



**HEALTHCARE
FRAUD & ABUSE
REVIEW 2017**

BASS
BERRY 
SIMS

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ABOUT BASS, BERRY & SIMS

A LOOK BACK... A LOOK AHEAD

While the uncertainty associated with legislative efforts to repeal the Patient Protection and Affordable Care Act (PPACA) dominated most of the headlines for the healthcare industry last year, it was mostly business as usual for the government's healthcare fraud enforcement efforts.

Civil fraud recoveries by the U.S. Department of Justice (DOJ) remained steady at \$3.7 billion in the fiscal year ending September 30, 2017 (FY 2017). Standing at more than \$20 billion, total recoveries during the trailing five fiscal years continued to reflect the long-term successes of the government's enforcement efforts. As is typical, the majority of DOJ's civil enforcement recoveries stemmed from matters involving false claims against federal healthcare programs in violation of the False Claims Act (FCA).¹

Whistleblowers filed 674 new *qui tam* lawsuits under the FCA in FY 2017, which represented a slight drop from the 706 *qui tam* lawsuits filed the previous year.² Whistleblowers recovered nearly \$400 million as their share of proceeds in *qui tam* judgments and settlements in FY 2017, bringing their total recoveries during the past five years to more than \$2.8 billion.³

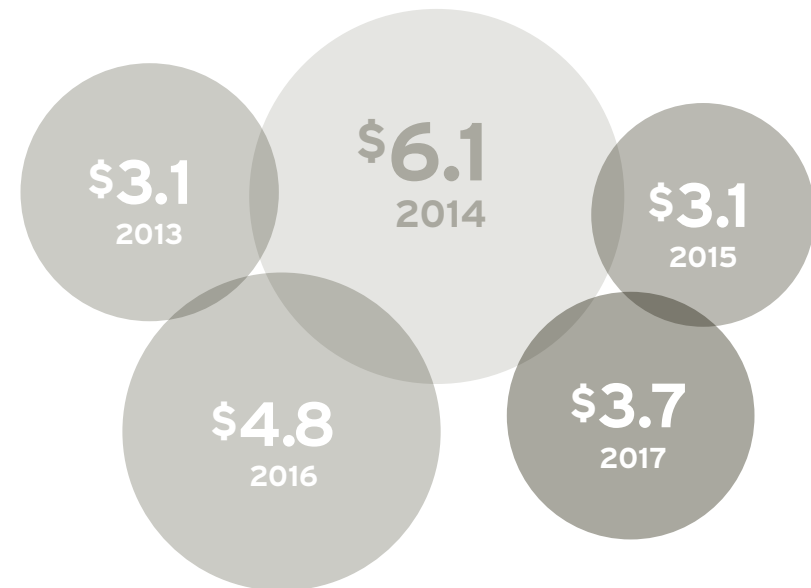
It was widely reported last year that DOJ's Civil Division had announced a change in policy regarding the dismissal of *qui tam* actions. While § 3730(c)(2)(A) of the FCA provides the federal government with the authority to dismiss *qui tam* lawsuits, this authority has rarely been exercised. According to reports, DOJ indicated that it would begin moving to dismiss *qui tam* cases that lacked merit.⁴ The formal change in DOJ policy followed in early 2018, with the release of an internal DOJ memorandum that outlined the framework for DOJ in evaluating whether to exercise its authority under § 3730(c)(2)(A).⁵ It remains to be seen whether DOJ actually intends to meaningfully increase the use of this authority in the coming year or whether this memorandum will amount to no real change for healthcare providers facing *qui tam* lawsuits.

In the largest enforcement action related to healthcare fraud in the history of the Medicare Fraud Strike Force, the U.S. Department of Health and Human Services Office of Inspector

General (HHS-OIG), along with federal and state law enforcement entities, including 30 Medicaid Fraud Control Units, charged more than 400 defendants, including 115 healthcare professionals, in 41 federal districts for allegedly participating in fraudulent healthcare arrangements resulting in over \$1.3 billion in false claims.⁶

Occurring in the context of combatting the opioid crisis, the takedown focused on individuals allegedly involved in fraudulent billing of Medicare, Medicaid and TRICARE for medically unnecessary prescription and compounded drugs that were not actually purchased or distributed to patients covered by a federal healthcare program. In total, more than 120 defendants, including physicians, were charged in connection with prescribing and distributing opioids and narcotics. Nearly 300 individuals—including physicians, nurses and pharmacists—received exclusion notices from HHS-OIG barring future participation in federal healthcare programs for their roles related to abuse and diversion of opioids.⁷

CIVIL FRAUD RECOVERIES FY 2013-2017 (\$BILLIONS)



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

2. *Id.*

3. *Id.*

4. David Glaser, Developing Story: DOJ Will Dismiss Qui Tam Cases Lacking Merit, RACmonitor (Nov. 2, 2017), <https://www.racmonitor.com/developing-story-doj-will-dismiss-qui-tam-cases-lacking-merit>.

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

6. <https://www.justice.gov/opa/pr/national-health-care-fraud-takedown-results-charges-against-over-412-individuals-responsible>; see also https://oig.hhs.gov/newsroom/media-materials/2017/2017HealthCareTakedown_FactSheet.pdf.

7. https://oig.hhs.gov/newsroom/media-materials/2017/2017HealthCareTakedown_FactSheet.pdf.

2017 STRIKE FORCE TAKEDOWN BY THE NUMBERS

412

DEFENDENTS
CHARGED

115

MEDICAL
PROFESSIONALS

\$1.3

BILLION IN
LOSSES

41

FEDERAL
DISTRICTS

30

MEDICAID FRAUD
CONTROL UNITS

295

EXCLUSION
NOTICES

350

OIG AGENTS

The Strike Force also racked up a number of convictions of healthcare providers, including physicians,⁸ home health,⁹ durable medical equipment (DME) suppliers,¹⁰ and ancillary service providers throughout the year.¹¹

HHS-OIG reported expected recoveries of more than \$4.13 billion.¹² HHS-OIG reported 881 criminal actions against individuals or entities that had engaged in crimes against federal healthcare programs and 826 civil actions, including lawsuits alleging false claims and unjust-enrichment and administrative recoveries related to provider self-disclosures. HHS-OIG also excluded more than 3,244 individuals and entities from participation in federal healthcare programs.

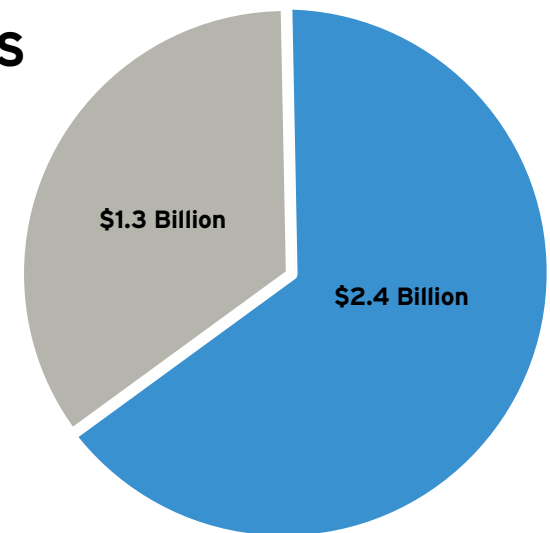
There were also a number of significant legal developments concerning the FCA. Courts continued to grapple with the implications of applying the FCA's "demanding" materiality standard set forth in *Universal Health Services, Inc. v. U.S. ex rel. Escobar*. Indeed, more than \$1 billion in jury verdicts obtained by relators in FCA actions were set aside as a result of a failure to meet *Escobar's* materiality standard.

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 change for the healthcare industry. While the industry continues to grapple with those changes, we certainly do not expect that the government's enforcement efforts will slow any time soon.

