decision’ to qualify as a ‘pending action.’” Likewise, district courts since **Wood** have concluded that changes to the first-filed action are immaterial to the first-to-file bar’s application in the second-filed action. In **U.S. ex rel. Hanks v. U.S. Oncology Specialty, LLP**, the district court dismissed a second-filed action under the first-to-file bar despite the earlier dismissal of the first-filed action.¹⁶⁰ The relator in **Hanks** suggested that, because the first-filed action had been dismissed during the pendency of the second-filed action, the first-filed action’s dismissal prevented the application of the first-to-file bar. Citing **Wood**, the district court rejected the relator’s argument, holding that “a qui tam action is barred by the first-to-file rule if, at the time it is filed, a related action is already pending. Since the first-to-file rule bar prohibits the bringing of an action, any subsequently filed, related action must be dismissed even if the [first]-filed action is dismissed while the second action is still pending.”

Government Action Bar. Analogous to the first-to-file bar, the FCA’s government action bar prohibits any suit “based upon allegations or transactions which are the subject of a civil suit or an administrative civil money penalty proceeding in which the Government is already a party.”¹⁶¹ In applying the government action bar, courts most frequently grapple with the

difficult question of whether an action is “based upon allegations or transactions” in a civil suit or an administrative proceeding.

In **Schagrin v. LDR Industries, LLC**, the district court concluded that the relator’s action was precluded by the government action bar because it was based upon the “critical elements” of an administrative civil money penalty proceeding.¹⁶² More specifically, the district court reasoned that the “critical element” of the alleged fraud in relator’s FCA action – a misrepresentation about imported pipe classifications – was also “at the heart of” the relevant administrative civil money penalty proceeding.¹⁶³

By contrast, the district court in **United States v. Coloplast Corp.** refused to apply the government action bar because of the lack of overlap between relators’ FCA action and an earlier civil suit involving the government.¹⁶⁴ The district court determined if the government action bar applied by asking whether: (1) relators’ action received “support, advantage or the like” from the prior civil action, and (2) relators’ action provided a “useful or proper return to the Government.” As to the first inquiry, the district court concluded that relators received no advantage from the prior civil action because, while the fraud in both suits included “the same modus operandi,” relators’ action concerned “a different manufacturer” and “a largely different time period.” With regard to the “return to the Government” inquiry, the district court held that relators’ action sufficiently benefited the government because it rooted out additional undetected fraud by defendants and “the government itself [did] not view” relators’ action as “parasitic” of the prior civil suit.

Relator Bankruptcy

FCA relators who file bankruptcy during the pendency of their lawsuits may face certain challenges with respect to whether they retain standing to pursue FCA claims on behalf of the United States or whether those claims belong to the bankruptcy trustee as an asset of the bankruptcy estate. A relator also can face a significant challenge if the relator files bankruptcy while the relator’s FCA case is pending under seal due to the relator’s obligation to disclose all assets in connection with the bankruptcy filing, which necessarily would include lawsuits filed by the relator.

Relator’s Request for Attorney’s Fees. At least one relator ran directly into the consequences of filing bankruptcy as it relates to the relator’s request for attorney’s fees and costs. In **U.S. ex rel. Jacobs v. CDS, P.A.**, defendants reached a settlement agreement with the bankruptcy trustee to resolve FCA allegations that claims for reimbursement violated the Stark Law after the relator had filed for bankruptcy.¹⁶⁵ Under the terms of the settlement agreement, the relator’s share would be paid to the bankruptcy estate, but there was no provision for the payment of attorney’s fees. Instead, the settlement agreement provided that the district court

¹⁵⁹ No. 14-CV-0567-CVE-PJC, 2018 WL 4839057 (N.D. Okla. Oct. 4, 2018).

¹⁶⁰ 2018 WL 4409832 (E.D.N.Y. Sept. 17, 2018).

¹⁶¹ 31 U.S.C. § 3730(e)(3).

¹⁶² 2018 WL 2332252 (N.D. Ill. May 23, 2018).

¹⁶³ In a recent motion to reconsider, however, the district court concluded that the government had not yet imposed a monetary penalty and therefore, despite the overlap between the FCA action and the relevant pending administrative proceeding, the government action bar did not apply. See *United States ex rel. Schagrin v. LDR Industries, LLC*, 2018 WL 6064699 (N.D. Ill. Nov. 20, 2018).

¹⁶⁴ 327 F. Supp. 3d 358 (D. Mass. 2018).

¹⁶⁵ 2018 WL 2745902 (D. Id. June 7, 2018).

would retain jurisdiction to enforce the terms of the settlement, including any claim by the relator for attorney's fees. In response to the relator's motion for an award of attorney's fees and costs, the district court determined that the relator did not have standing to bring that motion. The district court explained that the bankruptcy trustee would have to abandon any such claim before the relator would have standing, but that if the trustee were to abandon that claim, then the relator would be entitled to renew his motion.

Relator's Failure to Disclose FCA Lawsuit in Bankruptcy. The FCA's seal provision prohibits disclosure of the existence of an FCA lawsuit during the seal period. When a relator initiates a bankruptcy proceeding during that seal period, the relator is faced with the obligation in the bankruptcy petition to disclose all assets and liabilities, including "all suits ... to which the debtor is or was a party within one year immediately preceding the filing" of bankruptcy. This disclosure necessarily would include the FCA lawsuit brought by the relator regardless of the fact that the FCA lawsuit may be under seal. The failure to include the existence of litigation claims, including an FCA lawsuit, as an asset in the bankruptcy petition and/or in bankruptcy proceedings has significant consequences. Upon the filing of the bankruptcy petition, the FCA lawsuit itself would become the property of the bankruptcy estate, and therefore, the relator would no longer have standing to pursue those claims. Furthermore, the relator's failure to disclose the FCA lawsuit as an asset may very well bar the relator from participation in any relator's share upon settlement or judgment.

This was the very situation faced by the relator in *U.S. ex rel. Hinkle v. Caris Healthcare, L.P.* There, the relator filed FCA claims challenging the medical necessity of hospice services against her former employer. After the filing of her FCA lawsuit in May 2014 and during the seal period, the relator initiated bankruptcy proceedings in November 2014, but failed to disclose her FCA lawsuit as an asset of her bankruptcy estate. The relator was discharged from bankruptcy in April 2015, without ever having disclosed the FCA lawsuit. Nearly four years after the filing of the FCA lawsuit, the defendants uncovered the relator's bankruptcy omission and filed a motion for judgment on the pleadings against the relator, asserting that she did not have standing to pursue the FCA claims and otherwise should be equitably estopped from pursuing those claims as a result of the failure to disclose the FCA lawsuit in her bankruptcy.¹⁶⁶ For its part, the U.S. Trustee filed a motion to reopen the relator's bankruptcy proceedings and appointed a new bankruptcy trustee. That trustee filed a motion in the FCA lawsuit seeking to be substituted as a party to that action.¹⁶⁷ Before the district court ruled on these motions, the defendants reached a settlement with the United States. As a result of that settlement, however, the relator received no award of attorney's fees, and the relator's statutory share was paid to the relator's bankruptcy trustee to be included as part of the reopened bankruptcy estate.¹⁶⁸

RELATOR'S SHARE AND FEES

Where a relator is successful in their FCA case, the relator is generally entitled to a share of the proceeds of the action, whether or not the government intervenes.¹⁶⁹ Where the government pursues an "alternate remedy" to the FCA suit itself, how or whether a relator may obtain a share of those proceeds is less clear. Courts have continued to consider what constitutes an "alternate remedy" and what rights a relator may have with respect to such proceedings.

In *United States v. Couch*, the government chose to criminally prosecute the defendants for fraud and sought criminal forfeiture of the proceeds. The Eleventh Circuit affirmed the district court's denial of the relator's motion to intervene and, in doing so, the Eleventh Circuit distinguished its reasoning from the Ninth Circuit's decision in *United States v. Van Dyck*, in which the Ninth Circuit found a relator did not have standing to intervene in the criminal forfeiture proceeding.¹⁷⁰ Rather than basing its ruling on the issue of standing, the Eleventh Circuit relied on the fact that criminal forfeiture statutes expressly prohibited intervention on the part of the relator. The Eleventh Circuit noted, however, that should the relator prevail in her *qui tam* suit, the relator may be entitled to a share of the forfeiture to the extent the forfeiture were deductible from the recovery.¹⁷¹

RELEASE OF CLAIMS

The FCA *qui tam* provisions are intended to incentivize individuals to bring to light potential fraud on the government. This policy interest has been at the forefront of cases considering the enforceability of releases that otherwise would preclude relators from pursuing *qui tam* actions. In *U.S. ex rel. Class v. Bayada Home Health Care, Inc.*, the district court noted that while the Third Circuit had not ruled on the enforceability of releases signed by relators before filing of their FCA case, an "emerging agreement" among other circuits provides that such releases bar FCA claims if: (1) they can be fairly interpreted to encompass *qui tam* claims and (2) public policy does not otherwise outweigh enforcement of the release. The district court went on to hold that, although the release signed by relators upon leaving employment with the defendant was broad enough to encompass FCA claims, public policy precluded its enforcement because the government did not know of the claims before it received a draft copy of the complaint. The district court further found that the government's decision not to intervene should not be considered in determining whether public policy should bar enforcement.¹⁷²

¹⁶⁶ *U.S. ex rel. Hinkle v. Caris Healthcare, L.P.*, No. 3:14-cv-00212-TAV-HBG (E.D. Tenn.), Defs.' Motion for Judgment on the Pleadings (Dkt. No. 102).

¹⁶⁷ *In re Barbara Hinkle*, 2:14-bk-51856-MPP (Bankr. E.D. Tenn.), U.S. Trustee's Ex Parte Mot. To Reopen Case (Dkt. No. 21); *U.S. ex rel. Hinkle v. Caris Healthcare, L.P.*, No. 3:14-cv-00212-TAV-HBG (E.D. Tenn.), Defs.' Motion for Substitution of Party (Dkt. No. 107).

¹⁶⁸ *In re Barbara Hinkle*, 2:14-bk-51856-MPP (Bankr. E.D. Tenn.), Order dated June 11, 2018 (Dkt. No. 34).

¹⁶⁹ 31 U.S.C. § 3730(d)(1) & (2); see also 31 U.S.C. § 3730(c)(5).

¹⁷⁰ 866 F.3d 1130 (9th Cir. 2017).

¹⁷¹ 906 F.3d 1223 (11th Cir. 2018) (citing 866 F.3d 1130 (9th Cir. 2017)).

¹⁷² 2018 WL 4566157 (E.D. Pa. Sept. 24, 2018).

RETALIATION CLAIMS

The FCA's anti-retaliation provision, 31 U.S.C. § 3730(h), protects whistleblowers who report potential FCA violations to the government or their employers. To establish liability under the anti-retaliation provision, an employee must demonstrate that: (1) he or she engaged in protected activity; (2) the employer had knowledge of the protected activity; and (3) the employee suffered an adverse employment action resulting from the protected activity. In the past year, courts have issued noteworthy decisions addressing all three of these required elements.

Protected Activity

To establish protected activity, a plaintiff must demonstrate that he or she has undertaken acts "in furtherance of" an FCA action or engaged in "other efforts to stop [one] or more violations" of the FCA.¹⁷³ Because violations of the FCA must entail false or fraudulent claims for payment from the government, courts have continued to emphasize that, for purposes of the anti-retaliation provision, protected activity likewise must relate to fraud against the government.

For example, in *Hicks v. District of Columbia*, the district court granted summary judgment for the defendant where the plaintiff whistleblower "appear[ed] to be reporting on nothing more than his employer's non-compliance with federal or state regulations."¹⁷⁴ Because regulatory non-compliance is "not enough to sustain an FCA claim," the district court explained, the plaintiff's alleged report also was not enough to establish protected activity. Similarly, in *U.S. ex rel. Potter v. CASA de Maryland*, the district court dismissed a plaintiff's FCA retaliation claim because, although the plaintiff had alleged facts to show that she believed her employer was "non-compliant with immigration laws," she failed to sufficiently allege that a reasonable employee in the same circumstances would believe that such non-compliance could result in an FCA violation.¹⁷⁵

Assuming a plaintiff can adequately connect the alleged report to an actual or potential violation of the FCA, however, the plaintiff's burden for pleading protected activity is not otherwise particularly difficult to satisfy, as several courts confirmed this year. For instance, in *U.S. ex rel. Crockett v. Complete Fitness Rehabilitation, Inc.*, the Sixth Circuit held that retaliation claims "need not meet the heightened pleading requirements of Rule 9(b)," but are instead subject to "the more lenient plausibility standards of Rule 8(a)."¹⁷⁶ Accordingly, the Sixth Circuit explained that it is not necessary for a retaliation plaintiff to plead a specific FCA violation, provided the employee can "show some linkage between the activities they complain of and fraud on the government."¹⁷⁷

Employer's Knowledge of Protected Activity

To demonstrate that the employer knew the employee was engaged in protected activity – the second element of an FCA retaliation claim – the plaintiff must show that the employer was aware that his or her report or activity related to an actual or potential violation of the FCA. As several courts have noted, an employee's mere expression of compliance concerns – even concerns related to billing – may not provide the requisite notice standing alone.

In *U.S. ex rel. Lim v. Salient Federal Solutions, Inc.*, an employee alleged that he raised questions with his superiors regarding whether his employer, a federal contractor, was manipulating cost data to overbill the government.¹⁷⁸ Although the district court found that he had adequately pleaded the protected activity element, it nevertheless dismissed several of the plaintiff's retaliation theories based on his failure to adequately plead that his employer had knowledge of his protected activity. The court explained that the relevant reports were "couched in terms of concerns rather than threats or warnings of the possibility of FCA litigation," which was "a step removed from behavior that Courts have found to sufficiently provide notice to the employer."¹⁷⁹

Because violations of the FCA must entail false or fraudulent claims for payment from the government, courts have continued to emphasize that, for purposes of the anti-retaliation provision, protected activity likewise must relate to fraud against the government.

Courts also sometimes find the knowledge element lacking when the employee's report of problematic conduct arguably falls within his or her ordinary job responsibilities. As illustrated by several cases decided this year, courts often require the plaintiff in such scenarios to plead facts demonstrating that the nature of the alleged protected activity would have provided notice to the employer that the employee was doing something more than simply carrying out his or her assigned duties. In *Singletary v. Howard University*, for example, the district court dismissed a retaliation claim premised on a veterinarian's report to his superiors about the living conditions of laboratory animals because her job duties "included complying with all federal statutes and regulations governing animal research activity."¹⁸⁰ The district court found the allegations insufficient as they did not "adequately show that her alleged actions were beyond the scope of her regular work responsibilities."¹⁸¹

173 31 U.S.C. § 3730(h).

174 306 F. Supp. 3d 131 (D.D.C. 2018) (internal quotation marks omitted).

175 2018 WL 1183659 (D. Md. Mar. 6, 2018).

176 721 F. App'x 451, 460 (6th Cir. 2018).

177 For example, one district court declined to dismiss a retaliation claim where the plaintiff confronted his employer's president "with concerns that [the company's] practice of billing the government for unnecessary testing was not legal." *Uehling v. Millennium Labs., Inc.*, 2018 WL 2149312 (S.D. Cal. May 10, 2018). Because the plaintiff's report related to fraudulent billing, the court noted that it would qualify as protected activity regardless of whether the plaintiff specifically used words like "illegal," "fraudulent," or "unethical" when reporting his concerns.

178 2018 WL 2128666 (S.D. Cal. May 9, 2018).

179 *Id.* (internal quotation marks omitted). In *Potter*, the district court similarly found that the knowledge element had not been satisfied because the plaintiff had not pleaded facts to show that her employer was aware that her reports about non-compliance with the immigration laws were "related to a possible FCA action." See 2018 WL 1183659, at *9.

180 314 F. Supp. 3d 330 (D.D.C. 2018).

181 The district court reached a similar conclusion in *Hicks*, pointing out that the plaintiff's allegations would fail to establish protected activity – even if they did relate to fraud against the government – because the plaintiff served in an audit-related role, and flagging issues related to compliance with the law was part of his "normal job responsibilities as an auditor." 306 F. Supp. 3d at 160. See also *U.S. ex rel. Hutchins v. DynCorp Int'l, Inc.*, 2018 WL 4674577 (D.D.C. Sept. 28, 2018) (holding that plaintiffs failed to establish the employer-knowledge element of their retaliation claims because they essentially asserted that "performance of [their] normal job responsibilities constituted protected activity").

Finally, several decisions have emphasized the importance of establishing that the person or persons having knowledge of the protected activity were the same persons responsible for the alleged adverse employment action. In *U.S. ex rel. Aquino v. University of Miami*, the district court granted summary judgment for the employer where the plaintiff could not show that the individuals responsible for her termination were aware of her protected activity.¹⁸² Likewise, in *Armstrong v. the Arcanum Group, Inc.*, the Tenth Circuit held that the plaintiff could not rely on “agency principles” to impute one employee’s knowledge of her protected activity to the decision makers responsible for her termination.¹⁸³ In reaching this conclusion, the Tenth Circuit noted that “[t]he knowledge of someone who had no role in the decision is irrelevant to the motive for the decision.”

Adverse Employment Action

As courts have long confirmed, an adverse employment action under § 3730 includes not only actual termination, but also “constructive discharge,” among other materially adverse actions. In *U.S. ex rel. Herman v. Coloplast Corp.*, the district court affirmed that the inquiry into whether any particular action is materially adverse is holistic and must be based on an objective review of all the facts and circumstances.¹⁸⁴ In that case, the plaintiff alleged that her employer placed her on paid administrative leave and assigned her to smaller accounts after she filed a *qui tam* action alleging an illegal kickback scheme. Although she continued to receive her full salary and benefits and remained eligible for a raise, the district court held that whether any of these changes amounted to an adverse employment action was ultimately a question of fact for the jury. In adhering to this flexible approach, the district court notably diverged from the more categorical approaches of the Fourth, Fifth, Sixth and Eighth Circuits, all of which have held that “paid administrative leave pending a disciplinary investigation can never constitute an adverse employment action.”

In *Smith v. LHC Group, Inc.*, the Sixth Circuit clarified that, in attempting to prove constructive discharge, a retaliation plaintiff need not prove *specific* intent on behalf of his or her employer.¹⁸⁵ Rather, the Sixth Circuit explained, the “intent requirement can be satisfied so long as the employee’s resignation was a reasonably foreseeable consequence of the employer’s actions.” In *Smith*, the plaintiff resigned after allegedly learning that her employer, a home health provider, was manipulating patient information to improperly admit Medicare and Medicaid patients. She claimed that she was forced to quit because her employer ignored her concerns, effectively

requiring her to choose between acquiescing in fraud and resigning. The Sixth Circuit held that summary judgment should not have been granted for the defendant because the plaintiff’s “repeated complaints to management concerning illegal activity should have enabled [the defendant] to foresee that failure to take action against the fraudulent scheme would compel [the plaintiff] to leave,” whether or not the defendant specifically intended that result.¹⁸⁶

Causation

In addition to establishing that they were subject to an adverse employment action, a plaintiff in an FCA retaliation case must also show that the action in question resulted from protected activity. As several courts confirmed in the past year, this requires the plaintiff to 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 *DiFiore v. CSL Behring, LLC*, the Third Circuit applied the “but-for” causation standard to a plaintiff’s allegations that she was forced to resign after raising concerns relating to her employer’s off-label marketing of certain medications.¹⁸⁷ The Third Circuit rejected the plaintiff’s argument that a “motivating factor” standard should apply, analogizing FCA retaliation actions to similar kinds of claims under Title VII, the Age Discrimination in Employment Act, and the Family and Medical Leave Act, for which the more demanding “but-for” standard applies. The Fourth Circuit applied similar reasoning in adopting the “but-for” standard in *U.S. ex rel. Cody v. ManTech International Corp.*, noting that there is “no meaningful textual difference” between the relevant causation language in these other statutes and the FCA.¹⁸⁸

Nevertheless, proving causation does not necessarily require direct evidence, and several courts reaffirmed that temporal proximity may suffice. In *U.S. ex rel. O’Neill v. Somnia, Inc.*, for example, the district court held that the plaintiff had “plausibly alleged that her termination was motivated by her engaging in protected activity” where the termination occurred just over a month after she reported concerns about improper billing.¹⁸⁹ Similarly, in *Cody*, the district court found the evidence sufficient to establish causation where, among other facts, a relator was terminated approximately ten weeks after his employer learned of his *qui tam* action.¹⁹⁰ The district court emphasized, however, that “the temporal proximity ... must be very close,” and it reversed the jury’s verdict in favor of another relator who was not terminated until six months after the employer learned of his *qui tam* action.