COMPARISON OF RECOVERIES (2017)

HHS AS VICTIM
AGENCY V. OTHER
AGENCIES

■ ALL OTHERS
■ HHS AS VICTIM
AGENCY



8. See, e.g., <https://www.justice.gov/usao-edmi/pr/detroit-area-neurosurgeon-sentenced-235-months-prison-role-28-million-health-care-fraud> (neurosurgeon sentenced to 235 months in prison for role in healthcare fraud scheme involving fraudulent billing associated with spinal fusion surgeries); <https://www.justice.gov/opa/pr/clinical-psychologist-and-owner-psychological-services-centers-convicted-25-million> (owners of psychological services companies convicted of healthcare fraud associated with billing for services provided to nursing home residents that were medically unnecessary and/or which the residents did not actually receive). Physicians from the Detroit, Michigan, area accounted for a significant number of the physician-related Strike Force convictions last year. See, e.g., <https://www.justice.gov/opa/pr/second-detroit-area-physician-pleads-guilty-171-million-health-care-fraud-scheme>; <https://www.justice.gov/opa/pr/third-detroit-area-physician-convicted-171-million-health-care-fraud-scheme>; <https://www.justice.gov/opa/pr/detroit-podiatrist-charged-role-139-million-medicare-fraud-scheme>; <https://www.justice.gov/opa/pr/michigan-doctor-and-owner-medical-billing-company-sentenced-15-years-prison-26-million-health>.
9. See, e.g., <https://www.justice.gov/opa/pr/home-health-agency-administrator-pleads-guilty-78-million-medicare-fraud> (administrator of five Houston, Texas home health agencies pleaded guilty in connection with scheme involving provider attendant services and was sentenced to 480 months in prison); <https://www.justice.gov/opa/pr/mother-and-daughter-co-owners-seven-miami-florida-area-home-health-agencies-each-sentenced> (owners and operators of seven home health agencies in the Miami, Florida area were each sentenced to over 10 years in prison in connection with \$20 million Medicare fraud conspiracy involving paying illegal kickbacks to patient recruiters and medical professionals); <https://www.justice.gov/opa/pr/owner-home-health-agency-sentenced-absentia-80-years-prison-involvement-13-million-medicare> (owner of a Houston home health agency was sentenced to 80 years in prison for his role in a \$13 million Medicare fraud scheme and for filing false tax returns).
10. See, e.g., <https://www.justice.gov/opa/pr/operator-purported-durable-medical-equipment-providers-pleads-guilty-health-care-fraud> (operator of multiple DME companies pleaded guilty to fraud charges for role in a scheme to defraud New York-based health maintenance organization that administers Medicare Advantage plans and New York Medicaid Managed Care plans); <https://www.justice.gov/opa/pr/new-orleans-woman-convicted-role-32-million-medicare-kickback-scheme> (defendant convicted in connection with scheme to provide medically unnecessary DME, including power wheelchairs, to Medicare beneficiaries and receipt of kickback payments from the equipment supply company in return for providing eligible Medicare beneficiaries' personal information to the company, as well as to obtain physician signatures on order forms).
11. See, e.g., <https://www.justice.gov/usao-cdca/pr/former-employees-southern-california-ambulance-company-and-dialysis-center-plead-guilty> (employee of ambulance company and a former employee of dialysis treatment center pleaded guilty to fraud charges for their roles in a fraud scheme that resulted in more than \$6.6 million in fraudulent claims to Medicare).
12. <https://oig.hhs.gov/reports-and-publications/archives/semiannual/2017/sar-fall-2017.pdf>.

Of the \$3.7 billion in settlements and judgments reported by the government in fiscal year 2017, \$3.4 billion related to lawsuits filed under the *qui tam* provisions of the False Claims Act.

DOJ Civil Fraud Statistics FY 2017

NOTEWORTHY SETTLEMENTS

As in prior years, resolutions in healthcare fraud cases continued to account for more than half of the FCA recoveries obtained by the government in FY 2017. Of the \$3.7 billion in settlements and judgments—which represents the third-highest annual recovery under the FCA—recoveries from matters involving the healthcare industry amounted to more than \$2.4 billion. This is the eighth consecutive year that recoveries in federal civil healthcare fraud matters have exceeded \$2 billion.¹³

Not surprisingly, newly-filed *qui tam* complaints accounted for the overwhelming majority of the new fraud matters initiated in FY 2017. Settlements associated with *qui tam* lawsuits where the government intervened or otherwise pursued the allegations comprised more than 80% of the recoveries during FY 2017. But, it is noteworthy that settlements in declined *qui tam* actions involving healthcare providers increased significantly, from \$72 million in FY 2016 to \$380 million in FY 2017.¹⁴

The Appendix to our **Healthcare Fraud & 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 resolving FCA allegations. Most of these settlements related to allegations involving violations of the Stark Law or the Anti-Kickback Statute (AKS). The conduct at issue touched on many different forms of compensation, including an interest-free line of credit without the expectation of

repayment to induce referrals,¹⁵ physician compensation arrangements based on a formula that improperly took into account the value of physician referrals,¹⁶ payment of above-market rental rates for office space in physicians' offices, as well as providing marketing arrangements designed to unduly benefit referring physicians,¹⁷ and swapping arrangements between hospitals and various ambulance companies whereby patients received free or heavily discounted ambulance transports in exchange for the ambulance companies receiving rights to the hospitals' more lucrative Medicare and Medicaid referrals.¹⁸ Hospitals and health systems also resolved a number of cases involving allegations that care provided was not medically necessary.¹⁹

LONG-TERM CARE PROVIDERS

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

In the largest settlement involving the Medicare hospice benefit, Chemed, owner and operator of Vitas Hospice Services and Vitas Healthcare, agreed to pay \$75 million to resolve FCA allegations that they billed Medicare for: (1) services to hospice patients who were not terminally ill; and (2) continuous home care services that were not necessary, not actually provided, or not performed in accordance with Medicare requirements. The government

alleged that the defendants rewarded employees with bonuses for the number of patients receiving hospice services, without regard to whether they were actually terminally ill and whether they would have benefited from continuing curative care, and used aggressive marketing tactics and pressured staff to increase the volume of continuous home care claims, without regard to whether the patients actually required this level of crisis care. As part of the settlement, Vitas entered into a five-year Corporate Integrity Agreement (CIA) with HHS-OIG.²⁰

"Today's resolution represents the largest amount ever recovered under the False Claims Act from a provider of hospice services."

Acting Assistant Attorney General Chad A. Reader
DOJ Press Release, *Chemed Corp. and Vitas Hospice Services Settlement (Oct. 30, 2017)*

13. <https://www.justice.gov/opa/pr/justice-department-recovers-over-37-billion-false-claims-act-cases-fiscal-year-2017>.

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

15. <https://www.justice.gov/opa/pr/indiana-university-health-and-healthnet-pay-18-million-resolve-allegations-false-claims> (\$18 million settlement to resolve allegations related to AKS violations stemming from interest-free line of credit made to induce referrals).

16. <https://www.justice.gov/opa/pr/missouri-hospitals-agree-pay-united-states-34-million-settle-alleged-false-claims-act> (\$34 million settlement to resolve allegations that referring oncologists were compensated based on the value of their referrals to hospital); see also <https://www.justice.gov/usao-sdga/pr/meadows-regional-medical-center-inc-and-affiliates-pay-12875-million-resolve-alleged> (\$12.875 million settlement to resolve allegations that hospital had improper financial arrangements with referring physicians).

17. <https://www.justice.gov/opa/pr/los-angeles-hospital-agrees-pay-42-million-settle-alleged-false-claims-act-violations-arising> (\$42 million settlement to resolve allegations that owners and operators of acute care hospital entered into improper compensation arrangements involving above-market rental rates and marketing services); see also <https://www.justice.gov/opa/pr/dallas-based-physician-owned-hospital-pay-75-million-settle-allegations-paying-kickbacks> (physician-owned hospital agreed to pay \$7.5 million to resolve FCA allegations that it paid physicians kickbacks in the form of marketing services in exchange for surgical referrals).

18. <https://www.justice.gov/usao-sdtx/pr/four-area-hospitals-pay-millions-resolve-ambulance-swapping-allegations> (\$8.6 million settlement with hospitals to resolve allegations regarding swapping arrangements with ambulance companies).

19. See, e.g., <https://www.justice.gov/opa/pr/healthcare-service-provider-pay-60-million-settle-medicare-and-medicare-false-claims-act> (\$60 million settlement to resolve claims that physician billing was inflated relative to the care required); <https://www.justice.gov/usao-wdny/pr/catholic-health-pay-6000000-settle-false-claims-act-allegations> (\$6 million settlement to resolve allegations involving rehabilitation services billed at a higher than necessary level).

20. <https://www.justice.gov/opa/pr/chemed-corp-and-vitas-hospice-services-agree-pay-75-million-resolve-false-claims-act>.

Genesis Healthcare agreed to pay \$53.6 million to resolve FCA allegations regarding Genesis-acquired entities from three *qui tam* lawsuits and a separate government investigation. The government alleged that: (1) SunDance Rehabilitation Agency and related entities submitted or caused the submission of false claims to Medicare Part B by billing for outpatient therapy services that were not medically necessary or unskilled in nature; (2) SKG, Skilled Healthcare and/or Hallmark Rehabilitation GP, LLC, submitted or caused to be submitted false claims to federal healthcare programs for patients spending 30 days at certain facilities and who were classified at the Ultra High Resource Utilization Group (RUG) level for at least 65% of their rehabilitation time during their stay by assigning a higher RUG level than necessary to patients, providing therapy to patients longer than medically necessary, and/or billing for more therapy minutes than the patients actually received; (3) Skilled Healthcare billed Medicare and Medi-Cal for services that were not rendered, grossly substandard, and/or worthless, particularly as a result of failing to provide sufficient nurse staffing to meet residents' needs. This settlement also resolved claims regarding allegedly medically unnecessary hospice services.²¹

Finally, Foundations Health Solutions, Inc. (FHS), the corporate successor to a skilled nursing facility (SNF) management company, and Olympia Therapy Inc., a rehab therapy services provider, agreed to pay \$15,527,844 to resolve FCA allegations that: (1) Olympia and FHS submitted or caused the submission of false claims to Medicare for medically unnecessary rehabilitation therapy services at 18 skilled nursing facilities; and (2) two partial owners solicited and received kickbacks to refer patients from the SNFs to an unaffiliated home healthcare provider. The partial owners agreed to pay \$895,830 to resolve the matter. As part of the settlement, FHS and one of its owners entered into a five-year CIA with HHS-OIG.²²

PHARMACEUTICAL AND MEDICAL DEVICE COMPANIES

Pharmaceutical and medical device industry participants entered into a number of significant settlements, which amounted to an overwhelming percentage of the overall enforcement recoveries during the past year. These matters involved allegations regarding unlawful marketing, off-label promotion, and AKS violations, among others.

In one of the most highly-publicized matters, two subsidiaries of Mylan N.V. agreed to pay \$465 million to resolve FCA allegations that Mylan knowingly misclassified EpiPen as a generic drug to Medicaid despite the absence of any therapeutically equivalent drugs, enabling it to demand massive price increases in the private market while avoiding paying a higher rebate to Medicaid. As part of the settlement, Mylan entered into a five-year CIA with HHS-OIG.²³

Shire Pharmaceuticals LLC agreed to pay \$350 million to resolve FCA allegations stemming from six *qui tam* lawsuits that Shire and a company it acquired (Advanced BioHealing (ABH)) employed kickbacks and other unlawful marketing methods to induce clinics and physicians

to use or overuse its product "Dermagraft," a skin substitute that treats diabetic foot ulcers. The government also alleged that Shire and ABH unlawfully marketed Dermagraft for uses not approved by the U.S. Food and Drug Administration (FDA), made false statements to inflate Dermagraft's price, and caused improper coding, verification, or certification of Dermagraft claims and related services. Shire has been operating under a CIA since late 2014, after the alleged conduct resolved by this settlement occurred.²⁴

Celgene Corp., a pharmaceutical manufacturer, agreed to pay \$280 million to resolve FCA allegations in a *qui tam* action, in which the government declined to intervene, that it: (1) promoted two cancer drugs for uses that were not FDA-approved and not covered by federal healthcare programs; (2) made or caused to be made false and misleading statements about the two drugs; and (3) paid kickbacks (e.g., speaker programs, clinical trials, advisory boards) to physicians to induce them to prescribe the drugs, in violation of the AKS.²⁵

And, United Therapeutics Corp. (UT) agreed to pay \$210 million to resolve FCA allegations that it used a nonprofit foundation as a conduit to pay the copays of Medicare patients taking its pulmonary arterial hypertension drugs, in violation of the AKS. UT allegedly made donations to the foundation, which then used the donations to pay copays for the drugs to induce patients to purchase the drugs. UT routinely obtained usage data from the foundation to determine how much needed to be donated. As part of the settlement, the company entered into a five-year CIA with HHS-OIG.²⁶

COMPARISON OF TOTAL RECOVERIES: INTERVENED V. DECLINED CASES SETTLEMENTS AND JUDGMENTS (2013-2017)

| Year | Intervened Cases | Declined Cases |
|------|------------------|------------------|
| 2013 | \$2.87 billion | \$127.35 million |
| 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 |

21. <https://www.justice.gov/opa/pr/genesis-healthcare-inc-agrees-pay-federal-government-536-million-resolve-false-claims-act>.

22. <https://www.justice.gov/opa/pr/three-companies-and-their-executives-pay-195-million-resolve-false-claims-act-allegations>.

23. <https://www.justice.gov/opa/pr/mylan-agrees-pay-465-million-resolve-false-claims-act-liability-underpaying-epipen-rebates>.

24. <https://www.justice.gov/opa/pr/shire-plc-subsiidiaries-pay-350-million-settle-false-claims-act-allegations>.

25. <https://www.justice.gov/usao-cdca/pr/celgene-agrees-pay-280-million-resolve-fraud-allegations-related-promotion-cancer-drugs>.

26. <https://www.justice.gov/opa/pr/drug-maker-united-therapeutics-agrees-pay-210-million-resolve-false-claims-act-liability>.

PHARMACY SERVICES

Retail and specialty pharmacies entered into a number of high dollar settlements involving alleged AKS violations and alleged violations of usual and customary pricing obligations.

Walgreens Co. agreed to pay \$50 million to settle FCA allegations that it provided government beneficiaries with discounts and other monetary incentives under its Prescription Savings Club (PSC) program, to induce them to fill all their prescriptions at Walgreens pharmacies, in violation of the AKS. The government also alleged that Walgreens, despite knowing that government beneficiary participation in the PSC program was an AKS violation, nevertheless marketed the program to government beneficiaries and paid its employees bonuses for each customer they enrolled in the program, without verifying whether the customers were government beneficiaries.²⁷

DaVita Rx LLC, a nationwide pharmacy specializing in serving patients with severe kidney disease, agreed to pay \$63.7 million to resolve FCA allegations—stemming from the pharmacy's own self-disclosures and a subsequent *qui tam* lawsuit—that the pharmacy billed federal programs for prescribed medications that never shipped, and shipped but were later returned, as well as prescriptions that did not comply with documentation requirements such as proof of delivery, refill requests, or patient consent. The settlement also resolved alleged AKS violations that involved accepting manufacturer copayment discount cards in lieu of collecting copayments from Medicare beneficiaries, routinely writing off unpaid beneficiary debt, and extending discounts to beneficiaries who paid for their medications by credit card. The pharmacy already had repaid \$22.2 million of the \$63.7 million following its self-disclosures.²⁸

Finally, Kmart Corp. agreed to pay \$59 million to settle FCA allegations in a *qui tam* action, in which the government declined to intervene, that its stores failed to report discounted prescription drug prices to Medicare Part D, Medicaid, Tricare, and certain private insurers. The lawsuit alleged that the stores offered discounted generic drug prices to cash-paying customers through various club programs but knowingly failed to disclose those prices when reporting its usual and customary prices, in order to receive higher reimbursement from government healthcare programs.²⁹

27. <https://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-announces-50-million-settlement-walgreens-paying-kickbacks-induce>.

28. <https://www.justice.gov/opa/pr/davita-rx-agrees-pay-637-million-resolve-false-claims-act-allegations>.

29. <https://www.justice.gov/opa/pr/kmart-corporation-pay-us-323-million-resolve-false-claims-act-allegations-overbilling-federal>.

ISSUES TO WATCH

Each year, we identify key issues that are likely to drive the government's enforcement efforts in the coming year and that will have a significant impact on how healthcare fraud matters are pursued by relators asserting FCA claims and how they are defended on behalf of healthcare providers.

MANAGED CARE

Investigations and litigation involving FCA claims asserted against managed care plans have emerged as a key area of focus. Such focus stems from the tremendous incentive for federally funded managed care plans, primarily Medicare Advantage plans (MA Plans), to ensure they receive the maximum monthly payment—known as a capitation payment—for each member, coupled with federal requirements that MA Plans take certain steps to ensure and attest to the truth and accuracy of the member data submitted for use in determining the appropriate capitation payment.

Unlike Medicare's fee-for-service reimbursement model, MA Plans are compensated on a monthly basis with a fixed capitation payment for each member. The amount of the capitation payment is determined for each payment year through a process called "risk adjustment" based on data reflecting the diagnoses that were documented for that patient based on face-to-face encounters with certain types of healthcare providers that occurred in the 12 months before the beginning of the payment year. The codes submitted by MA Plans to the Centers for Medicare & Medicaid Services (CMS) to communicate these diagnoses must be supported by a proper medical record.³⁰ To protect against overcoding of diagnoses, federal law requires that CMS conduct regular audits—known as Risk Adjustment Data Validation (RADV) audits. Further, all MA Plans must agree to "certify (based on best knowledge, information, and belief) that the data it submits" for risk adjustment are "accurate, complete, and truthful."³¹ Additionally, as a condition of contract, MA Plans are required to maintain "an effective compliance program,

which must include measures that prevent, detect, and correct non-compliance with CMS' program requirements as well as measures that prevent, detect, and correct fraud, waste, and abuse."³² To the extent that a Plan identifies inaccurate codes that already have been submitted, the Plan is required to submit deletions to correct any overpayment even where the submission deadline for incremental data for a given payment year has passed.³³

In the context of this framework, traditional FCA claims, as well as those under the reverse false claims provisions and 60-day repayment rule, have focused primarily on allegations that the certifications as to truth and accuracy of the risk adjustment data are false for at least one of a variety of reasons, including inadequate compliance and diligence activities, one-way retrospective reviews, and blind retrospective reviews used only to identify incremental codes and not deletions.