¹⁸² 2018 WL 3814517 (S.D. Fla. Aug. 10, 2018). Notably, although the individual who signed the plaintiff’s termination letter was aware of the protected activity, the district court found no evidence to suggest that that person was a “decision maker” relative to the plaintiff’s termination.

¹⁸³ 897 F.3d 1283 (10th Cir. 2018).

¹⁸⁴ 295 F. Supp. 3d 37 (D. Mass. 2018).

¹⁸⁵ 727 F. App’x 100 (6th Cir. 2018).

¹⁸⁶ *U.S. ex rel. Bachert v. Triple Canopy, Inc.*, illustrates that more obviously intentional action may of course suffice as well. See 321 F. Supp. 3d 613 (E.D. Va. 2018). There, the plaintiff was re-assigned to lower paying positions after reporting the submission of false invoices related to weapons and armory inspections. Rather than accept those positions, the plaintiff resigned. In denying summary judgment for the employer, the district court explained that “[a]n employee is entitled to relief absent a formal discharge, if an employer deliberately makes the working conditions intolerable in an effort to induce the employee to quit.”

¹⁸⁷ 879 F.3d 71 (3d Cir. 2018).

¹⁸⁸ 2018 WL 3770141 (4th Cir. Aug. 8, 2018). The Fourth Circuit also formally endorsed the application of the *McDonnell Douglas* burden-shifting framework to FCA retaliation claims.

¹⁸⁹ 2018 WL 684765 (E.D. Cal. Feb. 2, 2018). Further, the court did not require the relator to allege the name of a specific person who made the termination decision, but determined that was an issue for discovery.

¹⁹⁰ 2018 WL 2770141, at *10.

DISCOVERY DEVELOPMENTS

Civil Investigative Demand Showdown

On November 19, 2018, a magistrate judge granted DOJ's petition to enforce a CID seeking deposition testimony from Anthem, Inc. The dispute provides unique insight into the government's pre-intervention investigation, which usually occurs outside of public view, regarding whether Anthem has received risk-adjustment payments related to Medicare Part C insurance plans while failing to ensure the validity of the data on which those payments are based. DOJ's petition requests the court to order Anthem to comply with a CID seeking testimony related to various policies, procedures and processes Anthem used to ensure the validity of this data, including data from two sources, retrospective chart review results, and provider-submitted claims data.¹⁹¹

The dispute stems from disagreements between Anthem and DOJ regarding the validity of a theory of FCA liability based on an insurer's failure to conduct chart reviews to identify potentially unsupported provider-submitted diagnosis codes, and thus, whether certain CID requests related to provider-submitted claims data are relevant to and properly within the scope of the government's investigation.

Unlike a litigated matter, in a DOJ investigation, the subject of the investigation does not have an opportunity to address the validity of a theory of liability through a motion to dismiss. Consequently, any challenges to a CID are largely limited to procedural grounds. To obtain enforcement of an administrative subpoena, the government must show: "(1) the investigation will be conducted pursuant to a legitimate purpose; (2) the inquiry may be relevant to the purpose; (3) the information sought is not already within [the Government's] possession; and (4) the administrative steps required have been followed." This is a relatively low bar. And, if the government establishes these elements, the subpoena will be enforced unless it is unreasonable, issued in bad faith or for an improper purpose, or compliance with the subpoena would be unnecessarily burdensome.

In recommending that the district court grant DOJ's petition, the magistrate judge sidestepped the particular arguments regarding the validity of the theory underlying the government's investigation. First, the magistrate judge explained that "[i]nvestigating whether Anthem violated the FCA is a legitimate purpose for the investigation." Furthermore, the magistrate judge determined that Anthem had not argued that the topics were not relevant, but rather that they were not proportional to the needs of the investigation. While Anthem had provided an affidavit stating that the requested testimony would take at least a dozen employees and six months to prepare, the magistrate judge found that Anthem failed to show compliance would be unnecessarily burdensome because the affidavit did not provide any "specific facts, examples or details" to support the alleged burden.

Anthem had also argued the meet-and-confer requirement in Rule of Federal Civil Procedure 37(1) applied, and the government did not comply with these requirements. The magistrate judge held that the FCA "does not contain a meet-and-confer certification requirements comparable to the one contained in [Rule 37(a)(1)]." The magistrate judge further noted that, even if a meet-and-confer requirement were applicable, letters between Anthem and the government indicated "Anthem viewed written correspondence between the parties as sufficient means of meeting and conferring," and the magistrate judge found the government had "engaged in good-faith meet-and-confer requirements."

Anthem has filed an objection to the magistrate judge's report and recommendation, which is scheduled for oral argument in January 2019.

Discovery in FCA "Bellwether Trial"

In *U.S. ex rel. Polansky v. Executive Health Resources*, the district court and parties are taking a novel "bellwether" approach to litigating a relator's claims alleging a nationwide fraud scheme that purportedly affected claims across dozens of hospitals. *Polansky* is a declined *qui tam* case in which the relator alleged that Executive Health Resources (EHR) engaged in a nationwide scheme to provide its client hospitals with fraudulent certifications of inpatient status, such that associated claims were reimbursed at a higher level than they would be if categorized as an outpatient claim. In 2017, the district court decided to schedule a "bellwether trial"¹⁹² related to a limited number of client hospitals and limited number of claims. The parties have spent the better part of last year slogging through discovery disputes related to the selection of claims.

After EHR produced data on approximately 38,000 patient cases associated with 24 hospitals, each side selected 220 cases for discovery prior to the bellwether trial. The relator asserted that he chose his 220 through random statistical sampling of cases coded as inpatient, while EHR selected its cases through a non-random method that was not explained. The relator filed a motion for randomization of the medical records review. The district court delayed ruling on the motion and suggested the parties address EHR's selection methodology through a 30(b)(6) deposition.¹⁹³

After a dispute regarding the scope of attorney-client and work product protection applicable to the EHR's record selection,¹⁹⁴ the district court concluded "that the most appropriate way to get a fair representation of the cases for trial and arrive at a final judgment in this case, assuming it is not settled, is to have a combination of cases of some randomly selected, and other selected by each party." As a result, each side was ordered to randomly select 110 cases including outpatient and inpatient certifications, and then select another 110 cases with no more than 25% being outpatient certifications. The district court emphasized that each side must disclose the facts underlying their selection, but suggested that the parties confer to explore engaging a statistician to select the random claims.

¹⁹¹ Report and Recommendation, *United States v. Anthem, Inc.*, No. 1:18-MC-379, at *1-2 (S.D.N.Y. Nov. 13, 2018).

¹⁹² A bellwether trial usually involves cases with multiple plaintiffs who have common facts, claims or theories, and a group of plaintiffs is chosen to represent all plaintiffs. After the representative cases are tried, the results are extrapolated across all remaining cases in an effort to help valuing settlement claims. In *Polansky*, the bellwether trial is used to refer representative claims submitted for Medicare reimbursement by EHR.

¹⁹³ 300 F. Supp. 3d 658, 659-60 (E.D. Penn. Mar. 13, 2018).

¹⁹⁴ *Id.*; see also 2018 WL 1964195 (E.D. Penn. Apr. 26, 2018).

Geographic and Temporal Limits

In *U.S. ex rel. Conroy v. Select Medical Corp.*, the district court focused the parties on proportional discovery by emphasizing the need to tailor the geographic and temporal scope of discovery to allegations in the complaint.¹⁹⁵ The relators argued that they were entitled to discovery related to each of the defendant's more-than 100 long-term acute care hospitals across the country. The complaint alleged that a corporate policy played a role in the submission of false claims by the Evansville facility and its chief medical officer. The district court concluded, however, that the case should not be treated like a nationwide fraud case for purposes of ensuring proportional discovery because there were not any specific allegations regarding other facilities or medical directors.¹⁹⁶

In determining the appropriate scope of discovery, the district court looked beyond the complaint and gave deference to the government's apparent view of the case based on the scope of its investigation and silence in light of the docketed discovery disputes. Specifically, the district court considered the fact that the government's pre-intervention decision investigation focused only on the company's Evansville hospital. Furthermore, the district court noted the government – which “is served with all filings in [the] case” – “could have expressed its views ... that nationwide discovery is appropriate,” but had not. Consequently, the district court concluded the “most natural reading of the complaint is that it is limited to fraudulent Medicare claims for patients at Evansville Hospital,” and limited discovery to Medicare claims at that facility.

In addressing the appropriate temporal scope of discovery, however, the district court rejected the defendants' argument that the outer limit of discovery should be the date that the relators filed their sealed complaint because “the nature of the allegations is that the scheme was ongoing, and the complaint was not even served on the defendants until years after it was filed.” For their part, the relators had not suggested an outer date for the discovery period. Acknowledging that “picking any end date is somewhat arbitrary,” the district court concluded an appropriate end date for discovery would be the date the court ruled on the motion to dismiss. The district court reasoned that this date would establish a “reasonable period of overall time” of more than six years that would be “manageable for discovering information about Evansville Hospital's alleged fraudulent Medicare claims.”

Processes and Privileges Relating to Obtaining Discovery from the Government

Included above in our analysis of issues relating to *Escobar* is a detailed discussion of the nature of discovery requests issued by parties to the government in light of *Escobar*. Several cases have also touched on unique privilege or procedural issues that arise when seeking information from the government.

Touhy Regulations. *Touhy* regulations are promulgated by specific government agencies to regulate disclosure of agency information and records when the government is not a party to a lawsuit. In *U.S. ex rel. Howard v. Caddell Construction Co.*, the district court clarified that relators do not have standing to assert that a defendant violated relevant *Touhy* regulations. In that non-intervened FCA case, the defendants retained two experts who were former employees of the Department of Defense (DOD). The relator moved to strike the experts' testimony because the defendants did not comply with *Touhy* regulations applicable to former DOD employees. The district court held that the relator did not have standing to assert a *Touhy* violation because the “concerns of executive privilege and agency efficiency that underlie *Touhy* regulations do not exist in this case.” Furthermore, government attorneys – who “receive notice of all filings in the case” – did not require the defendants to request permission under applicable regulations. As a result, the district court denied the relators motion to strike the defendants' experts' testimony.¹⁹⁷

Privilege Assertions by the Government. Courts also made clear that the government is held to the same privilege processes and analysis as private parties when asserting certain privileges, even if the asserted privileges are unique to the government. In *U.S. ex rel. Dean v. Paramedics Plus LLC*, the defendant sought communications between the government and third parties related to profit caps. The government “vaguely alluded” that information in “investigation and litigation files . . . might be privileged[,] but it [made] no argument regarding privilege, [had] not produced a privilege log, and [had] not asked the Court to review any documents *in camera*.” The district court made clear that the government cannot sidestep standard privilege processes and analysis through such broad assertions of privilege by flatly concluding that it “cannot and will not rule on such an objection.”¹⁹⁸

After *Escobar*, as defendants continue to seek information regarding government knowledge, defendants may face attempts by the government to withhold certain materials based on the deliberative process privilege. “The deliberative process privilege allows the government to withhold documents and other materials that would reveal advisory opinions, recommendations and deliberations comprising part of a process by which governmental decisions and policies are formulated.”¹⁹⁹ The deliberative process privilege, however, is a qualified privilege, and it can be overcome by a showing of need. As confirmed by a recent non-FCA case, the government may waive the privilege with regard to specific materials previously released.

In *UnitedHealthcare Ins. Co. v. Azar*, the district court held that the government had waived the deliberative process privilege with respect to two specific documents that had previously been released in response to a FOIA request.²⁰⁰ In the context of FCA cases, the deliberative process privilege will likely continue to provide the government with a powerful shield against broad discovery requests from defendants relating to the materiality of an alleged misconduct, but the government risks waiver of the privilege as it manages various types of requests for information, such as FOIA requests, that may serve different purposes.

¹⁹⁵ At least one court refused to stay discovery pending resolution of the motion to dismiss, but remained mindful of proportionality by noting it has sufficient details “to enable it to decide the issues of relevancy and proportionality should discovery motions be filed.” *United States v. Infilaw Corp.*, 2018 WL 889024 (M.D. Fla. Feb. 14, 2018).

¹⁹⁶ 307 F. Supp. 3d 896 (S.D. Ind.).

¹⁹⁷ 2018 WL 2291300 (E.D.N.C. Feb. 22, 2018).

¹⁹⁸ 2018 WL 620776, at *7.

¹⁹⁹ *UnitedHealthcare Ins. Co. v. Azar*, 316 F. Supp. 3d 339 (D.D.C. 2018) (citing *In re Sealed Case*, 121 F.3d 729, 737 (D.C. Cir. 1997)).

²⁰⁰ *Id.* at 348-49.

INTERVENTION, SETTLEMENT AND DISMISSAL

Intervention Decision and Seal Period. In *U.S. ex rel. Brasher v. Pentec Health, Inc.*, the district court refused to extend the seal period during which the government investigated kickback allegations in connection with an action that had been under seal for more than five years.²⁰¹ The district court denied the government's eleventh extension request and subsequent request for reconsideration even after both the relator and the defendant joined that request.

The district court held that the matter would not remain sealed to allow the government and defendant time to reach a settlement. It noted that "the purpose of the sealing provision is not to allow the Government to prosecute a civil action entirely under seal and then to present a settlement as a *fait accompli* to the Court and the general public."

The defendant also argued that the matter should remain sealed because a senior lender might back out of financing if it became aware that the defendant had been the subject of a parallel criminal investigation. The district court, however, found this argument insufficiently supported and dismissed Pentec's concern in the absence of additional information as "sheer speculation."

Quoting a 1986 Senate Judiciary Committee report, the district court observed that the purpose of the seal period is only to permit the government to determine "if that suit involves matters the Government is already investigating and whether it is in the Government's interest to intervene and take over the civil action." Furthermore, according to that report, "with the vast majority of cases, 60 days is an adequate amount of time to allow the Government coordination, review and decision."

Citing other district court opinions, the district court recognized that "courts have grown increasingly impatient with the Government's repeated requests for extension of the seal in *qui tam* actions." As a case in point, on the same day that the district court issued its opinion, the Fifth Circuit issued an opinion noting the district court's "frustration with the Government for taking so long to decide whether to intervene."²⁰²

It remains to be seen whether these cases evidence a growing trend. The implications of such a trend, if it does exist, might very well be mixed. Shorter government investigations might mean lower costs for FCA defendants. On the other hand, more fulsome investigations offer defendants more opportunity to rebut allegations stemming from a *qui tam* complaint or the government's resulting investigation or resolve FCA claims before they are made public.

Dismissal. Following the filing of an FCA action, the government may generally choose one of four options. The government may elect to "intervene [in the filed FCA action] and proceed with the action"²⁰³ or decide to take no action, allowing the "person who initiated the action ... the right to conduct the action."²⁰⁴ Rather than have the action proceed in federal court, the government can instead "pursue its claim through any alternate remedy available to the Government."²⁰⁵ Finally, the government possesses the right under the FCA to "dismiss the action notwithstanding the objections of the person initiating the action if the person has been notified by the Government of the filing of the motion and the court has provided the person with an opportunity for a hearing on the motion."²⁰⁶ The government's exercise of its dismissal authority has been the frequent subject of FCA litigation.

When the government chooses to dismiss an FCA action, a continuing point of contention is whether the government's justification for dismissal is sufficient. Relators often will dispute the dismissal of their FCA actions, contending dismissal is unwarranted. Courts, however, regularly defer to the government's reasons for dismissal. For example, in *U.S. ex rel. Toomer v. Terrapower, LLC*, the district court accepted – over a relator's challenge – the government's bases for dismissal, which were that: (1) "continued litigation [would] waste substantial government time and resources;" (2) the government "has not yet suffered any damages because of the [d]efendants' actions;" (3) "continued litigation [would] impair or delay" the government's work with the defendants; and (4) the relator had "failed to state viable FCA claims."²⁰⁷ The district court reasoned that the relator's challenge to the government's reasons for dismissal was mere disagreement "with the government's priorities," and such disagreement "is insufficient to establish the government's reasons for seeking dismissal are invalid." Likewise, in *U.S. ex rel. Stovall v. Webster University*, the district court accepted the government's assertion that "its interest in preserving scarce resources by avoiding the time and expense necessary to monitor this action" justified dismissal, despite the relator's contention that "the anticipated financial gain [of his action] outweighs the anticipated time and money to be expended on this case."²⁰⁸ According to the district court, the government's "interest in allocating its resources as it sees fit" was a sufficient basis for dismissal.

On occasion, defendants may challenge the government's decision to dismiss an FCA action, and those challenges often contest the government's justifications for dismissal. For example, in *U.S. ex rel. Vaughn v. United Biologics, LLC*, the defendants appealed the dismissal of an FCA action based on the government's request for dismissal and sought to keep the action in the Southern District of Texas rather than have to litigate a parallel action in the Northern District of Georgia.²⁰⁹ The defendants argued that dismissal of the FCA action in

201 *U.S. ex rel. Brasher v. Pentec Health, Inc.*, 2018 WL 5003474 (E.D. Pa. Oct. 16, 2018).

202 *U.S. ex rel. Vaughn v. United Biologics, LLC*, 907 F.3d 187 (5th Cir. 2018).

203 31 U.S.C. § 3730(b)(2).

204 31 U.S.C. § 3730(c)(3).

205 31 U.S.C. § 3730(c)(5).

206 31 U.S.C. § 3730(c)(2)(A).

207 2018 WL 4934070 (D. Idaho Oct. 10, 2018).

208 2018 WL 3756888 (D.S.C. Aug. 8, 2018).

209 907 F.3d 187 (5th Cir. 2018).

Texas was unwarranted, and that even if the dismissal were appropriate, it should have been with prejudice as to the government. Addressing the defendants' first contention, the Fifth Circuit concluded that the pendency of a parallel action in Georgia sufficiently justified the government's request for dismissal in Texas and that requiring "a more specific response" would "compromise" the government's litigation strategy. The Fifth Circuit also rebuffed the defendants' effort to have the FCA action's dismissal be with prejudice as to the government, concluding that "because the Government never intervened in the case, and therefore never became a 'party' to the litigation, no dismissal as to the Government would be appropriate."

STARK LAW/AKS

Several noteworthy developments involving the AKS and Stark Law occurred during the past year, including multiple cases and settlements that examined an array of important concepts related to these statutes and the broad scope of potential liability.