KEY ISSUES TO WATCH IN 2018:

FCA Claims Against Managed Care Plans

Enforcement Around EMR Technology

Medical Necessity

Individual Liability

Compliance Guidance

The United States intervened in two *qui tam* actions against UnitedHealthcare—***U.S. ex rel. Swoben v. Secure Horizons***³⁴ and ***U.S. ex rel. Poehling v. UnitedHealth Group, Inc.***³⁵ In both cases, the allegations focused on false diagnosis codes submitted to CMS for use in risk adjustment and one-sided review programs that focused on using medical records to identify any additional codes that had not been submitted to the plans without also using those reviews to identify and delete inaccurate codes.³⁶

In a significant blow to the government, the district court in ***U.S. ex rel. Swoben v. Scan Health Plan*** granted UnitedHealthcare's motion to dismiss the government's complaint for failure to plead scienter, failure to plead materiality, and failure to plead with particularity. Specifically, the

district court said that the government had failed to "identify the corporate officers who signed the attestations or allege that those individuals knew or should have known that the attestations were false," and, in fact, had not identified anyone at the company who had the requisite knowledge. The district court also said the government had failed to allege "that CMS would have refused to make risk adjustment payments to the United Defendants if it

30. See 42 U.S.C. § 1395w-23.

31. 42 C.F.R. § 422.504(l)(2).

32. 42 C.F.R. § 422.503(b)(vi).

33. See 42 C.F.R. § 422.310.

34. No. 2:09-cv-05013 (C.D. Cal.).

35. No. 2:16-cv-08697 (C.D. Cal.).

36. United States' Complaint-In-Partial-Intervention, *U.S. ex rel. Swoben v. Secure Horizons*, No. 2:09-cv-05013 (C.D. Cal. May 1, 2017); United States' Amended Complaint-In-Partial-Intervention, *U.S. ex rel. Poehling v. UnitedHealth Group, Inc.*, No. 2:16-cv-08697 (C.D. Cal. Nov. 17, 2017).

had known the facts about the United Defendants' alleged involvement with the Healthcare Partners' chart review process," and had only made conclusory allegations of materiality. Finally, the district court held the complaint failed to "identify the role of each defendant in the alleged fraudulent scheme."³⁷ While the district court granted the government leave to amend certain deficiencies, the government did not do so, instead filing a notice of dismissal. **Poehling** remains ongoing, with briefing on Defendants' motion to dismiss the government's amended complaint pending as of year's end.

During the pendency of the **Swoben** and **Poehling** cases, UnitedHealthcare filed suit under the Administrative Procedure Act that would potentially address some of the same questions of law at issue in **Swoben** and **Poehling**, namely "defining actuarial equivalence and the diligence obligations of MA providers." The government has argued that the filing of this case was an attempt by UnitedHealthcare to "end run the FCA Cases."³⁸ In **UnitedHealthcare Insurance Company v. Price (Price I)**, the district court denied the government's motion to dismiss this suit in which UnitedHealthcare claimed that a CMS rule encoded at 42 C.F.R. § 422.326, as interpreted by the responses to comments issued with that rule, violated the statutory requirement for actuarial equivalence between Medicare Advantage and traditional fee-for-service Medicare imposed by 42 U.S.C. § 1395-23(a)(1)(C)(i) and improperly interpreted the language from the PPACA requiring the return of overpayments within "60 days after the date on which the overpayment was identified."³⁹ 42 C.F.R. § 422.326 provides, in relevant part, that "[t]he MA organization has identified an overpayment when the MA organization has determined, or should have determined through the exercise of reasonable diligence, that the MA organization has received an overpayment." The response to comment language issued with the rule states that "at a minimum, reasonable diligence would include proactive compliance activities conducted in good faith by qualified individuals to monitor for the receipt of overpayments."⁴⁰ The district court held that the plaintiffs had Article III standing to pursue the claims because the CMS rule imposed a "novel legal obligation" on plaintiffs and statutory standing because the court saw no viable path for administrative review of the CMS Rule.⁴¹

Subsequently, in **UnitedHealthcare Insurance Company v. Price (Price II)**, the district court denied the government's motion to stay the case pending resolution of the **Poehling** and **Swoben** cases. The district court held that the cases and issues were insufficiently alike to warrant a stay of the case and noted that while the two FCA cases would require considerable discovery, the dispute as to the rule would rise and fall on the existing administrative record. It further stated that the relevant facts and legal standards would be entirely different.⁴² Each side has since filed motions for summary judgment in the case, and those motions remained pending as of year's end.⁴³

In **Graves v. Plaza Medical Centers**, the district court denied the defendant's motion for summary judgment, in which the plan argued that its compliance program precluded a finding that it had acted with reckless disregard as to any submission of inaccurate diagnosis codes for use in risk adjustment or false certifications as to the truth and accuracy of such codes. The district court found that there was a genuine issue of material fact as to whether the plan's compliance program had been operated in such a way as to constitute diligence regarding the truth and accuracy of the risk adjustment data submitted to CMS. The district court further explained that cooperation with the government's investigation was insufficient to preclude a jury from finding that the plan had knowingly retained overpayments based on false diagnosis codes submitted to CMS.⁴⁴

In a significant settlement of FCA claims, **Freedom Health, Inc.**, and its related entities agreed to pay \$31.6 million to settle allegations that it had inflated reimbursement to its plans by submitting and causing others to submit unsupported diagnosis codes to CMS for use in risk adjustment and made material misrepresentations to CMS about its network of providers. The company's former COO also agreed to pay \$750,000 to resolve his individual liability related to the conduct.⁴⁵

The developments this year have given rise to two takeaways that can be expected to continue developing over the next year. First, with respect to retrospective reviews—the process in which the MA Plan or its vendor collects medical records from providers and reviews them to see what diagnosis codes they support—reviews cannot be "one way" without subjecting the MA Plan to potential liability under the FCA from the government's perspective. If such reviews are used to identify incremental codes, they must also be used to identify deletions. Second, with respect to compliance programs, what is important from an FCA perspective is the qualitative impact of the program. A compliance program—no matter how robust—will be tested for its effectiveness in identifying inaccurate codes resulting in overpayment. If a program's effective result or intended design is focused more heavily on identifying incremental diagnoses for additional payment, rather than on identifying inaccurate diagnoses that should be deleted, it may very well be more likely to bolster FCA allegations against the company than to help in defending against such claims. Additionally, consideration of the question of materiality in cases such as **Poehling** will be of particular note given the government's loss in **Swoben** and the district court's language suggesting that materiality means that the government would have refused to make payment if it had known of the conduct.

37. 2017 WL 4564722 (C.D. Cal. Oct. 5, 2017).

38. *UnitedHealthcare Insurance Company v. Price (Price II)*, 255 F. Supp. 3d 208 (D.D.C. June 14, 2017).

39. 2017 WL 1207424 (D.D.C. March 31, 2017).

40. 79 Fed. Reg. 29844, 29923 (May 23, 2014).

41. *Price I*, No. 16-cv-00157, 2017 WL 1207424.

42. 255 F. Supp. 3d 208 (D.D.C. June 14, 2017).

43. *UnitedHealthcare Insurance Company v. Price*, No. 16-cv-00157 (D.D.C.).

44. 2017 WL 1102840 (S.D. Fla. Nov. 7, 2017).

45. <https://www.justice.gov/opa/pr/medicare-advantage-organization-and-former-chief-operating-officer-pay-325-million-settle>.

MEDICAL RECORDS/HITECH

The high-profile \$155 million settlement announced last year in ***U.S. ex rel. Delaney v. eClinicalWorks LLC*** suggests that FCA actions and enforcement efforts related to electronic medical record (EMR) systems will be an area to watch.⁴⁶ The 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. According to the United States, both "meaningful use" and properly certified technology are material to payment under the incentive program. In the case of eClinicalWorks, the complaint alleged that eClinicalWorks purposefully manipulated the test results, thereby causing providers who used the software to unknowingly submit false claims when the providers made certifications regarding the eClinicalWorks software used.

In ***U.S. ex rel. Petrowski v. Epic Systems Corporation***, the *qui tam* action brought against the EMR software vendor Epic Systems Corporation

TAKEAWAY:

Healthcare providers are ultimately responsible for the claims they submit for reimbursement through electronic medical record technology and should carefully monitor the validity of these claims.

was unsealed and included allegations that Epic's software, which is used by healthcare providers for tasks such as keeping electronic medical records, registering and scheduling patients, and submitting bills to private insurance companies and the government for reimbursement, was unable to handle changes associated with new Medicare billing and reimbursement policies.⁴⁷ The relator, who served as Supervisor of Physician coding, alleged that Epic's software was set up to include the sum of both the actual time spent rendering services as well as the base unit time, resulting in double reimbursement for anesthesia billing. Epic allegedly failed to fix these shortcomings when confronted about them by the relator. The relator's complaint, however, is short on facts and may not survive dismissal under Rule 9(b).

Although the government did not pursue FCA claims against the healthcare providers that used the software that allegedly resulted in the submission of false claims, such cases should be cautionary reminders that healthcare providers are ultimately responsible for the claims they submit for payment, and they should not blindly trust that the software always works as advertised.