EXPANDING THE CONTOURS OF REMUNERATION

Courts continued to examine the contours of what constitutes remuneration. In *U.S. ex rel. Riedel v. Boston Heart Diagnostics Corp.*, the complaint alleged that Boston Heart offered and provided multiple forms of remuneration to physicians to induce their referrals of Medicare patients for advanced lipid testing.²¹⁰ Denying Boston Heart's motion to dismiss, the district court found the relator plausibly alleged that the company's practice of waiving co-payments and deductibles for commercially insured patients constituted a kickback because it benefitted physicians by "saving [them] time . . . on explaining [such] charges to patients and providing them an opportunity to market free laboratory testing." The district court also held that the relator – a former member of Boston Heart's board of directors – adequately pleaded the existence of kickbacks in the form of inflated packaging fees, notwithstanding Boston Heart's attempt to distinguish the OIG guidance cited by the relator to support his allegations. The district court agreed with Boston Heart, however, that the relator's characterization of \$200,000 in speaking and consulting fees paid to a physician and nurse practitioner as "outrageous," without more, was conclusory and fell short of Rule 9(b)'s particularity requirements for alleging fraudulent conduct.

The relator in *U.S. ex rel. Health Choice Alliance, LLC v. Eli Lilly and Company, Inc.*, alleged that, among other things, Eli Lilly provided illegal remuneration in the form of free nurse educator services and reimbursement support services to induce physicians to recommend Eli Lilly's medications.²¹¹ Eli Lilly argued that these services were merely "product support services" similar to services the OIG had previously identified in its *Compliance Program Guidance for Pharmaceutical Manufacturers* as having no substantial independent value and that do not implicate the AKS. The magistrate judge rejected these arguments, explaining that the nurse educator services and the reimbursement support services had "independent value" that may have "eliminated a substantial expense Prescribers would otherwise have had to incur" and declined to dismiss the relator's allegations on these grounds. Although the relator had plausibly alleged provision of illegal remuneration by the defendants, ultimately, the magistrate judge recommended dismissing the relator's complaint for failure to plead the allegations with particularity while allowing the relator to file an amended complaint.

In *U.S. ex rel. Derrick v. Roche Diagnostics Corp.*, the second amended complaint alleged that Roche Diagnostics accepted an amount less than Humana's debt to it in exchange for Roche products remaining on Humana's Medicare Advantage formularies – a lucrative business opportunity.²¹² According to the allegations, Roche discovered that it had erroneously overpaid Humana in rebates by \$45 million, yet accepted less than \$11 million in settlement. Despite Roche's characterization of the debt settlement as a "routine, arms-length compromise involving a disputed contractual obligation," the district court determined that a settlement for less than the full debt could constitute "remuneration" and declined to dismiss the relator's allegations.

PHYSICIAN COMPENSATION/SWAPPING

Physician compensation continued to fall squarely within the crosshairs of enforcement actions. The relator in *U.S. ex rel. Bruno v. Schaeffer*, a former salesman for MedComp, alleged that his former employer set up non-functioning laboratories to serve as a "front" to compensate physicians who sent urine drug testing specimens to Quantum Laboratory.²¹³ Specifically, the relator alleged that MedComp set up four non-functioning laboratories and invited physicians to purchase ownership interest in these labs. These physicians then referred urine drug testing samples to either MedComp (if the testing was reimbursable by federal healthcare programs) or Quantum (if the testing was reimbursable by commercial insurers) and received payment from Quantum for every specimen referred for drug testing. The defendants moved to dismiss the complaint, arguing that any alleged remuneration for referrals to Quantum could not violate federal laws because Quantum only billed commercial insurers. The district court rejected this argument, concluding that compensation for referrals of services reimbursable by commercial insurers may constitute a payment to induce referrals of *federal* health care program business "if there is a nexus between the kickbacks for private insurance and Medicare or Medicaid business."

Citing OIG guidance and advisory opinions, the district court determined that it was "reasonable to infer" that the payments for referrals to Quantum would increase the chances that the physicians refer samples to MedComp, which bills Medicare and Medicaid.

Physician compensation continued to fall squarely within the crosshairs of enforcement actions.

In a significant settlement, SightLine Health, LLC, agreed to pay \$11.5 million to settle allegations it violated the FCA by participating in a kickback scheme to pay physician-investors for referrals to its cancer centers. SightLine, as a developer of radiation oncology centers, allegedly targeted certain physicians, who treat cancer patients, to become investors in its cancer centers and entered into arrangements that allowed the physicians to receive distributions for their investments. Knowing these cancer centers could only pay out distributions if they made profits, these physicians allegedly referred their patients to those cancer centers operated by SightLine, and in return, SightLine paid the physician-investors a portion of the cancer centers' profits in the

210 2018 WL 4354944 (D.D.C. Sept. 12, 2018).

211 2018 WL 3802072 (E.D. Tex. Aug. 10, 2018).

212 318 F. Supp. 3d 1106 (N.D. Ill. 2018).

213 328 F. Supp. 3d 550 (M.D. La. 2018).

form of distributions. SightLine and its parent company Integrated Oncology Network (ION) entered into a five-year CIA with the government, in which ION agreed to implement certain selection procedures for any arrangements entered with healthcare providers or cancer centers.

In a consolidated settlement of four *qui tam* lawsuits, William Beaumont Hospital agreed to pay \$84.5 million and to enter into a five-year CIA to settle FCA, AKS and Stark Law allegations. From 2004 until 2012, William Beaumont Hospital allegedly compensated numerous physician medical directors at rates above fair market value to induce referrals, while many of their agreements failed to identify services to be performed or meet regulatory requirements. During this time period, William Beaumont Hospital also provided office space to certain physicians and physician groups for free or at rates below fair market value to induce referrals.

Post-Acute Medical, LLC (PAM), which operates long-term acute care hospitals, rehabilitation hospitals and clinics, agreed to pay \$13 million to resolve allegations it paid physicians for referrals to their facilities in violation of the AKS and the Stark Law.²¹⁴ PAM allegedly entered into agreements for medical director, consultant, and other medical and administrative services with physicians, but under these agreements, physicians were allegedly paid for services not actually performed and referrals. PAM also allegedly participated in “reciprocal referral relationships” to refer patients to other healthcare providers in return for referrals to their hospitals and clinics. Besides payment of the settlement amount, PAM has entered into a five-year CIA.²¹⁵

UPMC Hamot, an Erie, Pennsylvania, hospital, and Medicor Associates, Inc., a physician cardiology practice, agreed to pay \$20.75 million to settle an FCA lawsuit alleging violations of both the Stark Law and AKS.²¹⁶ From 1999 to 2010, UPMC Hamot allegedly paid Medicor up to \$2 million per year under physician and administrative services arrangements. These arrangements were allegedly created to obtain patient referrals when UPMC Hamot had no legitimate need for the contracted services, some of which were duplicative services or never performed.

PROCEDURAL HURDLES IN ONGOING AKS AND STARK CASES

Over the past year, courts frequently were asked to decide AKS or Stark Law cases on their merits based upon claims that the pleadings failed to clear procedural or evidentiary hurdles with mixed results for providers. In ***U.S. ex rel. Greenfield v. Medco Health Solutions, Inc.***, the relator argued that Accredo, a specialty pharmacy that sells blood clotting drugs and provides nursing assistants to hemophiliacs in their homes, violated the AKS and FCA in connection with donations it made to two charitable organizations that aid the hemophiliac community.²¹⁷ The Third Circuit ultimately held an AKS violation does not “morph into a false claim unless a particular patient is exposed to an illegal recommendation or referral and [the] provider submits a claim for reimbursement pertaining to that patient.” Because the plaintiff failed to offer evidence of a single false claim, the Third Circuit affirmed the district court’s grant of summary judgment.

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particularity, the district court noted that a patient tracking log showing “the date the patient was referred, the date Addus started providing care, the payor source, and the referral source” was adequate evidence “to infer that Addus submitted false claims and created false records in violation of the AKS” As a result, the district court held that the mere allegation that a scheme was replicated across multiple facilities or markets was not enough to bring claims against those other facilities.

In ***U.S. ex rel. Silver v. Omnicare, Inc.***, the Third Circuit revived a complaint alleging that PharMerica Corporation violated the AKS by offering below-cost, flat per diem rates for servicing its nursing home customers’ Medicare Part A patients. Allegedly, PharMerica could then secure lucrative contracts to supply drugs to patients covered under Medicare Part D for which PharMerica could bill on a cost basis.²¹⁹ Reversing the district court’s grant of PharMerica’s motion for summary judgment and motion to dismiss, the Third Circuit concluded that the relator’s claims were not subject to the public disclosure bar where the alleged fraud could not reasonably have been discovered from documents in the public domain absent additional non-public information available to the relator. Specifically, although both the district court and PharMerica relied on the existence of government reports addressing the general concept of swapping in the nursing home industry, documents reflecting PharMerica’s status as a major player servicing nursing homes and aggregate financial information from PharMerica’s 10-K disclosure form, the Third Circuit found the public disclosure bar inapplicable where the relator’s knowledge of PharMerica’s non-public, actual per diem rates was “the key to uncovering the fraud.”

In ***U.S. ex rel. Stop Illinois Marketing Fraud, LLC v. Addus HomeCare Corp.***, the relator attempted to assert, for the third time, FCA allegations against Addus based on an alleged referral scheme between Addus and a number of senior living facilities in Illinois.²¹⁸ The relator alleged that Addus engaged in schemes aimed at providing kickbacks to senior living facilities in exchange for referrals, including agreements to cross-market each other’s services. The district court partially granted Addus’s motion to dismiss, focusing on the fact that, for the majority of senior living facilities, the relator failed to plead with particularity facts demonstrating that illegal referral schemes existed and that false claims were submitted as a result of those schemes. As for the FCA allegations the relator pleaded with sufficient

214 *U.S. ex rel. Johnson v. Post Acute Medical, LLC*, Civ. A. No. 17-cv-1269 (M.D. Pa.).

215 <https://www.justice.gov/opa/pr/post-acute-medical-agrees-pay-more-13-million-settle-allegations-kickbacks-and-improper>.

216 <https://www.justice.gov/opa/pr/pennsylvania-hospital-and-cardiology-group-agree-pay-2075-million-settle-allegations>.

217 880 F.3d 89 (3d Cir. 2018).

218 2018 WL 1411124 (N.D. Ill. Mar. 21, 2018).

219 903 F.3d 78 (3d Cir. 2018).

In **U.S. ex rel. Chase v. HPC Healthcare, Inc.**, the Eleventh Circuit affirmed the district court's dismissal of a *qui tam* action against a hospice provider for alleged FCA violations.²²⁰ Although the complaint provided a detailed overview of the defendant's improper billing practices and kickback schemes, the allegations were conclusory, lacking "some indicia of reliability" supporting that false claims were actually submitted. Specifically, the relator did not support her FCA claims with tangible examples of patients receiving medically unnecessary care, record falsification, persons making referrals or benefiting from referrals, or facts supporting the presence of an agreement to violate the FCA. Because the relator neither engaged in a "protected activity" related to the FCA nor established a causal link between her actions and the defendant's alleged retaliatory actions, the Eleventh Circuit also rejected her FCA retaliation claim.

In **U.S. ex rel. Bawduniak v. Biogen Idec, Inc.**, relators alleged that Biogen paid illegal kickbacks to providers through sham consulting arrangements and speaking programs to induce prescriptions of Biogen's multiple sclerosis drugs.²²¹ The complaint alleged that Biogen retained far more consultants than necessary, liberally paid consulting fees and retained consulting providers based on their prescribing volume and ability to influence their peers rather than their expertise. In 2009 and 2010, Biogen paid \$18 million under such arrangements to 1,500 physicians and nurses who wrote prescriptions for 60% of the multiple sclerosis market. Biogen allegedly paid providers for both speaker training sessions and for speaking engagements. According to the complaint, Biogen "constantly" trained hundreds of providers although most of these providers participated in speaking engagements only a few times a year often to a single person. Additionally, Biogen allegedly failed to use the feedback from its provider consultants. The district court determined that the complaint offered enough support that the consulting and speaking programs were not commercially reasonable. The complaint further alleged that Biogen's compliance department routinely expressed concerns there were too many meetings, consultants and payments to providers, but was ignored by marketing executives. In partially denying Biogen's motion to dismiss, the district court found that the relators' amended complaint was sufficient to show Biogen acted with actual knowledge, deliberate ignorance or reckless disregard it was violating the AKS and causing providers to present false claims.

In **U.S. ex rel. Piacentile v. Snap Diagnostics, LLC**, a provider of home sleep diagnostic testing, allegedly devised a scheme to bill Medicare for unnecessary and duplicative services and pay kickbacks to referring physicians by allowing them to bill for the professional component of the testing based on professional services performed by Snap's physicians in violation of the AKS and FCA.²²² While patients routinely undergo only a single night of home sleep testing to diagnose sleep apnea, Snap conducted two nights of testing for Medicare and self-pay patients when there was no medical need for an additional night of testing. The complaint alleged that Snap conducted only one night of testing for patients with private insurance. Snap encouraged its sales team, which was paid on a per-test basis, to push additional nights of medically unnecessary testing to generate commissions. The complaint detailed conversations between Snap executives discussing this business model's potential to increase referrals. Snap

also offered free or no-copay tests internally valued at more than \$1,000 per test to referring physicians, their families or key staff members to induce patient referrals. The district court denied Snap's motion to dismiss, finding that the allegations of Snap's provision of "effort-free billing opportunities" to referring physicians and scheme to bill medically unnecessary and duplicative services sufficiently pleaded violations of the AKS and FCA.

In **U.S. ex rel. Patel v. Catholic Health Initiatives**, relators argued that rescission payments made as part of a hospital buyout of physician-investors violated the Stark Law and AKS.²²³ The passage of the PPACA's limitations on physician-owned hospitals combined with poor performance led St. Luke's Health System to buy out physician-investors of its hospital in Sugar Land, Texas, through a statutory rescission process under the Texas Securities Act (TSA). The complaint alleged that the buyout resulted in payments to the physician-investors that were substantially above the market value of their investment in the hospital, and these high payments were intended to maintain a referral relationship with the physicians. At the time of sale, the units were appraised at only \$5,000, although they originally sold for \$40,000. However, the TSA rescission provision mandates that the buyer recover the consideration paid for the security plus interest less the amount of any income received on the security. The rescission payment is intended to be consideration for the release of potential legal claims. The relators already had a lawsuit pending in state court against St. Luke's. Therefore, St. Luke's faced a real risk of litigation, legitimizing its use of the rescission process. In dismissing the relators' claims, the district court determined that it was implausible that the buyout payments were made to induce referrals from the physician-investors or were in excess of fair market value because using rescission was legitimate and there was an existing threat of litigation. The district court further determined that the buyout fell within the isolated-transaction exception to the Stark Law.

CONTINUED SCRUTINY OF MEDICAL DIRECTOR ARRANGEMENTS

Arrangements involving medical directors remained a persistent risk area under the AKS and Stark Law. As mentioned above, William Beaumont Hospital agreed to pay \$84.5 million to resolve allegations, in part, that it violated the Stark Law and AKS by grossly overpaying cardiologists to serve as medical directors.²²⁴

And, Georgia Bone & Joint (GBJ), Southern Bone & Joint a/k/a Summit Orthopaedic Surgery Center (Summit Surgery Center), Southern Crescent Anesthesiology, PC (SCA), Sentry Anesthesia Management, LLC (Sentry), and David LaGuardia (LaGuardia), an associated nurse anesthetist and co-owner of the anesthesiology companies, agreed to pay \$3.2 million to settle, among other things, allegations of AKS and FCA violations stemming from the provision of a free medical director to Summit Surgery Center by SCA, Sentry and LaGuardia to encourage more procedures be performed at Summit Surgery Center rather than GBJ's office.²²⁵ The relator also had alleged

220 723 F. App'x 783 (11th Cir. 2018).

221 2018 WL 1996829 (D. Mass. Apr. 27, 2018).

222 2018 WL 2689270 (N.D. Ill. Jun. 5, 2018).

223 312 F. Supp. 3d 584 (S.D. Tex. May 16, 2018).

224 <https://www.justice.gov/opa/pr/detroit-area-hospital-system-pay-845-million-settle-false-claims-act-allegations-arising>.

225 <https://www.justice.gov/usao-ndga/pr/orthopaedic-and-anesthesia-providers-pay-32-million-settle-false-claim-act-allegations>; see also *U.S. ex rel. Kopko v. Georgia Bone & Joint, L.L.C.*, No. 3:13-CV-067 (N.D. Ga. Apr. 17, 2013).

that Sentry paid GBJ physicians annual bonuses to augment referrals to Summit Surgery Center and that Summit Surgery Center paid at least one GBJ physician to encourage the physician to perform procedures at Summit Surgery Center rather than his office in violation of the AKS.

ONGOING ENFORCEMENT AGAINST AMBULANCE PROVIDERS

Scrutiny of the ambulance industry has persisted as reflected in a notable settlement this year. Seven ambulance providers agreed to pay more than \$21 million to settle an FCA lawsuit, alleging AKS violations related to remuneration provided to secure ambulance business.²²⁶ East Texas Medical Center Regional Healthcare System, Inc., East Texas Medical Center Regional Health Services, Inc., and their affiliated ambulance company, Paramedics Plus, LLC allegedly offered kickbacks to several municipal entities to secure their ambulance business. Over the course of several years, Paramedics Plus paid millions of dollars in *quid pro quo* arrangements, including gifts and political contributions, for the referral of ambulance business. Municipal clients of the ambulance companies had previously agreed to separate settlements about the same conduct.

DEVELOPMENTS IN MEASURING DAMAGES RELATED TO AKS VIOLATIONS

In a case considering the proper measure of damages in FCA actions predicated on AKS violations, the district court in **United States v. Novak** rejected the argument proffered by the defendant that the harm to the government should be assessed based on a “net loss” theory.²²⁷ The defendant, the former CEO of Sacred Heart Hospital, was convicted by a jury in March 2015 on 27 counts of violating the AKS by funneling remuneration to referring physicians through sham personal service contracts, leases and other arrangements in exchange for referrals to the hospital, which was upheld on appeal. In a follow-on FCA case against the former CEO, the district court denied the defendant’s motion for summary judgment, holding that the government did not have to introduce evidence of both the amounts paid by Medicare and Medicaid *and* the value of the services actually provided by Sacred Heart Hospital to prove damages. Rather, relying on Seventh Circuit precedent, the district court found that, where an individual or entity conceals its ineligibility to receive payment for services tainted by the offer or payment of kickbacks, the government would be entitled to the full value of any amounts paid.

²²⁶ <https://www.justice.gov/opa/pr/ambulance-company-and-its-municipal-clients-agree-pay-over-21-million-settle-allegations>.

²²⁷ 2018 WL 4205540 (N.D. Ill. Sept. 4, 2018).

PHARMACEUTICAL AND MEDICAL DEVICE DEVELOPMENTS

Regulatory and enforcement agencies, including DOJ, HHS-OIG and FDA, continued to scrutinize the activities of pharmaceutical and medical device manufacturers this past year.

UNAPPROVED PROMOTION OF MEDICAL DEVICES

Two notable settlements in 2018 involving medical device companies – Medtronic, PLC and AngioDynamics – demonstrate the government’s continued scrutiny of unapproved promotion of medical devices.

On December 4, 2018, Medtronic PLC agreed to pay a combined \$50.9 million to settle three separate DOJ probes of alleged FCA and AKS violations involving improper marketing practices and kickback payments by two of its medical device manufacturer subsidiaries, ev3 Inc. and Covidien LP.²²⁸ ev3 agreed to pay \$17.9 million to settle allegations that it marketed Onyx Liquid Embolic System, a neurovascular medical device that treats brain defects, for unapproved uses from 2005 to 2009, despite FDA’s communicated safety concerns for such uses. The government alleged that ev3’s management financially incentivized the sales force to sell Onyx for unapproved uses, and that the company trained sales representatives to engage in off-label promotion. In addition, Medtronic agreed to pay \$13 million to resolve allegations that Covidien utilized a patient registry to funnel kickbacks to hospitals for using Solitaire, a blood flow restoration device for stroke patients, to induce hospitals to use their device. Finally, the parent company, Medtronic, agreed to pay \$20 million to settle a DOJ investigation involving ev3 and Covidien’s conduct relating to “various market development and physician engagement activities.”²²⁹

On July 18, 2018, a New York-based medical device manufacturer, AngioDynamics, agreed to pay \$12.5 million to resolve allegations that it violated the FCA through unapproved marketing and promotion of two medical devices – LC Bead and Perforator Vein Ablation Kit (PVAK).²³⁰ Specifically, the government alleged that from 2006 to 2011 AngioDynamics marketed an unapproved use of LC Bead, a drug-delivery device, in combination with chemotherapy drugs. The government alleged that AngioDynamics instructed healthcare providers to use inaccurate billing codes when submitting claims for unapproved uses, causing the healthcare providers to submit false claims to government healthcare programs. In addition, the settlement resolves the allegation that AngioDynamics marketed PVAK (renamed the 400 micron kit) to treat perforator veins when the only approved use was for the treatment of superficial veins.

FCA LIABILITY RELATED TO UNRELIABLE DIAGNOSTIC TESTING SERVICES

On March 23, 2018, a Massachusetts-based medical device manufacturer, Alere Inc., and its subsidiary, Alere San Diego, agreed to pay a combined \$33.2 million to settle allegations that the company violated the FCA by knowingly selling unreliable point-of-care diagnostic testing devices.²³¹ Specifically, the government alleged that from 2006 to 2012, Alere sold materially unreliable Triage® devices, despite receiving and failing to act on customer complaints until an FDA inspection prompted a nationwide recall in 2012. The government further alleged that Alere caused hospitals to submit false claims to federal healthcare programs by knowingly selling unreliable point-of-care diagnostic testing devices. The settlement serves as a reminder that FCA liability may apply to any entity that “causes” a false claim to be submitted, not just to those that submit claims. Abbott Laboratories purchased Alere in 2017.

OPIOID ENFORCEMENT

In June 2018, the CEO of Tri-County Wellness and four physicians were charged with a superseding indictment in connection with an investigation of a network of Michigan and Ohio pain clinics, laboratories and other providers.²³² The indictment charged numerous crimes, including wire fraud conspiracy and money laundering and further alleged that the defendants prescribed over 4.2 million dosage units of medically unnecessary controlled substances to Medicare beneficiaries. In October 2018, the CEO pleaded guilty to one count of conspiracy to commit healthcare fraud and wire fraud and one count of money laundering.²³³ Former Attorney General Sessions stated that the plea helped “bring the defendant to justice and reduce the supply of illegal drugs flowing into our communities,” also noting there would “be more cases like this.”

228 <https://www.justice.gov/usao-cdca/pr/medical-device-maker-ev3-plead-guilty-and-pay-179-million-distributing-adulterated>.

229 <https://www.medtronic.com/us-en/about/news/media-resources/medtronic-statement-regarding-doj.html>.

230 <https://www.justice.gov/opa/pr/medical-device-maker-angiodynamics-agrees-pay-125-million-resolve-false-claims-act>.

231 <https://www.justice.gov/opa/pr/alere-pay-us-332-million-settle-false-claims-act-allegations-relating-unreliable-diagnostic>.

232 <https://www.justice.gov/opa/pr/health-care-ceo-and-four-physicians-charged-superseding-indictment-connection-200-million>.

233 <https://www.justice.gov/opa/pr/health-care-ceo-pleads-guilty-150-million-health-care-fraud-scheme-involving-harmful>.

Likewise, civil opioid enforcement efforts continue, with the government focusing on the marketing activities of pharmaceutical manufacturers. In May 2018, for example, the government intervened in five FCA lawsuits accusing Insys Therapeutics Inc., an Arizona-based opioid manufacturer, of paying kickbacks to induce healthcare providers to prescribe its drug.²³⁴ Specifically, the lawsuits alleged that the opioid manufacturer offered improper speaker program payments, improper employment opportunities for prescribers' friends and relatives, and lavish meals and entertainment. The lawsuits also alleged that the opioid manufacturer encouraged healthcare providers to prescribe its drug for off-label medical conditions and that the company employees misrepresented patient diagnoses to obtain Medicare and TRICARE reimbursement.

CONTINUED SCRUTINY OF PATIENT ASSISTANCE PROGRAMS

DOJ continues its focus on manufacturers' use of charitable patient assistance programs (PAPs), which provide funding to assist financially needy patients with obtaining prescription medications for chronic illnesses. A growing number of settlements in 2018 demonstrated DOJ's industry-wide probe into relationships between pharmaceutical manufacturers and independent charitable foundations that administer PAPs.

In 2018, two pharmaceutical manufacturers agreed to settle DOJ investigations into alleged FCA and AKS violations based on the manufacturers' donations to charitable PAPs. In May 2018, Pfizer agreed to pay \$23.85 million and enter into a CIA to resolve FCA liability for allegedly using a charitable PAP administered by Patient Access Network (PAN) Foundation, as a conduit to pay the co-pay obligations of Medicare patients prescribed Pfizer drugs.²³⁵ DOJ alleged that Pfizer made donations to PAN, instead of providing free drugs to qualified patients. Concurrently, with respect to the drug Tikosyn, Pfizer raised the wholesale acquisition cost of the drug by more than 40% in the last three months of 2015, while allegedly knowing that the price increase would also increase Medicare patients' co-pay obligations for the drug.

In the largest PAP-related settlement to date, in December 2018, Actelion Pharmaceuticals, Inc., which was acquired by Johnson & Johnson, agreed to pay \$360 million to resolve an investigation into its financial support of a PAP. DOJ alleged that from 2014 to 2015, Actelion used a charitable PAP administered by Caring Voice Coalition (CVC), to channel its donations to improperly pay the co-pay obligations of Medicare patients using Actelion's pulmonary artery hypertension treatments. Actelion also allegedly used CVC to obtain data regarding patients that used Actelion drugs and then used that information to budget for future payments to CVC. Notably, CVC was at the center of another significant DOJ settlement, the \$210 million settlement by United Therapeutics Corp. in December 2017.

A growing number of settlements in 2018 demonstrated DOJ's industry-wide probe into relationships between pharmaceutical manufacturers and independent charitable foundations that administer PAPs.

²³⁴ <https://www.justice.gov/opa/pr/united-states-intervenes-false-claims-act-lawsuits-accusing-insys-therapeutics-paying>.

²³⁵ <https://www.justice.gov/opa/pr/drug-maker-pfizer-agrees-pay-2385-million-resolve-false-claims-act-liability-paying-kickbacks>.

APPENDIX – 2018 NOTABLE SETTLEMENTS

FCA SETTLEMENTS CHART

HOSPITALS AND HEALTH SYSTEMS

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
1/19/2018	Scripps Health	Healthcare system agreed to pay \$1.5 million to resolve FCA allegations that it billed Medicare and TRICARE for physical therapy services that were rendered by therapists who did not have billing privileges for these programs and were not supervised by an authorized provider. ¹	\$1.5 million
2/23/2018	Maine Medical Center (MMC)	Hospital agreed to pay \$600,000 to resolve FCA allegations that it improperly billed Medicare for medically unnecessary ambulance transportation provided by North East Mobile Health Services (North East). MMC allegedly provided North East with statements containing incomplete or inaccurate information about the medical necessity of transporting patients by ambulance, which North East thereafter used to bill Medicare. North East agreed to pay \$825,000 this year to resolve related FCA allegations. ²	\$600,000
2/26/2018	Brattleboro Memorial Hospital, Inc.	Hospital agreed to pay \$1.655 million to resolve federal and state FCA allegations that it presented false claims to Medicare and Medicaid for outpatient laboratory tests that lacked documentation necessary to support reimbursement. ³	\$1.655 million
3/7/2018	UPMC Hamot; Medicor Associates Inc.	Hospital and a physician cardiology practice agreed to pay \$20.75 million to resolve FCA allegations that the parties submitted claims for services that violated the AKS and Stark Law. The government alleged Hamot illegally induced patient referrals by paying Medicor \$2 million per year under 12 physician and administrative services arrangements for services for which it had no legitimate need or that were duplicative or never performed. In 2017, the U.S. District Court for the Western District of Pennsylvania held two of Hamot's arrangements violated the Stark Law. The case was set for trial when the parties settled. ⁴	\$20.75 million
3/16/2018	St. Agnes Healthcare, Inc.	Hospital agreed to pay \$69,906 to resolve FCA allegations that, in billing venous Doppler duplex examinations, it used CPT code 93970 and 93965, the latter referring to an older, different technology that generally had been replaced and was incorrectly billed. ⁵	\$69,906

1 <https://www.justice.gov/opa/pr/scripps-health-pay-15-million-settle-claims-services-rendered-unauthorized-physical>.
2 <https://www.justice.gov/usao-me/pr/ambulance-provider-and-hospital-agree-pay-1425000-settle-ambulance-transportation-claims>.
3 <https://www.justice.gov/usao-vt/pr/brattleboro-memorial-hospital-pays-1655000-united-states-and-state-vermont-resolve>.
4 <https://www.justice.gov/opa/pr/pennsylvania-hospital-and-cardiology-group-agree-pay-2075-million-settle-allegations>.
5 <https://www.justice.gov/usao-md/pr/united-states-reaches-settlement-maryland-healthcare-providers-settle-false-claims-act>.

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
3/27/2018	Genesis Medical Center	Acute care hospital agreed to pay \$1.88 million to resolve FCA allegations that it improperly retained Medicare overpayments for hospital inpatient admission claims when those claims should have been billed as either outpatient or observation services, which have a lower reimbursement rate. ⁶	\$1.88 million
4/12/2018	Banner Health	Owner and operator of acute care hospitals agreed to pay \$18.3 million to resolve allegations that 12 of its hospitals falsely billed Medicare for short-stay inpatient procedures that it should have billed on a less costly outpatient basis and submitted false reports inflating the number of hours for which patients received outpatient observation care. As part of the settlement, Banner Health entered into a five-year CIA with HHS-OIG. ⁷	\$18.3 million
5/4/2018	Charles Cole Memorial Hospital	Nonprofit hospital agreed to pay \$373,547 to resolve self-disclosed FCA allegations that it falsely billed Medicare by failing to use a modifier to reduce reimbursement for services provided by physician assistants and nurse practitioners for certain services and by failing to perform required face-to-face encounters with certain hospice patients prior to recertification. ⁸	\$373,547
5/10/2018	Mercy Health	Hospital and healthcare facilities operator agreed to pay \$14.25 million to resolve self-disclosed FCA allegations that it compensated six physicians at rates that exceeded the fair market value (FMV) of their services, in order to induce patient referrals to its affiliated healthcare facilities. ⁹	\$14.25 million
5/14/2018	Memorial Hermann Health System	Hospital system agreed to pay \$1.929 million to resolve FCA allegations that three of its hospitals overbilled Medicare for inpatient surgical procedures that should have been treated in an outpatient or observation setting. ¹⁰	\$1.929 million

⁶ <https://www.justice.gov/usao-sdia/pr/iowa-hospital-pay-188-million-resolve-false-claims-act-allegations-relating-improper>.

⁷ <https://www.justice.gov/opa/pr/banner-health-agrees-pay-over-18-million-settle-false-claims-act-allegations>.

⁸ <https://www.justice.gov/usao-mdpa/pr/charles-cole-memorial-hospital-agrees-settle-over-billing-allegations>.

⁹ <https://www.justice.gov/opa/pr/ohio-hospital-operator-agrees-pay-united-states-1425-million-settle-alleged-false-claims-act>.

¹⁰ <https://www.justice.gov/usao-sdtx/pr/memorial-hermann-health-system-pay-nearly-2-million-resolve-improper-billing>.

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
6/5/2018	Allegiance Health Management, Inc.; various affiliated hospitals	Hospital management company and four of its hospitals agreed to pay more than \$1.7 million to resolve FCA allegations that they submitted or caused other hospitals to submit false bills to Medicare for Intensive Outpatient Psychotherapy (IOP) services that were not medically reasonable or necessary. The government alleged the IOP services were not provided pursuant to individualized treatment plans; patient progress was not adequately tracked or documented; and the therapy provided was primarily recreational or diversional in nature and not therapeutic. ¹¹	\$1.7 million
6/21/2018	Livingston Regional Hospital, LLC	Hospital agreed to pay \$784,000 to resolve FCA allegations that it billed Medicare for inpatient psychiatric care that was not medically necessary. ¹²	\$784,000
7/9/2018	Health Quest Systems, Inc.; Health Quest Medical Practice, P.C.; Health Quest Home Health Care, Inc.; Health Quest Urgent Medical Care Practice, P.C.; Putnam Health Center	Healthcare system, certain subsidiaries and a subsidiary hospital agreed to pay \$15.595 million to resolve FCA allegations that they: (1) improperly billed for Evaluation and Management (E&M) services that lacked sufficient supporting documentation for the level billed; (2) improperly billed for home health services without required supporting documentation; and (3) submitted claims for services referred to the hospital by physicians with whom PHC had improper compensation arrangements, in violation of the AKS and the Stark Law. As part of the settlement, Health Quest entered into a five-year CIA with HHS-OIG. ¹³	\$15.595 million
8/2/2018	William Beaumont Hospital	Regional hospital system agreed to pay \$84.5 million to resolve FCA allegations that it: (1) submitted claims for services referred by physicians with whom it had improper compensation arrangements, violating the Stark Law and AKS; and (2) submitted claims that misrepresented that a CT radiology center qualified as an outpatient department of the hospital. The alleged improper financial arrangements included compensation that exceeded the FMV of the services actually provided and free or below-market office space and office staff. As part of the settlement, the hospital entered into a five-year CIA with HHS-OIG. ¹⁴	\$84.5 million
8/3/2018	Prime Healthcare Services, Inc.; Prime Healthcare Foundation, Inc.; Prime Healthcare Management, Inc.; Dr. Prem Reddy; various affiliated hospitals	Hospital system and certain affiliates agreed to pay \$61.75 million, and its founder and CEO agreed to pay \$3.25 million, to resolve FCA allegations that 14 affiliated hospitals improperly billed Medicare for inflated diagnoses and medically unnecessary inpatient admissions that should have been treated in a less costly outpatient or observation setting. As part of the settlement, Prime entered into a five-year CIA with HHS-OIG. ¹⁵	\$65 million

¹¹ <https://www.justice.gov/opa/pr/allegiance-health-management-pay-more-17-million-resolve-false-claims-act-allegations>.

¹² <https://www.justice.gov/usao-mdtn/pr/livingston-regional-hospital-llc-agrees-settle-false-claims-act-allegations>.

¹³ <https://www.justice.gov/opa/pr/health-quest-and-putnam-hospital-center-pay-147-million-resolve-false-claims-act-allegations>.

¹⁴ <https://www.justice.gov/opa/pr/detroit-area-hospital-system-pay-845-million-settle-false-claims-act-allegations-arising>.

¹⁵ <https://www.justice.gov/usao-cdca/pr/prime-healthcare-services-and-its-ceo-agree-pay-65-million-settle-medicare-overbilling>.

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
8/6/2018	Grenada Lakes Medical Center (GLMC)	Hospital agreed to pay more than \$1.1 million to resolve FCA allegations that it submitted claims to Medicare for medically unnecessary IOP services. The IOP services in question were performed on GLMC's behalf by Allegiance Health Management (Allegiance), a post-acute healthcare management company, but billed to Medicare by GLMC directly. Allegiance settled similar FCA allegations earlier in the year. ¹⁶	\$1.1 million
8/15/2018	Post Acute Medical, LLC (PAM); various affiliated entities	Operator of long-term care and rehabilitation hospitals and certain affiliated entities agreed to pay \$13.168 million to resolve FCA allegations that they paid kickbacks to medical providers in the form of sham medical director agreements and "reciprocal referral" arrangements with unaffiliated healthcare providers in exchange for patient referrals. As part of the settlement, PAM entered into a five-year CIA with HHS-OIG. ¹⁷	\$13.168 million
9/24/2018	Health Management Associates, LLC (HMA); various affiliated hospitals	Hospital operator and various affiliated hospitals agreed to pay more than \$258.5 million to globally resolve criminal charges and civil FCA allegations initially raised in eight separate <i>qui tam</i> actions. The settlement resolved allegations that HMA: (1) knowingly billed government healthcare programs for inpatient services that should have been billed as outpatient or observation services (\$35 million criminal; \$62.5 million civil); (2) paid remuneration to physicians in return for patient referrals at five hospitals in three states (approximately \$149 million civil); and (3) submitted inflated claims for emergency department facility fees (\$12 million civil). As part of the criminal resolution of the inpatient admission allegations, HMA entered into a three-year Non-Prosecution Agreement, and a related hospital pleaded guilty to conspiracy to commit healthcare fraud. As part of the settlement, HMA's successor company agreed to an amended and extended CIA with HHS-OIG. ¹⁸	\$223.5 million (civil) \$35 million (criminal)
9/25/2018	Virginia Commonwealth University Health System Authority	Health system agreed to pay \$3.994 million to settle self-disclosed FCA allegations that it overbilled various government programs for radiation oncology services. ¹⁹	\$3.994 million
9/28/2018	Kalispell Regional Healthcare System (KRH); various affiliated entities	Healthcare system and six related subsidiaries and related entities agreed to pay \$24 million to resolve FCA allegations that they excessively compensated more than 60 physician specialists and charged for administrative services at below FMV to reduce expenses and increase profits to physician investors, in order to induce referrals to the health system. ²⁰	\$24 million

16 <https://www.justice.gov/opa/pr/grenada-lake-medical-center-pay-more-11-million-resolve-false-claims-act-allegations>.

17 <https://www.justice.gov/opa/pr/post-acute-medical-agrees-pay-more-13-million-settle-allegations-kickbacks-and-improper>.

18 <https://www.justice.gov/opa/pr/hospital-chain-will-pay-over-260-million-resolve-false-billing-and-kickback-allegations-one>.

19 <https://www.justice.gov/usao-edva/pr/vcu-health-system-authority-agrees-4-million-settlement>.

20 <https://www.justice.gov/opa/pr/kalispell-regional-healthcare-system-pay-24-million-settle-false-claims-act-allegations>.

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
10/31/2018	Bozeman Health Deaconess Hospital d/b/a Bozeman Health; Deaconess-Intercity Imaging LLC d/b/a Advanced Medical Imaging (AMI)	Hospital and an affiliated radiology group agreed to pay \$238,820 to the state of Montana and an undisclosed amount to the federal government to settle a declined <i>qui tam</i> action alleging state and federal FCA violations related to a purported kickback scheme. The relator alleged Bozeman Health convinced a radiology group to enter into a joint venture with the hospital instead of opening an independent facility, then referred patients to the resulting radiology group, AMI, in exchange for nearly \$2 million per year, free services and majority ownership in the joint venture. ²¹	\$238,820 (state) Undisclosed (federal)
12/11/2018	Coordinated Health Holding Company, LLC; Emil Dilorio, M.D.	Hospital system agreed to pay \$11.25 million, and its principal owner and CEO agreed to pay \$1.25 million, to resolve FCA allegations that they improperly unbundled reimbursement claims for orthopedic surgeries by misusing Modifier 59 to separately bill for part of the same surgery. The government alleged that certain Coordinated Health executives were directly informed at least twice about the improper unbundling, including warnings to stop the practice from two separate outside consultants. The founder and CEO is an orthopedic surgeon who the government alleged personally engaged in a documentation practice allowing billers to unbundle surgeries using Modifier 59. As part of the settlement, Coordinated Health entered into a five-year CIA with HHS-OIG. ²²	\$12.5 million
12/11/2018	Aurora Health Care, Inc.	Healthcare system agreed to pay \$12 million to resolve FCA allegations that it billed Medicare and Medicaid for services provided by two physicians with whom it had entered into improper compensation arrangements with. The government alleged that the agreements were not commercially reasonable and the compensation exceeded the FMV of their services, took into account their anticipated referrals, and were not for identifiable services, in violation of the Stark Law. ²³	\$12 million

²¹ https://www.bozemandailychronicle.com/news/health/hospital-settles-federal-lawsuit-over-radiology-services/article_22d8ce7c-168f-500f-897e-b6e9f204ec50.html.