MEDICAL NECESSITY

Medicare only reimburses healthcare providers for services considered to be reasonable and necessary. FCA cases involving allegations regarding medically unnecessary procedures continued to remain a hot topic last year, with numerous high-dollar settlements, as well as significant victories for healthcare providers. In the year ahead, resolution of key appellate issues involving medical necessity and other district court litigation could significantly impact the FCA landscape in these matters. Three noteworthy appeals related to medical necessity allegations are likely to be resolved in 2018:

- ✦ In ***U.S. ex rel. Paradise v. AseraCare, Inc.***, the United States alleged that AseraCare, a hospice provider, submitted Medicare claims certifying patients as eligible for hospice despite those patients' lack of a terminal illness prognosis.⁴⁸ After conducting a trial on the issue of falsity resulting in a jury verdict in favor of the government, the district court set aside the verdict and entered judgment in favor of AseraCare. The district court explained that the government had failed to identify any objective evidence of falsity and had instead relied solely on subjective clinical analysis. To hold otherwise, the district court stated, "would totally eradicate the clinical judgment required of the certifying physicians." The appeal of the district court's opinion remains pending before the Eleventh Circuit.
- ✦ In ***U.S. ex rel. Wall v. Vista Hospice Care, Inc.***, a hospice provider faced allegations that it submitted false claims associated with patients who were not eligible to receive the Medicare hospice benefit.⁴⁹ The relator offered evidence disputing the clinical judgment of the hospice provider through an expert report reviewing certain patient files. The district court, however, concluded that "an FCA claim about the exercise of [clinical] judgment must be predicated on the presence of an objectively verifiable fact at odds with the exercise of that judgment, not a matter of questioning subjective clinical analysis." Following the district court's grant of summary judgment in favor of the hospice provider and the denial of a motion for reconsideration, the relator appealed to the Fifth Circuit, which remained pending at year's end.
- ✦ And, in ***U.S. ex rel. Polukoff v. St. Mark's Hosp.***, the relator alleged that a cardiologist performed medically unnecessary cardiac procedures.⁵⁰ The district court dismissed the relator's complaint for failing to plead that an objectively false claim was submitted for reimbursement. According to the district court, the relator's reliance on healthcare association guidelines was insufficient to demonstrate the absence of medical necessity, observing that Medicare "does not require compliance with an industry standard as a prerequisite to payment." The relator's appeal remained pending before the Tenth Circuit at year's end.

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

47. *U.S. ex rel. Petrowski v. Epic Sys. Corp.*, 8:15-cv-01408, (M.D. Fla.).

48. 176 F. Supp. 3d 1282 (N.D. Ala. 2016).

49. 2016 WL 3449833 (N.D. Tex. June 20, 2016).

50. 2017 WL 237615 (D. Utah Jan. 19, 2017).

In addition to those pending appeals, the recent resolution of two district court cases relating to medical necessity is also worth monitoring:

✦ ***U.S. ex rel. Ruckh v. CMC II LLC*** involved allegations that numerous skilled nursing facilities submitted claims for medically unnecessary therapy to Medicare.⁵¹ Defendants—skilled nursing facility operators—filed a motion for summary judgment, which was denied. The defendants had emphasized that “a difference in (qualified) medical opinion creates no claim for fraud,” but the district court stated simply that their motion, “although strong, [fell] short of compelling the conclusion that the record presents no genuine issue of material fact for determination by jury.”⁵² A trial ensued, resulting in a jury verdict in the relator’s favor and an award of more than \$115 million in damages. The district court then trebled that award and applied per claim penalties for a damages total of approximately \$348 million. The defendants filed a post-trial motion for judgment as a matter of law, challenging the sufficiency of the evidence presented at trial regarding the medical necessity of the therapy provided. The district court granted the defendants’ motion, vacated the judgments against the defendants, and conditionally granted a new trial. The district court found that the relator had failed to prove materiality as required under the FCA, rejecting relator’s “assert[ion] that a handful of paperwork defects ... compel[led] the decisive inference that the defendants never provided the therapy evidenced by the paperwork and billed to Medicare.”⁵³ A motion by relator for an injunction to “preserve the status quo” during an appeal remains pending.

✦ In ***U.S. ex rel. Ribik v. HCR Manor Care Inc.***, the United States alleged that the defendants encouraged employees to deliver skilled nursing services that were medically unnecessary.⁵⁴ Toward the conclusion of discovery, the magistrate judge struck the government’s expert witness’ report and barred the witness from testifying, after the government revealed it had failed to produce thousands of pages of the expert witness’s handwritten and electronic notes. The government then moved to dismiss its case against the provider, which was granted by the district court.

Such cases certainly could change the complexion of FCA cases involving medical necessity—either by strengthening the prohibition against reliance on disagreements with subjective clinical judgments or undercutting that prohibition and potentially inviting more FCA claims. Coupled with the uncertainty associated with pending litigation is the potential for policy change by governmental enforcement authorities. Former HHS Secretary Tom Price suggested at his confirmation hearings that the government should move away from verifying medical

necessity for “every single incident of care” and should instead focus on increasing the number of prepayment audits designed to ferret out fraud.⁵⁵ Yet, the government continues to pursue and enter into multimillion-dollar settlements based on the alleged provision of medically unnecessary services.⁵⁶ Time will tell whether any policy changes or key appellate decisions will impact the government’s enforcement efforts regarding questions of medical necessity.

CONTINUED FOCUS ON INDIVIDUAL LIABILITY

The government has continued to pursue individuals responsible for misconduct associated with corporate entities rather than merely resolving claims with those entities alone. In several high dollar settlements, individuals agreed to joint and several liability for settlement payments with their affiliated corporations. For example, in the eClinicalWorks settlement (\$155 million) and the Medstar Ambulance Inc. settlement (\$12.7 million),⁵⁷ company founders or owners agreed to joint and several liability for the settlement amounts with their respective companies. The government’s settlement with Hartford Dispensary and its former President and CEO Paul McLaughlin (\$627,000) also involved joint liability between the settling entity and the individual.⁵⁸

In other settlements, individuals were required to pay a specified amount of the total settlement. For example, in the Foundations Health Solutions/Olympia Therapy/Tridia Hospice settlement, the settlement agreement—which included both the entities and certain executives—required two executives to pay a specified amount of the \$19.5 million settlement.⁵⁹ Similarly, in the \$13.45 million settlement involving AMI Monitoring, its owner, and several affiliates, the settlement agreement for AMI Monitoring and its individual owner required the owner to pay \$1 million of the settlement amount.⁶⁰

The government also entered into several separate settlement agreements with individuals to resolve their liability for conduct that also resulted in a corporate settlement. Several employees of eClinicalWorks—Jagan Vaithilingam (\$50,000), Bryan Sequeira (\$15,000), and Robert Lynes (\$15,000)—entered into separate settlement agreements to resolve their individual liability.⁶¹ Urologist Meir Dallar agreed to pay \$3.8 million to resolve liability in connection with the earlier 21st Century Oncology LLC settlement in 2015.⁶² Former COO Siddhartha Pagidipati agreed to pay \$750,000 to resolve his individual liability in connection with the Freedom Health Inc. settlement.⁶³ The former CFO and COO of Southeast Orthopedic Specialists, Scott Muldrow, agreed to pay \$100,000 to resolve his individual liability related to the 2016 settlement with

51. No. 8:11-cv-01303 (M.D. Fla.).

52. Order, No. 8:11-cv-01303 (M.D. Fla. Dec. 1, 2016), Doc. No. 367, at p. 3, 8.

53. Order, No. 8:11-cv-01303 (M.D. Fla. Dec. 1, 2016), Doc. No. 468, at p. 1.

54. No. 1:09-cv-00013 (E.D. Va. Nov. 17, 2017).

55. https://archive.org/details/CSPAN_20170129_153300_HHS_Nominee_Representative_Tom_Price_Testifies_at_Confirmation_Hearing.

56. See, e.g., <https://www.justice.gov/opa/pr/genesis-healthcare-inc-agrees-pay-federal-government-536-million-resolve-false-claims-act>; <https://www.justice.gov/usao-sdny/pr/acting-us-attorney-announces-54-million-settlement-civil-fraud-lawsuit-against-benefits>.

57. <https://www.justice.gov/opa/pr/medstar-ambulance-pay-127-million-resolve-false-claims-act-allegations-involving-medically>.

58. <https://www.justice.gov/usao-ct/pr/connecticut-substance-abuse-treatment-provider-pays-627k-settle-false-claims-act>.

59. <https://www.justice.gov/opa/pr/three-companies-and-their-executives-pay-195-million-resolve-false-claims-act-allegations>.

60. <https://www.justice.gov/opa/pr/cardiac-monitoring-companies-and-executive-agree-pay-1345-million-resolve-false-claims-act>.

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

62. <https://www.justice.gov/usao-mdfl/pr/fort-myers-urologist-agrees-pay-more-38-million-ordering-unnecessary-medical-tests>.

63. <https://www.justice.gov/opa/pr/medicare-advantage-organization-and-former-chief-operating-officer-pay-325-million-settle>.