²² <https://www.justice.gov/usao-edpa/pr/coordinated-health-and-ceo-pay-125-million-resolve-false-claims-act-liability>.

²³ <https://www.justice.gov/usao-edwi/pr/aurora-health-care-inc-agrees-pay-12-million-settle-allegations-under-false-claims-act>.

HOSPICE

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
2/8/2018	365 Hospice LLC f/k/a Horizons Hospice LLC; John C. Rezk	Hospice company and its CEO agreed to pay \$1.24 million to resolve FCA allegations that the company billed Medicare and Medicaid for hospice services for patients who were ineligible for hospice because they did not have a life expectancy prognosis of six months or less. The settlement also resolved allegations that the defendants falsified records to support the purported false claims. As part of the settlement, the hospice company and CEO entered into a five-year CIA with HHS-OIG. The company's former CMO previously pleaded guilty to related criminal allegations and was sentenced to 15 months in prison in 2016. ²⁴	\$1.24 million
5/18/2018	Health and Palliative Services of the Treasure Coast, Inc.; The Hospice of Martin and St. Lucie, Inc.; Hospice of the Treasure Coast, Inc.	Hospice service providers agreed to pay \$2.5 million to settle FCA allegations that they billed for hospice services for 69 patients who were not eligible for all or part of their hospice care under Medicare requirements. As part of the settlement, each provider entered into a five-year CIA with HHS-OIG. ²⁵	\$2.5 million
6/25/2018	Caris Healthcare, L.P.; Caris Healthcare, LLC	Hospice provider and its subsidiary agreed to pay \$8.5 million to settle FCA allegations that they submitted claims to and retained overpayments from Medicare for hospice care for patients whose medical records did not support a terminal prognosis. ²⁶	\$8.5 million
12/13/2018	SouthernCare, Inc.	Hospice care provider agreed to pay over \$5.863 million to resolve FCA allegations arising from two <i>qui tam</i> actions that SouthernCare admitted patients into hospice who were not terminally ill and lacked appropriate documentation reflecting a terminal illness. ²⁷	\$5.863 million

²⁴ <https://www.justice.gov/usao-wdpa/pr/hospice-company-and-owner-agree-pay-124-million-settle-two-false-claims-act>.

²⁵ <https://www.justice.gov/usao-sdfl/pr/health-and-palliative-services-treasure-coast-inc-hospice-martin-and-st-lucie-inc-and>.

²⁶ <https://www.justice.gov/opa/pr/caris-agrees-pay-85-million-settle-false-claims-act-lawsuit-alleging-it-billed-ineligible>.

²⁷ <https://www.justice.gov/usao-edpa/pr/hospice-care-provider-pays-nearly-6-million-resolve-false-claims-act-allegations>.

HOME HEALTH

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
1/31/2018	Home Family Care Inc.; Alexander Kiselev	Home health provider and its co-owner/president agreed to pay \$6.415 million to resolve allegations that they billed Medicaid for home health aide and personal care aide services that were not provided to Medicaid recipients by directing employees to circumvent its system for verifying aides' attendance at the homes of Medicare beneficiaries to whom the aides were allegedly providing care. ²⁸	\$6.415 million
1/31/2018	Michael Gurevich	Former vice president of Home Family Care agreed to pay \$100,000 in a separate settlement to resolve the same allegations as asserted against the home health provider. ²⁹	\$100,000
6/1/2018	Healthquest, Inc.; Frank Jaramillo; Ruth Jaramillo	Home health provider and its owners agreed to pay \$1.5 million to resolve FCA allegations that the provider paid kickbacks to its marketers to induce them to refer patients to the provider for home health services. As part of the settlement, the defendants entered into a five-year integrity agreement with HHS-OIG. ³⁰	\$1.5 million
7/2/2018	Hope In-Home Care, LLC	Home health provider agreed to pay \$3.345 million to resolve FCA allegations that it engaged in the following schemes in billing Virginia Medicaid: (1) employed and submitted claims for uncertified "personal care aides" who were ineligible to provide services; (2) falsified documents and statements in order to qualify ineligible beneficiaries for services; (3) made false statements in Privacy Act requests in order to obtain approval and reimbursement for non-reimbursable "respite services;" (4) billed for services that were not performed; and (5) hired family members of Medicaid beneficiaries as "personal care aides" and submitted ineligible claims for compensation for care provided by those family members. An administrative director at one of the company's offices pleaded guilty to related criminal charges in 2017. ³¹	\$3.345 million
7/31/2018	Compassionate Home Care Services, Inc.; Carol Anders; Ryan Santiago	Federal court awarded a \$2.921 million judgment against a home care company, the individual who operated the company, and her son for their participation in billing North Carolina Medicaid for services not rendered and for services provided to patients by unlicensed, non-certified aides. Evidence at trial showed that Anders and her son falsified hundreds of documents when the government started investigating the matter in an effort to conceal their obligation to repay the government. ³²	\$2.921 million

28 <https://www.justice.gov/usao-edny/pr/brooklyn-based-home-health-care-service-and-its-president-agree-pay-over-64-million>.

29 <https://www.justice.gov/usao-edny/pr/brooklyn-based-home-health-care-service-and-its-president-agree-pay-over-64-million>.

30 <https://www.justice.gov/usao-sdfl/pr/palm-beach-florida-home-health-care-company-and-its-owner-agree-resolve-false-claims>.

31 <https://www.justice.gov/usao-edva/pr/healthcare-provider-agrees-3-million-false-claims-settlement>.

32 <https://www.justice.gov/usao-ednc/pr/federal-court-awards-nearly-3-million-damages-and-penalties>.

SKILLED NURSING FACILITIES (SNFs) AND NURSING HOMES

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
2/2/2018	Memphis Operator, LLC d/b/a Spring Gate Rehabilitation and Healthcare Center	SNF agreed to pay \$500,000 to resolve FCA allegations it billed Medicare and TennCare for services that were materially substandard, worthless and provided in violation of essential requirements. As part of the settlement, Spring Gate entered into a five-year CIA with HHS-OIG. ³³	\$500,000
3/22/2018	Caring Heart Rehabilitation and Nursing Center; GNH, LLC; OPOP, LLC; Riverview SNF, LLC; Global Healthcare Services Group, LLC; GHC Clinical Consultants, LLC	Four SNFs and two consulting companies agreed to pay a total of \$6 million to resolve FCA allegations that they billed Medicare for skilled therapy that was medically unnecessary. ³⁴	\$6 million
3/29/2018	New Oaklawn Investments, LLC, d/b/a Oaklawn Health and Rehabilitation Center and Elmcroft Senior Living, Inc.	SNF agreed to pay \$5.191 million to resolve FCA allegations that it billed Medicare for rehabilitation therapy services at the Ultra High and Very High RUG levels that were not reasonable or medically necessary. ³⁵	\$5.191 million
6/8/2018	Signature HealthCARE, LLC	SNF operator agreed to pay more than \$30 million to settle claims that it billed Medicare for rehabilitation therapy services that were not reasonable, necessary and skilled, as a result of the following alleged practices: (1) presumptively placing patients in the Ultra High RUG level, rather than relying on individualized evaluations to determine the level of care most suitable for each patient's clinical needs; (2) providing the minimum number of minutes required to bill at a given reimbursement level while discouraging the provision of additional therapy beyond that minimum threshold; and (3) pressuring therapists and patients to complete the planned minutes of therapy even when patients were sick or declined to participate in therapy. The settlement also resolved allegations that Signature submitted forged pre-admission certifications of patient need for skilled nursing to TennCare. As part of the settlement, Signature entered into a five-year CIA with HHS-OIG. ³⁶	\$30 million

33 <https://www.justice.gov/usao-wdtn/pr/memphis-operator-llc-dba-spring-gate-rehabilitation-and-healthcare-center-will-pay>.

34 <https://www.justice.gov/usao-md/pr/united-states-reaches-settlement-four-facilities-and-two-medical-companies-resolve>.

35 <https://www.justice.gov/usao-wdky/pr/louisville-skilled-nursing-facility-pay-5191470-settle-false-claims-allegations>.

36 <https://www.justice.gov/opa/pr/signature-healthcare-pay-more-30-million-resolve-false-claims-act-allegations-related>.

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
6/29/2018	Preferred Care, Inc.; Stanton Nursing and Rehabilitation Center; Thomas D. Scott; Preferred Care Management Group; affiliated entities	SNF operator, its owner, one of its facilities, a management company and other affiliated entities agreed to pay \$540,000 to resolve FCA allegations that the facility billed Medicare and Medicaid for skilled nursing services that were improperly coded for higher amounts than was medically necessary or actually received, and for services that were materially substandard or worthless. Each of the settling parties declared bankruptcy in 2017. ³⁷	\$540,000
7/18/2018	Southern SNF Management, Inc.; Rehab Services in Motion d/b/a Dynamic Rehab; affiliated skilled nursing facilities	Two consulting companies and nine affiliated SNF agreed to pay \$10 million to resolve FCA allegations that they submitted, or caused the submission of, claims to Medicare for rehabilitation therapy services which were medically unreasonable and unnecessary. ³⁸	\$10 million
8/23/2018	Reliant Rehabilitation Holdings, Inc.	Rehabilitation therapy provider agreed to pay \$6.1 million to resolve FCA allegations that, in violation of the AKS, Reliant paid kickbacks to SNFs in the form of: (1) Reliant-employed nurse practitioners who worked at client SNFs without charge or for a nominal, below fair market fee; and (2) above-FMV compensation paid to physicians working at SNFs for supervising and collaborating with Reliant nurse practitioners, in order to induce or reward the SNFs to contract with Reliant. ³⁹	\$6.1 million

³⁷ <https://www.justice.gov/usao-edky/pr/skilled-nursing-facility-management-company-and-owner-agree-pay-540000-resolve>.

³⁸ <https://www.justice.gov/opa/pr/two-consulting-companies-and-nine-affiliated-skilled-nursing-facilities-pay-10-million>.

³⁹ <https://www.justice.gov/opa/pr/reliant-pay-61-million-settle-false-claims-act-allegations-it-paid-kickbacks-nursing-homes>.

PHARMACEUTICAL AND DEVICE

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
1/23/2018	DJO Global Inc.	Medical device company agreed to pay \$7.62 million to resolve FCA allegations that its now-defunct subsidiary (Empi Inc.) billed TRICARE for excessive, unnecessary transcutaneous electrical nerve stimulation (TENS) electrodes that beneficiaries did not need or use. The government alleged Empi used inappropriate techniques such as “assumptive selling” to persuade some TRICARE beneficiaries to seek and accept unjustifiably large quantities of TENS electrodes. ⁴⁰	\$7.62 million
3/8/2018	Abiomed, Inc.	Medical device company agreed to pay \$3.1 million to resolve allegations it violated the FCA by purchasing lavish meals for physicians to induce them to use a line of heart pumps. The government alleged Abiomed: (1) paid for alcohol in an amount inconsistent with scientific discussion; (2) paid for expensive meals for physicians' spouses who had no legitimate business purpose for attending; (3) paid for physicians' meals which well exceeded the company's own per-person guideline; and (4) misrepresented the number of attendants so the cost per attendee appeared lower. ⁴¹	\$3.1 million
3/23/2018	Alere Inc.; Alere San Diego	Medical device manufacturer and its subsidiary agreed to pay \$33.2 million to resolve allegations that they caused hospitals to submit false claims to Medicare, Medicaid and other federal healthcare programs by knowingly selling materially unreliable point-of-care diagnostic testing devices. The government alleged Alere, after receiving complaints putting it on notice that certain devices produced erroneous results with the potential to create false positives and false negatives, failed to take appropriate corrective actions until FDA inspections initiated a nationwide recall in 2012. ⁴²	\$33.2 million
4/12/2018	Rotech Healthcare Inc.	Respiratory equipment supplier agreed to pay \$9.68 million to settle FCA allegations that it automatically billed Medicare for portable oxygen contents without verifying that the beneficiaries used or needed portable oxygen, and without obtaining the requisite proof of delivery despite knowing it resulted in claims ineligible for reimbursement. ⁴³	\$9.68 million

⁴⁰ <https://www.justice.gov/opa/pr/california-medical-device-company-pay-762-million-resolve-allegations-its-subsi-dary-billed>.

⁴¹ <https://www.justice.gov/usao-ma/pr/abiomed-inc-agrees-pay-31-million-resolve-kickback-allegations>.

⁴² <https://www.justice.gov/opa/pr/alere-pay-us-332-million-settle-false-claims-act-allegations-relating-unreliable-diagnostic>.

⁴³ <https://www.justice.gov/opa/pr/rotech-agrees-pay-968-million-settle-false-claims-act-liability-related-improper-billing>.

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
4/16/2018	Allergan, Inc.	Medical device manufacturer agreed to pay \$3.5 million to resolve allegations it caused providers to submit false claims to Medicare and other federal healthcare programs relating to its LAP-BAND Adjustable Gastric Banding System. The government alleged Allergan knowingly sold defective LAP-BANDS; misrepresented facts to conceal the defect; failed to collect or maintain required data and complaint files; offered and provided remuneration to healthcare professionals who reported the defect; advertised, marketed, and distributed the LAP-BAND for use in two non-FDA approved procedures; and provided remuneration (workshops, advisory boards, training events) to healthcare professionals to induce and market the use of the LAP-BAND for these unapproved uses. ⁴⁴	\$3.5 million
5/4/2018	Precision Medical Products, Inc.; Jeremy Perkins; Marc Reynolds	DME supplier and its presidents agreed to pay \$1.9 million to resolve FCA allegations that they: (1) paid independent contractors a commission based on the volume and value of their referrals to Precision in violation of the AKS; (2) waived patient co-pays to induce Medicare beneficiaries to use Precision in violation of the AKS; and (3) billed Medicare and TRICARE using prescriptions and certificates of medical necessity that had stamped, photocopied, and digitally forged physician signatures. ⁴⁵	\$1.9 million
5/24/2018	Pfizer	Pharmaceutical company agreed to pay \$23.85 million to resolve FCA allegations that it used a foundation as a conduit to pay the co-pay obligations of Medicare beneficiaries taking three of its drugs. As part of the settlement, Pfizer entered into a five-year CIA with HHS-OIG. ⁴⁶	\$23.85 million
7/18/2018	AngioDynamics, Inc.	Medical device manufacturer agreed to pay \$11.5 million to resolve allegations that it caused providers to submit false claims for procedures involving an unapproved drug-delivery device that was marketed with false and misleading promotional claims, and allegations that it instructed providers to use inaccurate billing codes when submitting claims for certain procedures that it knew insurers would decline to cover. AngioDynamics agreed to separately pay \$1 million to resolve FCA allegations that it falsely represented to providers that Medicare would cover the use of a device despite knowing Medicare's coverage restrictions to the contrary. ⁴⁷	\$12.5 million

⁴⁴ <https://www.justice.gov/usao-md/pr/allergan-pay-35-million-settle-false-claims-act-allegations-relating-lap-band-bariatric>.

⁴⁵ <https://www.law360.com/articles/1047775/medical-supplier-pays-feds-1-9m-to-end-fca-suit>.

⁴⁶ <https://www.justice.gov/opa/pr/drug-maker-pfizer-agrees-pay-2385-million-resolve-false-claims-act-liability-paying-kickbacks>.

⁴⁷ <https://www.justice.gov/opa/pr/medical-device-maker-angiodynamics-agrees-pay-125-million-resolve-false-claims-act>.

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
9/28/2018	AmerisourceBergen; AmerisourceBergen Specialty Group; AmerisourceBergen Drug Corporation; Oncology Supply Company; Medical Initiatives Inc.	Drug company and its subsidiaries agreed to pay \$625 million to settle FCA allegations arising for the operation of a facility that improperly repackaged oncology-supportive injectable drugs into pre-filled syringes and improperly distributed those syringes to physicians treating cancer patients. In 2017, AmerisourceBergen Specialty Group pleaded guilty to related criminal charges and paid \$260 million to resolve criminal liability. The civil settlement also resolved allegations that the defendants gave kickbacks to physicians – in the form of general pharmacy credits provided to customers, but which were not identifiable as specific to Procrit on the invoice – to induce the purchase of Procrit through the company's pre-filled syringe program. As part of the settlement, AmerisourceBergen entered into a five-year CIA with HHS-OIG. ⁴⁸	\$625 million
10/26/2018	Abbott Laboratories; AbbVie Inc.	Two drug companies agreed to pay \$25 million to settle FCA allegations that they provided kickbacks to physicians – including gift baskets, gift cards, consulting services and speaking engagements – to induce or reward physicians for Tricor prescriptions. The government also alleged the defendants engaged in unlawful methods of off-label marketing and promotion concerning the sale of Tricor for unapproved indications. ⁴⁹	\$25 million
12/4/2018	Covidien LP	Medical device manufacturer agreed to pay \$13 million to resolve FCA allegations that it paid kickbacks to hospitals and institutions to induce them to use one of its devices. Specifically, the government alleged that Covidien started a registry to pay hospitals and institutions to collect data about user experiences with the device. Covidien allegedly: (1) paid a fee to hospitals and institutions that participated in a registry each time they used a new device and reported certain clinical data about their practices for treating stroke patients to Covidien; (2) solicited certain hospitals and institutions for the registry in order to convert their business from the competitor's product and/or persuade them to continue using Covidien products; and (3) used the registry as a means of increasing device sales. ⁵⁰	\$13 million
12/4/2018	LivaNova USA, Inc. f/k/a Cyberonics, Inc.	Medical device company agreed to pay \$1.87 million to resolve FCA allegations that it paid speaking fees to physicians, who were the highest referral sources for a LivaNova device, for participating in events where the attendees were primarily the physicians and their staff, in violation of the AKS. ⁵¹	\$1.87 million
12/6/2018	Actelion Pharmaceuticals US, Inc.	Pharmaceutical company agreed to pay \$360 million to resolve FCA allegations that, in violation of the AKS, it used a foundation as a conduit to pay the co-pay obligations of Medicare patients taking its pulmonary arterial hypertension drugs, in order to induce those patients to purchase the drugs, knowing the prices it set for those drugs otherwise could be a barrier to such purchases. ⁵²	\$360 million

48 <https://www.justice.gov/opa/pr/amerisourcebergen-corporation-agrees-pay-625-million-resolve-allegations-it-illegally>.

49 <https://www.justice.gov/usao-edpa/pr/abbott-laboratories-and-abbvie-inc-pay-25-million-resolve-false-claims-act-allegations>.

50 <https://www.justice.gov/opa/pr/medical-device-maker-ev3-plead-guilty-and-pay-179-million-distributing-adulterated-device>.

51 <https://www.justice.gov/usao-ndga/pr/livanova-agrees-pay-187-million-resolve-false-claims-act-allegations-arising-improper>.

52 <https://www.justice.gov/opa/pr/drug-maker-actelion-agrees-pay-360-million-resolve-false-claims-act-liability-paying>.