Southeast Orthopedic Specialists.⁶⁴ Finally, several individuals who were owner operators of provider facilities have settled FCA cases with DOJ this year.⁶⁵

On a policy note, U.S. Deputy Attorney General Rod Rosenstein stated in a September 14, 2017 address that the Yates Memo, which established the focus on individual liability as a key component of DOJ's policy on corporate prosecutions in 2015, was under review and that he expected there may be some changes to the policy; however, DOJ has not yet announced any such changes.⁶⁶

COMPLIANCE GUIDANCE

When investigating a corporate entity and deciding whether to bring charges or negotiate a plea deal, DOJ considers a series of ten "Filip Factors" outlined in the Principles of Federal Prosecution of Business Organizations contained in the U.S. Attorneys' Manual, which includes "the existence and effectiveness of the corporation's pre-existing compliance program," and "the corporation's remedial actions, including any efforts to implement an effective corporate compliance program or to improve an existing one[.]"⁶⁷ In February 2017, DOJ released the **Evaluation of Corporate Compliance Programs**,⁶⁸ which identifies 11 topics DOJ considers when analyzing the effectiveness of a company's compliance program. For each topic, the guide provides a host of questions, and although it warns that it is "neither a checklist nor a formula," it does provide helpful insight into what companies can expect in the event of an investigation.

For example, the guide contains questions emphasizing that a compliance program should be well integrated throughout the company. Senior leaders should be both a working part of the compliance program and also appropriately monitored by the compliance program. Compliance personnel also should be empowered to take real action; the government may ask about specific instances of wrongdoing and how the company responded. The guide focuses not only on having mechanisms in place to prevent misconduct but also learning from misconduct to prevent similar issues in the future. The government may ask whether the compliance program conducted training on the issue at the root of the investigation or if employees are aware of—and have access to—corporate policies. Overall, although not a definitive checklist, the guide is helpful in determining whether the corporate compliance components of the Filip Factors have been met and whether a company's efforts are sufficient to avoid a fraud investigation or prosecution.

HHS-OIG and the Health Care Compliance Association (HCCA) also released a compliance guide in 2017, joining together to provide their interpretation of what a competent compliance

program should look like.⁶⁹ **Measuring Compliance Program Effectiveness-A Resource Guide** follows the 2015 OIG Guidance for Boards,⁷⁰ and discusses possible ideas on how to implement an effective compliance program. The stated purpose of the guide is not to be a "'checklist' to be applied wholesale to assess a compliance program." Instead, it is "to give healthcare organizations as many ideas as possible" when implementing and evaluating its compliance program.

The HHS-OIG/HCCA guide focuses on the seven elements of an effective compliance program set forth in the United States Sentencing Guidelines:

- 1) standards, policies, and procedures;
- 2) compliance program administration;
- 3) screening and evaluation of employees, physicians, vendors and other agents;
- 4) communication, education, and training on compliance issues;
- 5) monitoring, auditing, and internal reporting systems;
- 6) discipline for non-compliance; and
- 7) investigations and remedial measures.

Under each element, the guide lists specific ideas of what to measure, and specific ways to measure it.

For example, in suggesting ways to implement the first element—standards, policies, and procedures—the guide suggests that an employer measure employees' access to the company policies, and suggests that employers do this by auditing exactly how many "hits" the link to such policies receives. Under element six, discipline for non-compliance, the guide suggests that an employer measure the culture surrounding disciplinary action and suggests doing this by conducting a survey to ask whether employees feel that other "employees who engage in improper work-related activities will be caught[.]" Ultimately, while the guide is not meant to be a specific list of actions a company must undertake, it is certainly helpful when deciding how to measure certain aspects of a competent corporate compliance program.

64. <https://www.justice.gov/usao-mdfl/pr/former-jacksonville-chief-financial-officer-resolves-healthcare-fraud-allegations>.

65. <https://www.justice.gov/usao-sdfl/pr/plantation-physician-and-physician-practice-pay-750000-resolve-false-claims-act>; <https://www.justice.gov/usao-wdky/pr/louisville-based-physician-settles-federal-false-claims-act-and-state-civil-claims>.

66. <http://www.heritage.org/the-constitution/event/constitution-day-address>. See also Sarah N. Lynch, Justice Department Mulls Changing Corporate Prosecution Policy, Reuters (Sept. 14, 2017), available at <https://www.reuters.com/article/us-usa-justice-whitecollar/justice-department-mulls-changing-corporate-prosecution-policy-idUSKCN1BP2KD>.

67. 9-28.300(A) - Factors to Be Considered.

68. U.S. Department of Justice, Criminal Division, Fraud Section, Evaluation of Corporate Compliance Programs (Feb. 8, 2017), available at <https://www.justice.gov/criminal-fraud/page/file/937501/download>.

69. Measuring Compliance Program Effective - A Resource Guide, available at <https://oig.hhs.gov/compliance/101/files/HCCA-OIG-Resource-Guide.pdf>.

70. Practical Guidance for Health Care Governing Boards on Compliance Oversight, available at <https://oig.hhs.gov/compliance/compliance-guidance/docs/practical-guidance-for-health-care-boards-on-compliance-oversight.pdf>.

FALSE CLAIMS ACT UPDATE

The FCA is the federal government's primary civil enforcement tool for investigating allegations that healthcare providers defrauded federal healthcare programs. The pursuit of FCA claims by the government and relators has continued unabated. As a result, there continue to be a number of legal developments involving the FCA that will greatly impact healthcare fraud enforcement efforts.

THE CONTINUED IMPACT OF ESCOBAR

As we reported last year, perhaps the most significant FCA development in recent years was the U.S. Supreme Court's decision in *Universal Health Services, Inc. v. U.S. ex rel. Escobar*,⁷¹ which affirmed the viability of the implied certification theory of liability and articulated the standard for analyzing the FCA's materiality requirement. The decision continues to have a dramatic impact on lower court decisions.

Implied False Certification

In confirming the validity of the implied false certification theory, *Escobar* held that a plaintiff can satisfy the FCA's falsity element "at least" when two conditions are met: (1) the defendant submits a claim that "does not merely request payment, but also makes specific representations about the goods or services provided;" and (2) "the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths."⁷²

Escobar did not decide, however, whether those two conditions represent the *only* viable path to establishing an implied false certification claim, or rather, only one possible option. Indeed,

the Supreme Court expressly declined to address the validity of a more expansive implied false certification theory, leaving open the question of "whether all claims for payment implicitly represent that the billing party is legally entitled to payment."⁷³

The lower courts have been left to grapple with whether implied false certification claims may succeed even in the absence of a "specific representation[]" about the goods or services provided." Courts have been divided over that question in *Escobar's* wake, and the split only deepened over the past year.

A number of courts have held that *Escobar's* two conditions are mandatory, dismissing implied false certification claims in the absence of any "specific representations" about the goods or services provided. For example, in *U.S. ex rel. Kelly v. Serco, Inc.*, the Ninth Circuit affirmed summary judgment in favor of a government contractor accused of violating certain cost-tracking requirements, explaining that the relator's "implied false certification claim ... fail[ed] as a matter of law" in part due to the lack of evidence that the defendant's "public vouchers made any specific representations about [its] performance."⁷⁴

By contrast, several other courts have indicated that "specific representations" are not required, heeding *Escobar's* caveat that it did not rule out the possibility that *all* claims for payment implicitly certify that the billing party is legally entitled to payment. Emblematic of this position, in *United States v. Triple Canopy, Inc.*, the Fourth Circuit reconsidered—but declined to alter—its pre-*Escobar* decision endorsing a relator's theory that a government contractor's bills for security services provided by armed guards implicitly certified compliance with marksmanship standards outlined in the contract. In doing so, the Fourth Circuit rejected the contention that "specific representations" were required, noting that *Escobar* had not overruled the Fourth Circuit's prior holding that "the Government pleads a false claim when it alleges a request for payment under a contract where the contractor withheld information about its noncompliance with material contractual requirements."⁷⁵

Notably, the split among lower courts on the necessity of "specific representations" has persisted not only *across* circuits, but also *within* circuits as well, and even within individual judicial districts. In *United States v. DynCorp International, LLC*, for instance, the district court heeded prior D.C. Circuit precedent holding that, to support an implied false certification claim, an FCA plaintiff need show only "that the contractor withheld information about its noncompliance with material contractual requirements."⁷⁶ Several months later, however, a different district judge sitting on the same district court rejected a relator's implied false certification claim, in part, based on his failure to "satisfy" *Escobar's* "requirement[]" that an FCA plaintiff aver "specific representations about the goods or services" provided.⁷⁷

71. 136 S. Ct. 1989 (2016).

72. *Id.* at 2001.

73. *Id.* at 2000.