PHARMACY SERVICES

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
1/10/2018	Healthy Meds Pharmacy Corporation	Pharmacy agreed to pay \$350,000 to resolve FCA allegations that it violated TRICARE's policy on telemedicine by making unsolicited calls, providing medically unnecessary compound medications, and filling prescriptions from doctors who did not meet or properly consult with beneficiaries. ⁵³	\$350,000
3/8/2018	Kmart Corporation	Retailer agreed to pay \$525,000 to resolve FCA allegations that it failed to confirm and document the requisite diagnoses for drugs on Medi-Cal's formulary list, and in some instances, dispensed drugs for non-approved diagnoses, and subsequently billed Medi-Cal for such prescriptions. ⁵⁴	\$525,000
5/29/2018	Wal-Mart Stores, Inc.; Sam's West, Inc. d/b/a Sam's Club	Retailers agreed to pay \$825,000 to resolve claims that they enrolled patients in an automatic refill program. They then billed the Minnesota Medicaid program for such refills, in violation of the program's policy which requires an explicit request from the beneficiary for each refill. ⁵⁵	\$825,000
5/31/2018	Irina Minkovich; Yelena Babchinetskya	Pharmacy owners agreed to pay \$3.2 million to settle allegations that they submitted claims to Medicare for prescriptions that were not filled. As part of the settlement, the owners entered into an integrity agreement with HHS-OIG. ⁵⁶	\$3.2 million
7/12/2018	Weis Markets, Inc.	Food retailer agreed to pay \$77,320 to settle FCA allegations that it induced Medicare and Medicaid beneficiaries to transfer or fill their prescriptions at its affiliated pharmacies by using gift cards. ⁵⁷	\$77,320
8/10/2018	Trinity Medical Pharmacy, LLC; Krutika Patel; Devan Patel; Jay Martinez; Nicholas Petrillo	Pharmacy, its CEO, COO, national sales director and national account director agreed to pay \$2.244 million to settle FCA allegations that they submitted claims to TRICARE and the Federal Employees Health Benefits Program (FEHBP) for compounded medicine tainted by the payment of kickbacks to patients and providers. The government also alleged that the pharmacy failed to disclose the prior felony conviction of its COO when it sought to become an authorized provider with Express Scripts, the pharmacy benefit manager for TRICARE and certain FEHBP-affiliated carriers. ⁵⁸	\$2.244 million

53 <https://www.justice.gov/usao-sdfl/pr/broward-county-pharmacy-agrees-pay-united-states-350000-settle-allegations-it-submitted>.

54 <https://www.justice.gov/usao-edca/pr/kmart-corporation-pays-525000-settle-false-claims-act-allegations-improper-medi-cal>.

55 <https://www.justice.gov/usao-mn/pr/walmart-sam-s-club-pay-825000-resolve-fraud-allegations-concerning-auto-refilling>.

56 <https://www.justice.gov/usao-edpa/pr/pharmacy-owners-agree-pay-32-million-resolve-false-claims-case>.

57 <https://www.justice.gov/usao-wdpa/pr/weis-markets-inc-settles-false-claims-act-allegations>.

58 <https://www.justice.gov/usao-mdfl/pr/united-states-settles-false-claims-act-allegations-against-trinity-medical-pharmacy-and>.

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
9/28/2018	RS Compounding, LLC; Renier Gobeia	A now-defunct compounding pharmacy and its owner agreed to pay \$1.2 million to resolve FCA allegations that they billed TRICARE in violation of its policy prohibiting pharmacies from charging TRICARE more than they charged the public. The government alleged the defendants billed TRICARE at least 2,000% more than cash-paying customers were charged for the same drugs, and in some cases, charged more than 10,000% more. After they determined the practice violated TRICARE policy, they made only prospective changes and did not return any profits obtained from the overcharges. ⁵⁹	\$1.2 million
10/22/2018	Cooley Medical Equipment, Inc.	Medical equipment supplier that previously operated a pharmacy agreed to pay \$5.254 million to resolve self-disclosed FCA allegations that it misrepresented the ingredients in its compounded medical creams – to avoid the prior authorization process for certain payors and limited reimbursement from Medicare – resulting in the submission of thousands of false claims. According to the government, because of the self-disclosure, Cooley was able to resolve its liability for 1.5 times the government's alleged single damages, and HHS-OIG agreed not to pursue any administrative action to exclude Cooley from further participation in federal healthcare programs. ⁶⁰	\$5.254 million
10/24/2018	Passavant Memorial Homes; Passavant Development Corporation; PDC Pharmacy Pittsburgh; PDC Pharmacy Philadelphia; PDC Pharmacy Colorado	Pharmacy company and its subsidiaries agreed to pay \$1.85 million to resolve alleged FCA and Controlled Substances Act violations, which Passavant voluntarily disclosed, stemming from their dispensing of controlled substances to patients for a legitimate medical purpose and with a physician order, but without a valid prescription. ⁶¹	\$1.85 million
12/11/2018	Target Corporation	Retailer agreed to pay \$3 million to resolve FCA allegations that its pharmacies routinely enrolled MassHealth beneficiaries in the company's auto-refill program and billed MassHealth for such prescriptions in violation of program regulations. ⁶²	\$3 million

⁵⁹ <https://www.justice.gov/usao-mdfl/pr/government-settles-12-million-lawsuit-against-florida-compounding-pharmacy-and-its>.

⁶⁰ <https://www.justice.gov/usao-edky/pr/medical-equipment-company-agrees-pay-525-million-resolve-allegations-fraudulent-claims>.

⁶¹ <https://www.justice.gov/usao-wdpa/pr/passavant-memorial-homes-and-subsidiaries-settle-false-claims-act-allegations>.

⁶² <https://www.justice.gov/usao-mn/pr/target-corporation-pay-3000000-resolve-false-claims-act-allegations-concerning-auto>.

MANAGED CARE/INSURANCE

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
3/28/2018	CenterLight Health System, Inc.; CenterLight Healthcare, Inc.	Managed care organization agreed to pay \$10.3 million to resolve state and federal FCA allegations that its former managed long-term care plan: (1) submitted fraudulent requests to New York's Medicaid program for monthly capitation payments that it received for certain members who lived in adult homes and who, for at least some portion of their plan enrollment, did not receive the community-based long-term care services required by contract and thus, should have been disenrolled; and (2) failed to repay Medicaid for the monthly payments after becoming aware the members should have been disenrolled. ⁶³	\$10.3 million
9/12/2018	Centers Plan for Healthy Living	Provider of long-term care services agreed to pay \$1.65 million to resolve allegations that it submitted false claims to Medicaid by: (1) improperly enrolling into its managed long-term healthcare plan individuals who were only eligible for social adult day care or transportation services; and (2) failing to disenroll members from the plan who were no longer receiving qualified community-based long-term care services. ⁶⁴	\$1.65 million
10/1/2018	HealthCare Partners Holdings LLC d/b/a DaVita Medical Holdings LLC (DaVita Medical); various corporate affiliates	Managed care organization, which operated a Medical Services Organization (MSO) that contracted with Medicare Advantage Organizations (MAO) to provide care to its beneficiaries and collect and submit diagnoses to the MAOs, agreed to pay \$270 million to resolve FCA allegations – voluntarily disclosed to the government – that it engaged in practices causing MAOs to submit incorrect diagnoses codes to CMS and obtain inflated payments, including by issuing medical coding guidance directing physicians to use an improper diagnosis code for a particular spinal condition. The settlement also resolved allegations from a qui tam action that DaVita Medical engaged in “one-way” chart reviews, looking only for “missed” diagnoses to submit to MAOs for use in obtaining increased Medicare payments. ⁶⁵	\$270 million

⁶³ <https://ag.ny.gov/press-release/ag-schneiderman-announces-103-million-joint-state-federal-settlement-centerlight-over>.

⁶⁴ <https://www.justice.gov/usao-edny/pr/staten-island-based-health-care-service-agrees-pay-more-16-million-settle-false-claims>.

⁶⁵ <https://www.justice.gov/opa/pr/medicare-advantage-provider-pay-270-million-settle-false-claims-act-liabilities>.

LABORATORY, PATHOLOGY, RADIOLOGY AND DIAGNOSTICS

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
1/25/2018	Primex Clinical Laboratories; Mitch Edland	Laboratory providing clinical diagnostic testing services agreed to pay \$3.5 million to resolve FCA allegations that it engaged in kickback schemes with a laboratory management company involving improper sales and services agreements, as well as the provision of in-office medical technicians to physicians for work related to a Primex-sponsored study to induce those physicians to order tests from Primex. The settlement also resolved allegations that the defendants submitted claims for pharmacogenetic tests that were medically unnecessary. The owner and CEO of Primex agreed to pay \$270,000 to resolve similar allegations. As part of the settlement, Primex entered into a five-year CIA with HHS-OIG. ⁶⁶	\$3.77 million
2/16/2018	Precision Testing Laboratories, Inc.; David Fromm	Clinical laboratory and its owner/president agreed to forfeit \$656,912 in suspended Medicaid payments and be excluded from Connecticut's Medicaid program for 10 years to resolve FCA allegations that it billed Medicaid for medically unnecessary urine drug tests under the provider agreement because the tests were: (1) not part of a physician's drug treatment program; (2) not specifically tailored to address each individual resident's particular medical condition; and (3) much more costly than alternative drug testing. ⁶⁷	\$656,912
3/8/2018	Natera, Inc.	Genetic testing company agreed to pay \$11.391 million to resolve FCA allegations that it improperly billed TRICARE for Natera's non-invasive prenatal test (Panorama), improperly billed for non-invasive prenatal screening of certain microdeletion syndromes that TRICARE did not cover, and improperly billed federal government health programs for Panorama and the prenatal screening by using an improper code which misrepresented the services Natera was billing to the programs. ⁶⁸	\$11.391 million
4/9/2018	Gamma Healthcare Inc.; Jerrod Murphy; Jerry Murphy	Laboratory service provider and two executives agreed to pay \$525,000 to resolve FCA allegations that they billed Medicare for travel fees for each individual specimen when in fact multiple specimens were transported together and for fees that were not related to travel by a laboratory technician. As part of the settlement, Gamma entered into a five-year CIA with HHS-OIG. ⁶⁹	\$525,000
4/19/2018	Biotheranostics Inc.	Diagnostic laboratory agreed to pay \$2 million to resolve allegations it billed Medicare for Breast Cancer Index tests that were not reasonable and necessary based on published clinical trial data and clinical practice guidelines because the patients had not been in remission for five years and had not been taking tamoxifen. ⁷⁰	\$2 million

66 <https://www.justice.gov/usao-ndtx/pr/laboratory-and-owner-lab-management-services-company-pay-377-million-resolve-kickback>.

67 <https://www.telegram.com/news/20180217/precision-testing-labs-of-southbridge-settles-fraud-claims-for-400k>.

68 <https://www.justice.gov/usao-wdny/pr/california-genetic-testing-service-pays-11-million-resolve-false-claims-allegations>.

69 <https://www.bizjournals.com/stlouis/news/2018/04/11/u-s-reaches-525-000-settlement-with-gamma.html>.

70 <https://www.justice.gov/opa/pr/san-diego-laboratory-agrees-pay-2-million-settle-false-claims-act-allegations-related>.

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
8/29/2018	Atlantic Mobile Imaging Services, Inc.	Provider of mobile x-ray services agreed to pay \$321,388 to settle FCA allegations that it billed federal healthcare programs for services without a valid license. ⁷¹	\$321,388
9/4/2018	Singulex	Laboratory testing services company agreed to pay \$1.25 million to resolve allegations that it caused false claims to be submitted to Medicare and TRICARE for medically unnecessary tests by pressuring providers to order lab tests without regard to medical necessity, made misrepresentations to providers to convince them to order additional lab tests, and/or added certain procedure codes to lab test requisition forms without the provider's knowledge or consent. ⁷²	\$1.25 million
9/25/2018	East Alabama Medical Center; Aperian Laboratory Services; Summitt Diagnostics; Compass Laboratory Solutions	Hospital and its subsidiary laboratory (Aperian) agreed to pay \$4.25 million, and two marketing companies agreed to pay \$2.4 million, to resolve FCA allegations from a qui tam action, in which the government declined to intervene, that the defendants engaged in a kickback scheme in which Aperian paid percentage commission kickbacks to the marketing companies in exchange for arranging for physicians to refer toxicology tests to the laboratory, and the hospital and Aperian billed Medicare for the tests. ⁷³	\$6.65 million

⁷¹ <https://www.justice.gov/usao-mdfl/pr/atlantic-mobile-imaging-services-inc-agrees-pay-more-320000-settle-false-claims-act>.

⁷² <https://www.justice.gov/usao-ndca/pr/alameda-laboratory-pay-125-million-settle-claims-conducting-unnecessary-testing>.

⁷³ <https://www.valleytimes-news.com/2018/09/whistleblower-recovers-more-than-6-6-million/>.

BEHAVIORAL HEALTH AND SUBSTANCE ABUSE TREATMENT

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
2/9/2018	South Bay Mental Health Center, Inc.	Mental health facility agreed to pay \$4 million to resolve state FCA allegations it billed MassHealth for services provided to patients by unlicensed, unqualified and unsupervised staff members, in violation of state law and contractual requirements. As part of the settlement, South Bay agreed to certain internal compliance requirements and independent audits for five years. A whistleblower and the State of Massachusetts are continuing to litigate with South Bay, its founder, an executive and private equity funds that acquired South Bay regarding similar allegations in the case styled <i>U.S. ex rel. Martino-Fleming v. South Bay Mental Health Center</i> (D. Mass.), in which the federal government declined to intervene. ⁷⁴	\$4 million
4/27/2018	New Era Rehabilitation Center; Dr. Ebenezer Kolade; Dr. Christina Kolade	Behavioral health and substance abuse services provider and its owners agreed to pay \$1.378 million to resolve FCA allegations that they billed Medicaid for psychotherapy services which were not provided to patients and were already included in a weekly bundled rate for methadone maintenance services. ⁷⁵	\$1.378 million
5/14/2018	Waire, LLC d/b/a Ellington Behavioral Health; Dr. Erum Shahab	Psychiatric medical practice and its psychiatrist owner agreed to pay \$805,071 to settle FCA allegations that they billed Medicare for multiple units of urine drug screening tests when they should have known only one unit of service per patient encounter could be billed, and for tests that did not occur at all or did not occur in a timely manner. ⁷⁶	\$805,071
6/19/2018	A Prospering Vision, LLC; Home of Hope, Inc.; Elijah Caldwell	Licensed clinical social worker agreed to pay more than \$55,000, and two behavioral health practices she owns or controls agreed to pay more than \$144,000 through payments suspended during a government investigation to settle state FCA allegations that they billed the Connecticut Medicaid program for counseling services that were either not provided, were provided by unlicensed individuals, or were upcoded. As part of the settlement, the defendants are excluded from the Connecticut Medicaid program for 10 years. ⁷⁷	\$200,000
7/3/2018	Dawn Sykes	Owner of three companies providing mental health and other support services agreed to make an initial payment of \$50,000 and to a consent judgment of \$1.111 million to resolve federal and state FCA allegations involving: (1) billing Medicaid for services not provided; (2) paying kickbacks to an individual to induce client referrals; and (3) billing Medicaid for services provided to ineligible recipients. As part of the settlement, the owner agreed to a lifetime exclusion from the Virginia Medicaid program. ⁷⁸	\$1.111 million

⁷⁴ <https://www.mass.gov/news/mental-health-center-to-pay-4-million-under-ag-settlement-for-illegally-billing-masshealth-for>.

⁷⁵ <https://www.justice.gov/usao-ct/pr/substance-abuse-treatment-providers-pay-more-13-million-settle-false-claims-act>.

⁷⁶ <https://www.justice.gov/usao-ct/pr/ellington-psychiatrist-and-mental-health-clinic-pay-over-800000-settle-false-claims-act>.

⁷⁷ <http://www.hartfordbusiness.com/article/20180619/news01/180619903/waterbury-clinician-settles-ct-medicare-fraud>.

⁷⁸ <https://www.justice.gov/usao-edva/pr/mcicaid-provider-agrees-lifetime-exclusion-mcicaid>.

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
7/10/2018	Affinity Behavioral Health LLC; Julie Longton; Leanda Zupka	Behavioral health practice and its owners agreed to pay \$300,000 to resolve state FCA allegations that they billed the Connecticut Medicaid program for services provided by unlicensed individuals employed by the owners. As part of the settlement, the practice and owners agreed to implement a five-year compliance program. ⁷⁹	\$300,000
8/2/2018	Early Autism Project, Inc. (EAP)	Provider of intensive behavioral treatment to children with autism agreed to pay more than \$8.833 million to settle FCA allegations that it billed TRICARE and Medicaid for therapy services which were misrepresented because certain staff were not actively working with the children, or were not provided at all because EAP allowed its therapists to “pad” the hours it billed. As part of the settlement, EAP and its parent company entered into a five-year CIA with HHS-OIG. ⁸⁰	\$8.833 million
8/8/2018	Hung K. Do; H.K.D. Treatment Options	Physician and his addiction treatment clinic agreed to pay \$23,000 to resolve alleged FCA and Controlled Substances Act violations arising from Dr. Do’s directing another physician to sign hundreds of blank prescriptions for use by unsupervised non-physicians while the physician was on vacation, and billing Medicare for services related to the same. ⁸¹	\$23,000
10/24/2018	Melchor Martinez; Melissa Chlebowski; Northeast Community Mental Health Centers; Lehigh Valley Community Mental Health Centers; Carolina Community Mental Health Centers	Federal district judge entered a \$3 million consent judgment against a couple and their community mental health clinics as part of a settlement to resolve FCA allegations that the defendants: (1) managed the clinics despite the husband being excluded from such activity due to a prior Medicaid fraud conviction; (2) profited from these activities by funneling money from the clinics to the husband and concealing these payments; (3) employed individuals lacking the requisite credentials for mental health therapists; (4) failed to have an onsite psychiatrist at certain clinics as required by Medicare; and (5) billed for 15-minute psychiatric medication management when clinic doctors were actually only spending two to three minutes with the patient. As part of the settlement, Chlebowski and the clinics are excluded from participating in federal healthcare programs for five years, and Martinez is excluded for an additional 10 years. ⁸²	\$3 million
11/1/2018	Maryland Treatment Centers (MTC)	Provider of mental health and substance abuse services agreed to pay \$500,000 to resolve FCA allegations that it billed for services that failed to comply with state regulations because the provider: (1) failed to document in any way the services allegedly provided; (2) failed to write daily progress notes and place them in patients’ charts; (3) failed to document that patients attended, participated and/or received the services allegedly rendered; and (4) documented procedures on patient progress notes that were inconsistent with the billed procedures. As part of the settlement, MTC entered into a three-year integrity agreement with HHS-OIG. ⁸³	\$500,000

79 <http://www.norwichbulletin.com/news/20180712/norwich-behavioral-health-practice-to-pay-300k-to-settle-false-claims-act-allegations>.

80 <https://www.justice.gov/usao-sc/pr/early-autism-project-inc-south-carolinas-largest-provider-behavioral-therapy-children>.

81 <https://www.justice.gov/usao-ma/pr/lowell-physicians-settle-drug-diversion-allegations>.

82 <https://www.justice.gov/usao-edpa/pr/united-states-obtains-3-million-consent-judgment-and-federal-healthcare-exclusions-0>.

83 <https://www.justice.gov/usao-md/pr/maryland-treatment-centers-agrees-pay-500000-resolve-allegations-it-submitted-claims>.

SPECIALTY CARE AND OTHER PROVIDER ENTITIES

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
1/10/2018	Benevis LLC; various affiliated Kool Smiles dental clinics	Dental management company and more than 130 affiliated clinics agreed to pay \$23.9 million to resolve FCA allegations that they falsely billed Medicaid for medically unnecessary dental services performed on children and for services that were never performed. ⁸⁴	\$23.9 million
1/24/2018	PMC LLC; various affiliated entities; Matthew Anderson; Cindy Scott	Pain clinic management company and its chiropractor owner agreed to pay \$1.45 million and be excluded from federal healthcare programs for five years to resolve allegations that they violated the FCA by: (1) causing pharmacies to submit claims to federal healthcare programs for medically unnecessary pain killers; (2) upcoding claims for office visits that were not reimbursable at the levels sought; and (3) submitting claims for services provided by two nurse practitioners who were not collaborating with a physician as required by Tennessee law. As part of the settlement, three of the four now-closed pain clinics managed by PMC will forfeit \$53,840, and nurse practitioner Cindy Scott agreed to pay \$32,000 and surrender her DEA registration until October 2021 to resolve allegations that she violated the Controlled Substances Act. ⁸⁵	\$1.45 million
3/13/2018	Marshfield Medical, Inc., f/k/a Bromedicon, Inc.	Surgical monitoring company agreed to pay \$550,000 to resolve FCA allegations that it improperly billed for remote Intraoperative Neurophysiological Monitoring services for which it failed to provide a qualified interpreting physician to monitor the surgeries and, in some cases, failed to provide any remote monitoring. ⁸⁶	\$550,000
3/16/2018	Horizon Vascular Specialists; Riverside Medical Associates; Maryland Specialty Group; Itsuro Uchino, M.D.	Three vascular care practices and a physician agreed, in separate settlement agreements, to pay various amounts totaling \$873,860 to resolve FCA allegations that, in performing venous Doppler duplex examinations, they billed Medicare for CPT code 93970 and 93965, the latter referring to an older, different technology that generally had been replaced and was incorrectly billed. ⁸⁷	\$873,860
3/21/2018	Advanced Neurological Services, LLC; Advanced Neurological Services of Dallas, LLC; Cynthia L. Kidd; Joanie C. Powell; Progress Pediatric Therapy LLC; Abraham Armani; Shahriah Raoufpour	Therapy companies, physicians and related individuals agreed to pay various amounts in separate settlements totaling more than \$15 million to resolve allegations in connection with a purported conspiracy to avoid repaying the Texas Medicaid program \$2.7 million in overpayments and alleged false statements to the state regarding the control and ownership of the companies and identity of subcontractors and prior criminal convictions. As part of the settlements, several defendants were permanently banned from participating as a Texas Medicaid provider, or owning or managing any Texas Medicaid provider. ⁸⁸	\$15.2 million

84 <https://www.justice.gov/opa/pr/dental-management-company-benevis-and-its-affiliated-kool-smiles-dental-clinics-pay-239>.

85 <https://www.justice.gov/opa/pr/tennessee-chiropractor-pays-more-145-million-resolve-false-claims-act-allegations>.

86 <https://www.justice.gov/usao-edpa/pr/intra-operative-monitoring-company-agrees-pay-550000-settle-false-claims-act-claims>.

87 <https://www.justice.gov/usao-md/pr/united-states-reaches-settlement-maryland-healthcare-providers-settle-false-claims-act>.

88 <https://www.texasattorneygeneral.gov/news/releases/ag-paxton-reaches-152-million-settlement-fraudulent-medicaid-providers>.

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
3/29/2018	Georgia Bone & Joint (GBJ); Southern Bone & Joint a/k/a Summit Orthopedic Surgery Center; Southern Crescent Anesthesiology PC (SCA); Sentry Anesthesia Management, LLC; David LaGuardia	Various orthopedic and anesthesiology clinics and an associated nurse anesthetist agreed to pay \$3.2 million to resolve FCA allegations that: (1) LaGuardia, Sentry and SCA provided a free medical director to Summit Orthopedic Surgery Center to induce it to choose to perform more services at the Surgery Center rather than GBJ, in violation of the AKS; and (2) GBJ and LaGuardia caused the submission of false claims to Medicare for non-FDA approved drugs purchased outside of the United States. ⁸⁹	\$3.2 million
3/29/2018	SightLine Health LLC; Integrated Oncology Network Holdings LLC (ION)	Radiation therapy provider and its successor company agreed to pay \$11.5 million to resolve FCA allegations that it paid physicians kickbacks for patient referrals. SightLine allegedly formed a series of leasing companies in which referring physicians were permitted to invest, and through which SightLine allegedly distributed the profits its physician-investors generated by referring cancer patients for radiation therapy. As part of the settlement, SightLine, ION and other related entities entered into a five-year CIA with HHS-OIG. ⁹⁰	\$11.5 million
4/10/2018	World Health Clinicians, Inc.; Scott Gretz; Gary Blick	Medical practice specializing in the treatment of HIV/AIDS and STIs and its CEO agreed to pay more than \$361,000, and a former physician agreed to pay more than \$289,000, to settle state and federal FCA allegations that they billed Medicare and Medicaid for physical therapy and certain office visit services when the patients instead received massages from a massage therapist. ⁹¹	\$650,830
4/27/2018	Cardiovascular and Thoracic Surgeons of Nevada, Inc. (CTS)	CTS agreed to pay \$1.5 million to resolve FCA allegations that it billed federal healthcare programs for surgical services not actually provided to cardiac patients and for more expensive surgical and E&M services than those actually provided to patients. ⁹²	\$1.5 million
5/1/2018	CityMD	Urgent care chain agreed to pay \$6.606 million to resolve FCA allegations that it billed Medicare for services that were not provided, services that were more expensive and complex than the services actually provided, and services rendered by physicians who were not credentialed with Medicare. ⁹³	\$6.606 million
5/14/2018	Foot Healers Holdings – St. Louis; various subsidiaries	Podiatry company agreed to pay \$125,000 to resolve FCA allegations that it submitted claims with improperly billed modifiers and claims which falsely indicated a medically necessary toenail debridement was provided when the service actually provided was a routine nail trimming not covered by Medicare. As part of the settlement, Foot Healers entered into a three-year integrity agreement with HHS-OIG. ⁹⁴	\$125,000

89 <https://www.justice.gov/usao-ndga/pr/orthopaedic-and-anesthesia-providers-pay-32-million-settle-false-claim-act-allegations>.

90 <https://www.justice.gov/opa/pr/radiation-therapy-company-agrees-pay-115-million-settle-allegations-false-claims-and>.

91 <https://www.justice.gov/usao-ct/pr/norwalk-medical-practice-ceo-and-physician-pay-650830-settle-false-claims-act-allegations>.

92 <https://www.justice.gov/usao-nv/pr/cardiovascular-and-thoracic-surgeons-nevada-inc-agrees-pay-15-million-settle-false-claims>.

93 <https://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-announces-66-million-settlement-against-citymd-submitting-false>.

94 <https://www.justice.gov/usao-edmo/pr/united-states-reaches-125000-civil-settlement>.

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
5/16/2018	Crescent Community Health Center	Nonprofit community health center agreed to pay \$47,503 to resolve FCA allegations that it improperly billed Medicare and Medicaid for eight controlled substance refills issued by practitioners lacking the requisite credentials or authority to prescribe, and for 71 other improperly-issued prescriptions or refills for non-controlled substances. ⁹⁵	\$47,503
5/25/2018	Riverside Spine & Pain Physicians, LLC	Pain management practice agreed to pay over \$1.204 million to resolve FCA allegations that it billed federal healthcare programs for medically unnecessary urine drug tests. ⁹⁶	\$1.204 million
6/5/2018	CityMD	Urgent care chain agreed to pay \$883,000 to the state of New York to resolve state FCA allegations that it billed the state's Empire Plan health insurance program for inappropriate facilities fees related to government workers and their families, when such fees are not permitted under the plan. ⁹⁷	\$883,000
6/20/2018	Healogics, Inc.	Provider of advanced chronic wound care services agreed to pay \$398,162 to resolve FCA allegations that it submitted claims to government healthcare programs using Modifier 25 to signify that a separate E&M service was performed on the same date as another procedure when no such separate service had been performed. ⁹⁸	\$398,162
6/20/2018	Healogics, Inc.	Provider of advanced chronic wound care services agreed to pay up to \$22.51 million to resolve FCA allegations that it caused wound care centers to submit claims to Medicare for medically unnecessary and unreasonable hyperbaric oxygen therapy. As part of the settlement, Healogics entered into a five-year CIA with HHS-OIG. ⁹⁹	\$17.5 million (guaranteed) \$5.01 million (contingent)
6/28/2018	Mountain Medical Services; Michael Pond, M.D.	Urgent care chain and its owner agreed to pay \$110,000 to resolve FCA allegations that they billed Medicare for services provided by physician assistants and nurse practitioners as if the services had been performed or supervised by physicians. ¹⁰⁰	\$110,000
6/28/2018	Circulatory Centers of America, LLC; Thomas E. Certo; David Gilpatrick; Everett Burns; Dr. Louis Certo	Company providing treatment for varicose veins, along with its former owner/CEO, president, CFO, and medical director, agreed to pay \$1.205 million to resolve FCA allegations that they billed Medicare for services provided by non-physicians as if they had been supervised by a physician when in fact, they were not. The settlement also resolved allegations that the company billed for ultrasound services that were not provided and for medically unnecessary ultrasound services that were provided by unqualified individuals. ¹⁰¹	\$1.205 million

⁹⁵ <https://www.justice.gov/usao-ndia/pr/dubuque-clinic-agrees-pay-40000-false-claims-penalties-resolve-allegations-related-8>.

⁹⁶ <https://www.justice.gov/usao-mdfl/pr/united-states-settles-false-claims-act-allegations-against-riverside-spine-pain>.

⁹⁷ <https://ag.ny.gov/press-release/ag-underwood-announces-883000-settlement-citymd-submitting-false-claims-government>.

⁹⁸ <https://www.justice.gov/usao-ndia/pr/nationwide-wound-services-provider-agrees-pay-nearly-400000-resolve-false-claims-act>.

⁹⁹ <https://www.justice.gov/usao-mdfl/pr/healogics-agrees-pay-2251-million-settle-false-claims-act-liability-improper-billing>.

¹⁰⁰ <https://www.justice.gov/usao-ndny/pr/upstate-new-york-urgent-care-practice-and-its-physician-owner-pay-110000-submitting>.

¹⁰¹ <https://www.justice.gov/usao-wdpa/pr/varicose-vein-treatment-company-agrees-pay-1205000-resolve-false-claims-act-allegations>.

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
7/2/2018	FWC Urogynecology, LLC	Network of urogynecology practitioners agreed to pay \$1.7 million to resolve FCA allegations that it billed government healthcare programs using Modifier 25 to signify that a separate E&M service was performed on the same date as another procedure when no such separate service had been performed. ¹⁰²	\$1.7 million
7/13/2018	Southwest Orthopaedic Specialists, PLLC; Dr. Anthony Cruse; Dr. R.J. Langerman, Jr.; Dr. Daniel J. Jones; Dr. Mehdi Adham; Dr. Derek West; Dr. Brian Levings; Dr. Shane Hume; Dr. Brad Reddick; Dr. Kristopher Avant	Orthopedic practice and nine physician-owners agreed to pay \$670,000 to resolve FCA allegations that they submitted claims to federal healthcare programs for medically unnecessary procedures involving ultrasonic guidance for needle placement imaging supervision and interpretation. The settlement also resolved allegations that the practice and Dr. Levings submitted claims for services that were not provided by the indicated surgery assistant. ¹⁰³	\$670,000
7/26/2018	Northwest ENT Associates, P.C.	ENT practice group agreed to pay \$1.195 million to resolve FCA allegations that it improperly submitted claims to federal healthcare programs for sinus dilation procedures in which it re-used balloon catheters that are intended for single use only. Northwest accepted responsibility for its actions pursuant to a Non-Prosecution Agreement with the United States. As part of the settlement, Northwest entered into a three-year integrity agreement with HHS-OIG. ¹⁰⁴	\$1.195 million
8/16/2018	Lincare, Inc.	Oxygen and respiratory therapy services provider agreed to pay \$5.25 million to resolve FCA allegations that it billed services for which it waived or reduced co-insurance, co-payments and deductibles for beneficiaries participating in Medicare Advantage Plans through private insurers, in violation of the AKS. ¹⁰⁵	\$5.25 million
8/28/2018	Dermatology Healthcare, LLC; Robert A. Norman, D.O., P.A.; Robert A. Norman, D.O.; Carol Norman	Dermatology practice and related individuals agreed to pay \$4 million to resolve FCA allegations that they submitted claims to Medicare and Medicaid for superficial radiation skin cancer treatments that were up-coded and/or not adequately supervised or medically necessary. ¹⁰⁶	\$4 million
10/23/2018	Eye Centers of Florida	Ophthalmology practice agreed to pay \$525,000 to resolve FCA allegations that it falsified medical records in order to bill for cataract surgeries on patients that would not have otherwise qualified for surgery. ¹⁰⁷	\$525,000

¹⁰² <https://www.justice.gov/usao-mdfl/pr/fwc-urogynecology-llc-agrees-pay-17-million-settle-false-claims-act-liability-misuse>.

¹⁰³ <https://www.justice.gov/usao-wdok/pr/oklahoma-orthopedic-company-and-physicians-agree-pay-670000-settle-allegations-false>.

¹⁰⁴ <https://www.justice.gov/usao-ndga/pr/northwest-ent-associates-pc-pay-approximately-12-million-resolve-false-claims-act>.

¹⁰⁵ <https://www.justice.gov/usao-sdil/pr/durable-medical-equipment-provider-lincare-pays-525-million-resolve-false-claims-act>.

¹⁰⁶ <https://www.justice.gov/usao-mdfl/pr/dermatology-healthcare-agrees-pay-4-million-false-claims-act-settlement>.

¹⁰⁷ <https://www.justice.gov/usao-mdfl/pr/eye-centers-florida-agrees-pay-525000-settle-false-claims-act-liability-medically>.

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
11/2/2018	Metropolitan Retina Associates, Inc.; Dr. Kenneth S. Felder	Ophthalmologist and his practice agreed to pay \$2.064 million to resolve claims that they billed Medicare and Medicaid for: (1) substandard fluorescein angiography diagnostic tests that were of such poor quality as to be effectively worthless; and (2) ophthalmic ultrasounds that were either not performed or lacked any supporting documentation. ¹⁰⁸	\$2.064 million
11/6/2018	ImmediaDent of Indiana, LLC; Samson Dental Partners, LLC	Operator of dental practices and its administrative support provider agreed to pay \$5.139 million to resolve FCA allegations that they submitted claims to Medicaid for tooth extractions that were improperly classified as surgical extractions and for deep cleanings that were not medically necessary or not performed at all. The companies refused to agree to a CIA with HHS-OIG and, as such, HHS-OIG determined that absent such oversight, the companies pose a continuing high risk to the federal healthcare programs and their beneficiaries. ¹⁰⁹	\$5.139 million
11/26/2018	Vital Energy Occupational Therapy and Wellness Center, LLC	Therapy services provider agreed to pay \$200,000 to resolve FCA allegations that it improperly billed Medicare and Medicaid for: (1) individual therapy services when group services were actually provided; and (2) claims under the names and billing numbers of former employees who did not actually provide the therapy services. ¹¹⁰	\$200,000
11/29/2018	Dermatology Associates of Central New York, PLLC	Dermatology practice agreed to pay \$811,196 and admitted to causing the submission of false claims to government healthcare programs for services provided by non-physicians even though it represented that one of its physicians was the rendering or supervising provider. The practice also admitted that some of the non-physicians treating Medicaid beneficiaries were not credentialed in New York to provide such treatment, and so they billed in a physician's name. ¹¹¹	\$811,196
12/11/2018	Oviatt Hearing and Balance, LLC	Audiology practice agreed to pay \$566,263 to settle FCA allegations that it: (1) billed for audiology exams provided by unlicensed individuals with no licensed audiologist or other qualified provider onsite; and (2) offered gift cards and contests to win free iPads to Medicare and Medicaid beneficiaries to induce them to come to the practice for services. ¹¹²	\$566,263

¹⁰⁸ <https://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-announces-2-million-settlement-health-care-fraud-claims-against>.

¹⁰⁹ <https://www.justice.gov/usao-wdny/pr/51-million-dollar-settlement-reached-indiana-dental-firm-resolve-false-claims>.

¹¹⁰ <https://www.justice.gov/usao-sc/pr/lexington-therapy-practice-agrees-pay-200000-resolve-allegations-it-submitted-false>.

¹¹¹ <https://www.justice.gov/usao-ndny/pr/dermatology-associates-central-new-york-pay-more-811000-submitting-false-claims-federal>.

¹¹² <https://www.justice.gov/usao-ndny/pr/audiology-practice-locations-throughout-central-new-york-pay-more-566000-settle-false>.

MEDICAL TRANSPORTATION

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
1/30/2018	AmeriCare Ambulance Service Inc.; AmeriCare ALS Inc.	Ambulance provider and its sister company agreed to pay \$5.5 million to resolve allegations that they billed Medicare and TRICARE for Basic Life Support, non-emergency ambulance transports that were not medically necessary. As part of the settlement, AmeriCare entered into a five-year CIA with HHS-OIG. ¹¹³	\$5.5 million
2/23/2018	North East Mobile Health Services	Ambulance provider agreed to pay \$825,000 to resolve FCA allegations that it billed Medicare, and knowingly retained overpayments from Medicare, for non-emergency ambulance transports that were medically unnecessary or based on false representations that the patients were "bed-confined." Maine Medical Center agreed to pay \$600,000 this year to resolve related FCA allegations. ¹¹⁴	\$825,000
3/28/2018	Medical Transport LLC	Ambulance services provider agreed to pay \$9 million to resolve FCA allegations that it billed federal healthcare programs for ambulance transports that were medically unnecessary, did not qualify as Specialty Care Transports, and should have been billed to non-government payors. As part of the settlement, Medical Transport entered into a five-year CIA with HHS-OIG. ¹¹⁵	\$9 million
7/10/2018	Liberty Ambulance Service, Inc.	Ambulance company agreed to pay \$1.2 million to resolve FCA allegations from a <i>qui tam</i> action in which the government intervened in 2015 and litigated for several years. The government alleged that Liberty upcoded claims for life support services from "Basic" to "Advanced" without justification, unnecessarily transported patients, and unnecessarily transported patients to their homes in an emergent manner. As part of the settlement, Liberty entered into a five-year CIA with HHS-OIG. ¹¹⁶	\$1.2 million
8/27/2018	Paramedics Plus; East Texas Medical Center Regional Healthcare System, Inc.; East Texas Medical Center Regional Health Services, Inc.	A medical center and its affiliated ambulance company agreed to pay \$20.649 million to resolve FCA allegations that they offered kickbacks to certain municipal entities to secure their ambulance business. ¹¹⁷	\$20.649 million
8/27/2018	Emergency Medical Services Authority; Herbert Stephen Williamson; Alameda County; Pinellas County Emergency Medical Services Authority	In connection with the Paramedics Plus matter, three municipal entities and the owner of one of those entities separately agreed to pay various amounts totaling \$501,200 to resolve FCA allegations related to the purported kickback scheme. ¹¹⁸	\$501,200

¹¹³ <https://www.justice.gov/usao-mdfl/pr/tampa-s-largest-ambulance-providers-agree-pay-55-million-resolve-false-claims-act>.

¹¹⁴ <https://www.justice.gov/usao-me/pr/ambulance-provider-and-hospital-agree-pay-1425000-settle-ambulance-transportation-claims>.

¹¹⁵ <https://www.justice.gov/opa/pr/ambulance-company-pay-9-million-settle-false-claims-act-allegations>.