74. 846 F.3d 325, 332 (9th Cir. 2017); *accord U.S. ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890, 901 (9th Cir. 2017); *U.S. ex rel. Schimelpfenig v. Dr. Reddy's Labs. Ltd.*, 2017 WL 1133956, at *4-5 (E.D. Pa. Mar. 27, 2017). The United States has recently argued that the Ninth Circuit's statements in *Kelly* and *Campie* are dicta, thereby leaving open the possibility that implied false certification claims remain viable in the Ninth Circuit even in the absence of "specific representations" accompanying the relevant claims for payment. But one district court has rejected the government's reading, concluding that *Kelly*, at least, binds Ninth Circuit district courts to the rule that "specific representations" are mandatory. See *U.S. ex rel. Mateski v. Raytheon Co.*, 2017 WL 1954942, at *3 (C.D. Cal. Feb. 10, 2017). The Ninth Circuit itself may resolve the uncertainty in *U.S. ex rel. Rose v. Stephens Institute*, No. 17-15111, a case argued in December 2017, which remains pending.

75. 857 F.3d 174, 178 n.3 (4th Cir. 2017) (internal quotation marks omitted).

76. 253 F. Supp. 3d 89, 99-100 (D.D.C. 2017) (quoting *United States v. Science Applications Int'l Corp.*, 626 F.3d 1257, 1269 (D.C. Cir. 2010); *accord U.S. ex rel. Landis v. Tailwind Sports Corp.*, 234 F. Supp. 3d 180, 198 (D.D.C. 2017) (relying on pre-*Escobar* circuit precedent to reject argument that implied false certification claim failed because the invoices at issue "merely requested payment" and "did not represent anything about the nature of the services rendered").

77. *U.S. ex rel. Lott v. Not-For-Profit Hosp. Corp.*, 2017 WL 5186344, at *6 (D.D.C. Nov. 8, 2017) (dismissing claim alleging that defendant violated the FCA by submitting reimbursement claims to federal healthcare programs despite knowing that defendant was not in compliance with certain "[OIG] guidelines and other federal laws regarding healthcare facilities and nursing programs").

A similar intra-district split has developed within the U.S. District Court for the Southern District of New York.⁷⁸

As we noted in last year's **Healthcare Fraud & Abuse Review**, the split on the necessity of satisfying *Escobar's* two conditions ultimately may have limited importance for the healthcare industry. After all, most claims submitted to federal healthcare programs do make "specific representations" about the nature of the services provided. Moreover, that requirement itself may not prove particularly demanding. For example, the Ninth Circuit's decision in *Campie* suggested that even the mere inclusion of a drug's name in a claim for payment could be a "specific representation" implicitly certifying that the drug's FDA approval complied with relevant regulations.⁷⁹

Nonetheless, at least a few courts have emphasized that not just any "specific representation" will do. In *U.S. ex rel. Forcier v. Computer Sciences Corporation*, the district court held that *Escobar's* conditions were not satisfied—despite the defendant having made "specific representations" about the cost of healthcare services provided—because its representations "had nothing to do with" the regulatory provisions it was accused of violating. In the absence of such a connection, the district court explained the defendant's representations could not be viewed as misleading half-truths.⁸⁰ Similarly, the district court in *U.S. ex rel. Lisitza v. Par Pharmaceutical Companies* rejected the contention that claim forms submitted by the defendant contained the kind of "specific representations" that *Escobar* had in mind, even though they included codes corresponding to specific drugs for which reimbursement was sought. The district court observed that if various statements on the forms constituted "specific representations" at all, "none of them [were] the focus of plaintiffs' arguments, which rest[ed] instead on the inflated costs of drugs that the plaintiffs say should not have been dispensed."⁸¹ Together, these cases appear to leave open at least a possibility that

More than \$1 billion in jury verdicts in FCA actions were set aside as a result of a failure to meet *Escobar's* materiality standard.

healthcare providers may avoid liability for implied false certifications even in instances where an FCA plaintiff can point to certain "specific representations" made in connection with a claim for payment.

Application of *Escobar's* Materiality Standard

The Supreme Court explained that the FCA's materiality requirement is "rigorous" and "demanding," and must be strictly enforced to prevent the FCA from becoming an "all-purpose

antifraud statute or a vehicle for punishing garden-variety breaches of contract or regulatory violations."

To guide courts in applying the materiality requirement, the Supreme Court stated that courts may consider the following factors:

- ✦ It is not sufficient for a finding of materiality that the government "would have had the option to decline to pay if it knew of the defendant's noncompliance."
- ✦ The government's decision to "expressly identify a provision as a condition of payment is relevant, but not automatically dispositive" of the materiality inquiry.
- ✦ It is evidence of materiality "that the defendant knows that the government consistently refuses to pay claims in the mine run of cases based on noncompliance" with a requirement.
- ✦ It is "[v]ery strong evidence" of immateriality "if the government pays a particular claim in full despite its actual knowledge that certain requirements were violated."
- ✦ It is "[s]trong evidence" of immateriality "if 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."

Courts continued to develop case law surrounding *Escobar's* materiality standard in 2017. While the outcomes often were fact specific, some notable trends emerged.

Proof of Materiality Required. *Escobar* held that the materiality standard is not "too fact intensive for courts to dismiss False Claims Act cases on a motion to dismiss or at summary judgment." Consistent with the Supreme Court's statement, materiality continued to be a viable basis for dismissal both at the pleadings stage and at summary judgment. While relators and the government satisfied materiality in some cases, defendants enjoyed considerable success asserting lack of materiality as a defense. As a threshold matter, courts held that cases should be dismissed where they contain only conclusory allegations of materiality. In *Scan Health Plan*, the district court dismissed the United States' complaint in intervention because it contained only conclusory allegations of materiality.⁸² Similarly in *U.S. ex rel. Smith v. Sanders*, the district court granted summary judgment to certain of the defendants because the relator offered no proof that the alleged false statements were material to payment.⁸³ In *U.S. ex rel. Schimelpfenig v. Dr. Reddy's Labs., Ltd.*, the district court found the complaint failed to sufficiently allege materiality because it contained little "beyond broad conclusory statements" of materiality.⁸⁴ Notably, the district court rejected the relator's citation to research highlighting the importance of the regulated issues, explaining, "[t]hat the Government or a federal agency found a particular issue important enough to regulate speaks little to the intended consequence of noncompliance."

78. Compare *U.S. ex rel. Forcier v. Computer Scis. Corp.*, 2017 WL 3616665, at *12 (S.D.N.Y. Aug. 10, 2017) ("agree[ing] with the majority view in this Circuit" that "implied false certification claim[s] may proceed only if Defendant made specific representations that were rendered misleading by its failure to disclose noncompliance with material regulatory requirements"), with *U.S. ex rel. Wood v. Allergan, Inc.*, 246 F. Supp. 3d 772, 815-16 (S.D.N.Y. 2017) ("After *Escobar*, liability under the implied certification theory does not ... require a showing that the submitted claims amount to misleading half-truths, as the *Escobar* Court expressly refrained from defining the outer limit of implied certification claims." (internal citation omitted)).

79. 862 F.3d at 902-03 (declining to dismiss claim premised on allegation that "drug names" listed on claims for payment "necessarily refer to specific drugs under the FDA's regulatory regime" and thus can be "misleading" to the extent that the defendant "omitted critical information regarding compliance with FDA standards"). Notably, *Campie* also held that representations made prior to submission of the claim for payment—and to a different agency altogether—may still constitute the kind of "specific representation" contemplated by *Escobar*. *Id.* at 903 ("[I]f a false statement is integral to a causal chain leading to payment, it is irrelevant how the federal bureaucracy has apportioned the statements among layers of paperwork.").

80. 2017 WL 3616665, at *12-13 (S.D.N.Y. Aug. 10, 2017).

81. 2017 WL 3531679, at *12-14 (N.D. Ill. Aug. 17, 2017).

82. 2017 WL 4564722 (C.D. Cal. Oct. 5, 2017).

83. 2017 WL 4536005 (N.D. Tex. Sept. 15, 2017).

84. 2017 WL 1133956 (E.D. Pa. Mar. 27, 2017).

Recently, in two of the stronger wins for defendants asserting lack of materiality, district courts in two separate matters vacated jury verdicts upon reviewing the evidence on the question of materiality in light of **Escobar**. The district court in **U.S. ex rel. Ruckh v. Salus Rehabilitation, LLC** vacated the jury's \$348 million judgment against the defendants after finding that the relator failed to offer evidence of materiality.⁸⁵ The judgment could not stand, the district court reasoned, because "[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."

"As the interests of the government and relator diverge, this congressionally created enlistment of private enforcement is increasingly ill served. 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 Indus. Inc.

FCA's materiality standard: "If the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material."

Going forward, relators and the government are likely to adjust their pleadings and arguments not only to contain specific proof of materiality, but also in response to other developments in the case law discussed below.