¹¹⁶ <https://www.justice.gov/usao-mdfl/pr/united-states-settles-false-claims-act-allegations-against-liberty-ambulance-12-million>.

¹¹⁷ <https://www.justice.gov/opa/pr/ambulance-company-and-its-municipal-clients-agree-pay-over-21-million-settle-allegations>.

¹¹⁸ <https://www.justice.gov/opa/pr/ambulance-company-and-its-municipal-clients-agree-pay-over-21-million-settle-allegations>.

INDIVIDUAL PROVIDERS

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
1/23/2018	Aytac Apaydin; Stephen Worsham	Two urologists agreed to pay \$1.085 million to resolve FCA allegations they referred and billed for image guided radiation therapy (IGRT) in violation of the Stark Law and AKS. The government alleged the two urologist-defendants: (1) solicited eight other urologists to enter into lease agreements with an oncology center owned by the defendants under which the other urologists could bill for, and profit from, their referrals of IGRT performed at the center; and (2) billed Medicare for their own IGRT referrals to the center, even though the center and the urology practice the defendants owned and operated were separate entities and their financial arrangements failed to comply with any Stark Law exceptions. The lessee urologists previously agreed to pay \$900,000 collectively to resolve allegations regarding the leasing arrangement. ¹¹⁹	\$1.085 million
2/6/2018	Phillip B. Klapper, PSC; Phillip Klapper, M.D.; Patricia Klapper	Ear, nose and throat physician agreed to pay \$2.79 million and be permanently excluded from the Federal Employees' Compensation Act program to resolve FCA allegations that he improperly billed for audiological tests that were performed by unqualified personnel and altered test results to enable some patients to appear to have hearing loss. ¹²⁰	\$2.79 million
2/8/2018	Vincent Koh; Milly Koh	Oncologist and his office manager agreed to pay \$500,000 to resolve FCA allegations that they knowingly billed Medicare for chemotherapy drugs which had not been approved by the FDA. The couple pleaded guilty to related criminal charges in 2017. ¹²¹	\$500,000
2/8/2018	Jitendra Swarup	Physician agreed to pay \$2.9 million to settle FCA allegations that he accepted kickbacks, including hunting and international fishing trips, from Sightpath, Precision Lens, and Precision Lens' owner in order to induce the physician to utilize the companies' ophthalmological services and products; and that he received consulting agreements with Sightpath paying more than \$100,000 per year, in excess of FMV, as the services were either not fully performed or not properly tracked. As part of the settlement, the physician entered into a three-year integrity agreement with HHS-OIG. Sightpath and its former CEO settled related allegations for \$12 million in 2017. The government is continuing to litigate similar allegations against Precision Lens and its owner. ¹²²	\$2.9 million
3/6/2018	Bradley Brown, D.C.; Brown Chiropractic, P.C.	Chiropractor and his clinic agreed to pay \$79,919 to resolve FCA allegations that they provided free electrical stimulation to Medicaid beneficiaries in order to induce them to receive chiropractic adjustments from the clinic. ¹²³	\$79,919

119 <https://www.justice.gov/opa/pr/two-california-urologists-agree-pay-more-1-million-settle-false-claims-act-allegations>.

120 <https://www.justice.gov/usao-wdny/pr/kentucky-otolaryngologist-pays-279-million-resolve-false-claims-allegations>.

121 <https://www.justice.gov/usao-ndny/pr/queensbury-oncologist-and-spouse-pay-500000-submitting-false-claims-medicare>.

122 <https://www.justice.gov/usao-mn/pr/united-states-files-complaint-against-precision-lens-paul-ehlen-alleged-kickback-scheme>.

123 <https://www.justice.gov/usao-ndia/pr/oelwein-chiropractor-and-clinic-agree-pay-nearly-80000-resolve-false-claims-act>.

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
3/19/2018	Vidya Banka, M.D.	Cardiologist and former director of Pennsylvania Hospital agreed to pay \$126,617 to resolve allegations that he billed Medicare for medically unnecessary cardiac stent procedures. The hospital voluntarily disclosed the allegations to the government and resolved them in a separate settlement in 2017. As part of the settlement, the cardiologist was excluded from participating in federal healthcare programs for five years. ¹²⁴	\$126,617
4/5/2018	Estate of Dr. Leroy Pelicci	Estate of a pain relief physician and practice owner agreed to pay \$625,000 to settle FCA allegations that he billed for trigger point injections which were upcoded to receive a higher reimbursement amount than permitted. ¹²⁵	\$625,000
4/25/2018	Freed, Kleinberg, Nussbaum, Festa & Kronberg M.D., LLP; Arnold W. Scherz; Mitchell Kleinberg; Michael Nussbaum; Robert Festa; Jason Kronberg	Pediatrics practice and current and former partner physicians agreed to pay \$750,000 to resolve allegations they billed Medicaid for services provided by physicians they employed who were not enrolled in Medicaid. The government alleged that the practice misrepresented the identities of the individuals who were actually providing treatment. ¹²⁶	\$750,000
4/26/2018	Dr. Brenna Green	Physician agreed to pay \$199,425 to resolve FCA allegations involving a kickback scheme in which the physician acquired shares in a laboratory for a nominal sum in exchange for a guaranteed "dividend" of approximately \$5,000 per month, if she met or exceeded a certain level of urine drug screen referrals. ¹²⁷	\$199,425
5/7/2018	Dr. Robert Fetchero, D.O.; Dr. Sridhar Pinnamaneni, M.D.; Dr. Thelma Green-Mack, M.D.	Three physicians agreed to pay various amounts totaling \$700,000 to settle allegations that they received payment from a drug testing lab in exchange for referring Medicare patients to the lab, in violation of the Stark Law and AKS. The medical director of the lab pleaded guilty to related criminal charges. ¹²⁸	\$700,000
5/10/2018	Robert Gennaro	Medical assistant agreed to be excluded from federal healthcare programs for 10 years to settle FCA allegations that he impersonated a physician when providing remote surgical monitoring services, which resulted in false claims being submitted to the government. The physician was sentenced to more than three years in prison for his role in the scheme in 2016. ¹²⁹	Exclusion

¹²⁴ <https://www.justice.gov/usao-edpa/pr/united-states-resolves-claims-philadelphia-cardiologist-billed-medicare-unnecessary>.

¹²⁵ <https://www.justice.gov/usao-mdpa/pr/estate-scranton-physician-agrees-pay-625000-settle-false-claims-act-violations-0>.

¹²⁶ <https://www.justice.gov/usao-edny/pr/long-island-pediatrics-practice-agrees-pay-750000-settle-false-claims-act-suit-alleging>.

¹²⁷ <https://www.justice.gov/usao-ndwv/pr/tennessee-physician-agrees-pay-nearly-200000-government-kickback-scheme>.

¹²⁸ <https://www.justice.gov/usao-wdpa/pr/three-physicians-agree-pay-total-700000-settle-alleged-false-claims-act-violations>.

¹²⁹ <https://www.justice.gov/usao-ndga/pr/medical-assistant-resolves-false-claims-act-allegations>.

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
5/14/2018	Sureshkumar Muttath, M.D.	Internist agreed to pay \$1.526 million to resolve FCA allegations that he billed for autonomic nervous function tests that were not medically necessary according to Local Coverage Determinations because he: (1) did not have the necessary equipment to perform these tests; (2) did not clinically diagnose the patients with an autonomic function disorder before conducting the tests; (3) lacked the specific training required to conduct the tests or interpret their results; (4) failed to follow Local Coverage Determinations regarding coverage indications and limitations for autonomic function testing; and (5) performed the tests merely to monitor patient symptoms or conduct patient screenings without signs or symptoms of autonomic dysfunction and not to make any clinical decisions or manage patient care. The settlement also resolved allegations that Dr. Muttath improperly billed for neurobehavioral status exams by misrepresenting the services he actually performed because he did not spend the required amount of time with patients or conduct the necessary assessments. As part of the settlement, Dr. Muttath entered into a three-year integrity agreement with HHS-OIG. ¹³⁰	\$1.526 million
6/4/2018	Dr. Michael Frey, M.D.	Interventional pain management specialist agreed to pay \$2.8 million to resolve civil FCA allegations that he billed for definitive urine drug testing that was not reasonable and medically necessary and that he received improper reimbursements through a kickback scheme in which an anesthesia practice he owned provided services exclusively for procedures performed by a pain management practice he also partly owned. As part of a global settlement, Dr. Frey pleaded guilty to conspiring to receive healthcare kickbacks, including speaker fees for bogus Insys Therapeutics speaker event programs. ¹³¹	\$2.8 million
7/3/2018	Arlene Werner, Ph.D.	Psychologist agreed to pay \$126,760 to resolve claims that she billed Medicaid for services that were not provided and for family psychotherapy sessions when individual services should have been billed. ¹³²	\$126,760
7/3/2018	Brent E. Clark, M.D.	Family practice physician agreed to pay \$360,000 to resolve FCA allegations that he billed Medicare and Medicaid for medically unnecessary and unreasonable office visits and procedures and falsified records to support the claims. The physician previously pleaded guilty to related criminal charges. ¹³³	\$360,000
8/8/2018	Dr. Donald Chamberlain; Karen Chamberlain	Physician and his wife, who managed his practice, agreed to pay \$428,700 to resolve FCA allegations that they billed federal healthcare programs for foreign-sourced anticancer drugs that were not approved by the FDA. ¹³⁴	\$428,700

¹³⁰ <https://www.justice.gov/usao-md/pr/united-states-reaches-settlement-riverdale-internist-resolve-false-claims-act-allegations>.

¹³¹ <https://www.justice.gov/usao-mdfl/pr/fort-myers-pain-management-physician-pleads-guilty-healthcare-offenses-and-agrees-28>.

¹³² <https://www.justice.gov/usao-ct/pr/waterford-psychologist-pays-126760-settle-allegations-under-false-claims-act>.

¹³³ <https://www.justice.gov/usao-wdpa/pr/family-practice-doctor-pays-360000-settle-false-claims-act-allegations>.

¹³⁴ <https://www.justice.gov/usao-edtn/pr/physician-and-wife-pay-428000-settle-false-claims-act-allegations-billing-government>.

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
9/6/2018	Orrin K. McLeod, D.O.	Family practitioner agreed to pay \$300,000 to resolve alleged violations of the FCA and Controlled Substances Act resulting from his billing for services while he was out of the country and leaving signed, blank prescriptions in his office for others to use in writing prescriptions for controlled substances. ¹³⁵	\$300,000
9/26/2018	Helar Campos, M.D.	Physician agreed to pay \$99,912 to settle FCA allegations that he billed for E&M office services under CPT code 99214 when he should have used CPT code 99213 or 99212, which are less complex services reimbursed at a lower rate. ¹³⁶	\$99,912
11/20/2018	V. Erin Files	Advanced practice RN agreed to pay \$130,000 to resolve allegations that she prescribed pain creams in exchange for payments – labeled “medical director fees” – from the compounding company that sold the creams. ¹³⁷	\$130,000
11/28/2018	Dr. Thomas Baker; Dr. Carolyn Kochert; Dr. Larry L. Zhou; Dr. Julie Y. Chao	Four physicians agreed to pay various amounts totaling \$1.541 million to settle FCA allegations that they submitted false claims to Medicare due to participation in a kickback scheme with two laboratories and their sales reps. ¹³⁸	\$1.541 million
12/4/2018	Dr. Zahid Aslam	Physician agreed to pay \$3.07 million to resolve civil FCA allegations that walk-in clinics he owns billed for services that were not medically necessary, were not eligible for reimbursement, were not provided, listed the incorrect provider, listed the wrong service, and/or lacked supporting documentation. In this global resolution, Dr. Aslam and one of his clinics also pleaded guilty to healthcare fraud and to making a false statement to a financial institution in a loan application. Dr. Aslam agreed to be excluded from all federal healthcare programs and to surrender his medical licenses. ¹³⁹	\$3.07 million
12/5/2018	Anil J. Desai, M.D.; Rockdale-Newton Hematology-Oncology; East Metro Internal Medicine, L.L.C.	Physician and two practices he owns agreed to pay \$213,000 to resolve FCA allegations that they billed Medicare and Medicaid for: (1) Procrit, an anemia treatment, without documentation showing they purchased enough Procrit to cover the amount billed; and (2) the use of another drug which had not received FDA approval. ¹⁴⁰	\$213,000
12/7/2018	M. Wagdi Attia, M.D.	Retired physician agreed to pay \$400,000 to settle claims that he billed for psychotherapy services that were not rendered because his time-stamped medical records reflected less than the requisite amount of documented face-to-face time with the patient; failed to reflect the provision of all requisite elements of the psychotherapy; and used repetitive, common language that raised questions about the nature and extent of the services actually provided. ¹⁴¹	\$400,000

135 <https://www.justice.gov/usao-nm/pr/east-mountain-family-practice-doctor-pays-300000-resolve-alleged-false-claims-federal>.

136 <https://www.justice.gov/usao-ct/pr/southeastern-connecticut-doctor-pays-99912-settle-allegations-under-false-claims-act>.

137 <https://www.justice.gov/usao-ndok/pr/edmond-nurse-agrees-pay-130000-allegedly-engaging-illegal-kickback-scheme>.

138 <https://www.justice.gov/usao-ndwv/pr/physicians-pay-more-15-million-government-kickback-scheme>.

139 <https://www.justice.gov/usao-de/pr/physician-and-medical-practice-plead-guilty-making-false-statement-financial-institution>.

140 <https://www.justice.gov/usao-ndga/pr/anil-j-desai-md-and-related-entities-pay-over-200000-resolve-false-claims-act>.

141 <https://www.justice.gov/usao-md/pr/former-maryland-physician-agrees-pay-400000-united-states-resolve-allegations-fraudulent>.

ABOUT BASS, BERRY & SIMS

The Bass, Berry & Sims Healthcare Fraud Task Force represents healthcare providers in connection with fraud and abuse matters, including responding to governmental inquiries by the U.S. DOJ and U.S. Attorneys' Offices, the Office of Inspector General of the U.S. Department of Health and Human Services, federal program safeguard contractors, and various states' Attorneys General offices. We have a track record of successfully representing providers in related FCA litigation, including multiple declinations and dismissals in FCA *qui tam* cases. 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.

The firm's healthcare fraud and abuse practice is led by former members of the U.S. DOJ and a number of former Assistant U.S. Attorneys 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 University Law School teaching Health Care Fraud and Abuse. For more information, please visit our website at www.bassberry.com/healthcare-fraud.

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Brian Bewley is a former senior healthcare attorney in Washington, D.C. with both HHS-OIG and DOJ. He advises and defends clients dealing with complex issues involving compliance with laws governing participation in federal healthcare programs. He has successfully defended companies under investigation pursuant to the FCA and HHS-OIG's Civil Monetary Penalties law. Brian has also handled numerous voluntary disclosures to HHS-OIG and CMS and helped companies navigate their respective obligations under CIAs with the OIG.

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, the 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 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 University Law School, teaching Healthcare Fraud and Abuse.

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 governmental agencies. He also represents assisted living facilities with investigations of incidents at facilities.

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.

Jeff Gibson has extensive experience representing clients in complex civil litigation and defending individuals and companies facing government investigations, white collar criminal charges and civil fraud claims. 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 Grizzle focuses her practice exclusively on helping healthcare clients address enforcement and compliance issues and in responding to legal and regulatory violations alleged as part of governmental investigations and FCA lawsuits. Anna routinely advises on the reporting and repayment of overpayments and in responding to payor audits and audit appeals 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.

John Kelly is a former federal healthcare fraud prosecutor, experienced trial attorney and Managing Partner of the firm's Washington D.C. office. John represents companies and executives in internal investigations and government enforcement actions concerning the FCA, AKS, Stark Law, FDCA and FCPA. John previously served as a prosecutor with DOJ where he held a number of leadership positions, 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 Rivera, a former federal prosecutor, focuses her practice on compliance and investigation matters related to civil and criminal healthcare fraud and abuse. Lisa previously served for more than 13 years as an Assistant U.S. Attorney, with 10 years in the U.S. Attorney's Office for the Middle District of Tennessee where she was the Civil and Criminal Healthcare Fraud Coordinator, investigating and litigating both civil and criminal healthcare fraud cases, responsible for the review of all criminal and civil healthcare fraud investigations in the U.S. Attorney's Office. Lisa also counsels clients on data breach and information security issues, and responds to state and federal enforcement in breach and privacy matters.

Brian Roark leads the firm's Healthcare Fraud Task Force and concentrates his practice on representing healthcare clients in responding to governmental 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 University Law School, teaching Healthcare Fraud and Abuse.

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 Sloane helps life science and healthcare clients navigate federal and state healthcare laws and regulations. She frequently advises clients on compliance; fraud and abuse; healthcare due diligence; and operational matters, including self-disclosures, voluntary repayments, compliance plans, and reviews.

Allison Acker defends healthcare providers in connection with alleged violations of the FCA, AKS, Stark Law and other healthcare statutes. She also counsels clients in connection with internal investigations and responding to government inquiries by DOJ, HHS-OIG and the SEC.

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

Christopher Climo helps healthcare clients navigate government investigations, as well as related civil and criminal litigation matters under the FCA, AKS and the Stark Law.

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

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.

Kaitlyn Dunn counsels healthcare clients in matters related to regulatory compliance, fraud and abuse and government investigations. She helps clients respond to civil, criminal and administrative enforcement actions, including those brought under the FCA, AKS and Stark Law. Katie previously served for three years as Associate Counsel at the HHS-OIG, where she was team leader for the New York, Chicago and Kansas City regions.

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.

Lauren Gaffney represents healthcare clients in connection with self-disclosures, internal investigations and responding to governmental inquiries regarding potential regulatory, compliance and clinical issues. She also represents clients in responding to and appealing payor claims audits, including UPIC audits.

Scott Gallisdorfer assists healthcare providers in responding to government investigations and related civil and criminal proceedings. He routinely counsels clients related to compliance and defense of FCA violations, self-disclosures and responding to governmental inquiries.

Maleaka Guice provides healthcare regulatory counsel as it relates to compliance, operational and transactional matters.

Kate Hunter-Salas concentrates her practice on investigations and litigation related to inquiries involving alleged violations of the FCA, the FPCA, various securities laws and other federal statutes.

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 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.

Elaine Naughton provides healthcare regulatory counsel as it relates to transactional and operational matters, including compliance with FCA, Stark Law and AKS. She works with a range of the firm's healthcare clients, including hospitals, health systems, hospice and home health providers and specialty pharmacies.

Brianna Powell provides counsel to a range of clients, including hospital systems and physician groups, in the areas of healthcare fraud and abuse; healthcare contracting, regulatory and operational matters; as well as healthcare mergers and acquisitions.

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 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.

Olivia Seraphim represents healthcare clients in government actions, investigations and related litigation arising from fraud and abuse allegations brought under the FCA, AKS, the Stark Law, Medicare and Medicaid reimbursement rules, and various other federal and state healthcare statutes and regulations.

Page Smith provides healthcare regulatory counsel as it relates to compliance, operational, fraud and abuse, and transactional matters.

Julia Tamulis advises healthcare providers on healthcare regulatory compliance matters, including daily operations issues and internal investigations, and assists with Medicare appeals and hearings related to reimbursement denials. Additionally, Julia provides guidance on governmental investigations of healthcare providers concerning potential fraud and abuse matters. Julia previously was an attorney-advisor for HHS's Departmental Appeals Board.

Hannah Webber represents healthcare providers in connection with government enforcement actions, investigations and related litigation. She routinely counsels clients related to compliance and defense of FCA violations, self-disclosures and responding to governmental inquiries.

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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