Express Condition of Payment. **Escobar** held that whether a statutory, regulatory or contractual requirement "is labeled a condition of payment is relevant to but not dispositive of

And, in **U.S. ex rel. Harman v. Trinity Industries, Inc.**, the Fifth Circuit vacated a \$663 million judgment, concluding that **Escobar** doomed plaintiff's FCA claims on the issue of materiality.⁸⁶ Trinity Industries, a manufacturer of highway guardrail systems, faced FCA allegations brought by a former competitor based on the theory that federally subsidized purchases of Trinity's guardrail systems resulted in false claims as a result of unapproved design modifications. During the course of the litigation before the district court, the government had provided a statement that the guardrails manufactured by Trinity had been and continued to be eligible for reimbursement. Notwithstanding that statement, the district court denied summary judgment for Trinity and entered a \$663 million judgment following the jury verdict against Trinity. The Fifth Circuit granted Trinity judgment as a matter of law, holding that "the jury's findings of liability [could not] stand for want of materiality." Quoting **Escobar**, the Fifth Circuit emphasized the demanding nature of the

the materiality inquiry." This was notable because prior to **Escobar**, some courts had held that whether a provision was expressly labeled a condition of payment was dispositive of materiality. In last year's coverage, we noted the tension in how this factor had been applied, with some courts dismissing cases that alleged a violation of an express condition of payment, and other courts allowing such cases to move forward. That tension continued in 2017.

In **U.S. ex rel. McBride v. Halliburton Co.**, for example, the D.C. Circuit affirmed the district court's grant of summary judgment for the defendant where the relator alleged that the defendant inflated the recorded number of U.S. troops who visited the defendants' recreation centers in Iraq, but could not identify any express condition of payment this violated.⁸⁷ In reaching this decision, the D.C. Circuit rejected the relator's reliance on a government contracting officer's statement that he "might" have investigated if he had known of false headcounts, reasoning "the statement amounts to the far-too-attenuated supposition that the Government *might* have had the 'option to decline to pay.'"

By contrast, in **U.S. ex rel. Hinkle v. Caris Healthcare, L.P.**, the district court denied the defendants' motion to dismiss and determined that the United States' complaint sufficiently pleaded materiality where it alleged that the defendant hospice providers violated an express condition of payment that they certify their patients were terminally ill.⁸⁸ This allegation was sufficient standing on its own, the district court reasoned, because the government would not have paid claims for hospice patients the provider knew were not terminally ill.

Essence of the Bargain. Several other courts showed a willingness to find materiality satisfied where they deemed the alleged violations sufficiently important or found the violations went to "the essence of the bargain" with the government. In **U.S. ex rel. Badr v. Triple Canopy, Inc.**, the relator alleged that the defendant, a security contractor with the United States government in Iraq, hired guards who could not meet contractual marksmanship requirements.⁸⁹ The Fourth Circuit found that materiality was met and "readily" reversed the district court's dismissal, analogizing to a passage in **Escobar** about the FCA's roots in the Civil War and reasoning that "[g]uns that do not shoot are as material to the Government's decision to pay as guards that cannot shoot straight."

Likewise, in **U.S. ex rel. Emanuele v. Medicor Assocs.**, the relator alleged that a physician practice continued to provide medical director services to a hospital after the practice's medical director agreements had expired, in violation of requirements under the Stark Law that such services be provided according to a written agreement.⁹⁰ Going perhaps farther than any other court in 2017, **Emanuele** found the violation was material despite little evidence connecting the writing requirement to the payment of claims. Instead, the district court construed the regulatory framework as a whole and found the writing requirement went to the "essence of the bargain," especially considering the Stark Law's insistence on transparency and verification. That said, the district court may have been persuaded by evidence suggesting other healthcare providers had paid penalties for self-reporting violations of the same requirement.

85. 2018 WL 375720 (M.D. Fla. Jan. 11, 2018).

86. 872 F.3d 645 (5th Cir. 2017).

87. 848 F.3d 1027 (D.C. Cir. 2017).

88. 2017 WL 3670652 (E.D. Tenn. May 30, 2017).

89. 857 F.3d 174 (4th Cir. 2017).

90. 242 F. Supp. 3d 409 (W.D. Penn. 2017).

The district court employed similar reasoning when finding materiality satisfied in **United States v. Quicken Loans, Inc.**, explaining that even though the government failed to allege the violation of an express condition of payment, it went to the “essence of the bargain” that the defendant allegedly underwrote, approved and endorsed mortgage loans for Federal Housing Administration (FHA) insurance that violated applicable underwriting requirements.⁹¹ As in **Emanuele**, the district court’s decision may have been tipped by other factors, here by allegations of internal company emails and statements suggesting the defendant knew the violation was material.

Government Action Factor. Perhaps the biggest takeaway from 2017 is the importance of allegations or proof about how the government responded to the defendant’s alleged violations or to similar violations in the past. Such facts often were dispositive of cases in 2017. Perhaps surprisingly given the lack of discovery, this factor was important not only at summary judgment, but also at the pleading stage.

Several courts dismissed FCA cases where the government continued to pay the defendant’s claims or investigated and took no action despite actual knowledge of the violations. In **Abbott v. BP Exploration & Prod., Inc.**, the relator alleged that BP failed to obtain proper documentation for its construction and maintenance of an off-shore oil production facility.⁹² The relator’s allegations led to congressional hearings and the preparation of an investigational report by the Department of the Interior, which ultimately found there were no grounds to suspend the project or revoke BP’s license. The Fifth Circuit found this was “strong evidence” that the claims were not material and affirmed summary judgment for the defendants. The district court reached a similar decision in **U.S. ex rel. Kolchinsky v. Moody’s Corp.**, granting a motion to dismiss the relator’s claim because of allegations that the government had investigated purported inaccuracies in Moody’s credit ratings, yet continued to pay Moody’s for its credit-ratings products.⁹³

Likewise, in **U.S. ex rel. Petratos v. Genentech Inc.**, the Third Circuit affirmed the district court’s dismissal of the relator’s allegation that the defendant suppressed data about health risks of a cancer drug.⁹⁴ Even though the statute allegedly violated was an express condition of payment, the relator conceded that the government would have paid the claims with full knowledge of the alleged noncompliance. The Third Circuit also found it persuasive that the relator had disclosed some of his allegations to the government, and the government took no action against the defendant, including revoking FDA approval or intervening in the lawsuit. Notably, the Third Circuit held that while the relator showed the defendants’ misstatements might have caused the submission of false claims, this went to the causation element and not the materiality element.

In **U.S. ex rel. Kelly v. Serco, Inc.**, the relator alleged that a project management company filed progress tracking reports that violated industry standards.⁹⁵ The Ninth Circuit affirmed

summary judgment for the defendant, finding that the violations alleged were not material because compliance with industry standards was not an express term of the company’s contract and because the government found the reports unhelpful, eventually eliminating the progress tracking process entirely. In **U.S. ex rel. Spay v. CVS Caremark Corp.**, the Third Circuit affirmed the district court’s grant of summary judgment, finding that the alleged misstatements were not material, in part, because the government paid claims despite knowing that the defendant-pharmacies submitted claims using “dummy” provider IDs.⁹⁶

In **U.S. ex rel. Prather v. Brookdale Senior Living Cmty. Inc.**, the district court granted the defendants’ motion to dismiss allegations that it failed to obtain timely physician signatures on home healthcare certifications of need.⁹⁷ Although the district court found that Medicare regulations expressly conditioned payment on the timing of the certification, the district court concluded based on a review of the regulations that while it was material for the physician to sign the certification, the timing of the signature was not material. The district court further noted that the relator had not alleged any instances in the 50-year history of the regulation where the government had denied claims because of the alleged violation.

Other decisions were not in defendants’ favor. In **U.S. ex rel. Worthy v. Eastern Maine Healthcare Sys.**, the district court declined to grant summary judgment to the defendants because the government had taken action to prevent similar violations in the past.⁹⁸ Notably, the district court did not require proof that the government had denied prior claims, but

found it sufficient to defeat summary judgment that the government had investigated similar misconduct. There was also evidence, however, that the defendant had taken actions to conceal its violation, which further supported materiality.

Given the importance of the government-action factor, courts carefully scrutinized whether the government’s actions were relevant to materiality. In **U.S. ex rel. Campie v. Gilead Scis., Inc.**, the Ninth Circuit considered allegations that the defendant submitted claims for payment of drugs it knew to contain materials from unapproved facilities.⁹⁹ The Ninth Circuit rejected the defendant’s argument that the violations were immaterial because the FDA continued to approve the drug after learning of the noncompliance. The Ninth Circuit was troubled by allegations that FDA approval had been fraudulently obtained,

Perhaps the biggest takeaway from 2017 is the importance of allegations or proof about how the government responded to the defendant’s alleged violations or to similar violations in the past. Such facts often were dispositive of cases in 2017.

91. 239 F. Supp. 3d 1014 (E.D. Mich. 2017).

92. 851 F.3d 384 (5th Cir. 2017).

93. 238 F. Supp. 3d 550 (S.D.N.Y. 2017).

94. 855 F.3d 481 (3d Cir. 2017).

95. 846 F.3d 325 (9th Cir. 2017).

96. 2017 WL 5491935 (3d Cir. Nov. 16, 2017).

97. 265 F. Supp. 3d 782 (M.D. Tenn. 2017).

98. 2017 WL 211609 (D. Me. Jan. 18, 2017).

99. 862 F.3d 890 (9th Cir. 2017).

and noted that it was disputed whether the government actually knew about the alleged violations. Additionally, the ninth circuit reasoned that the FDA might have reasons to maintain approval even if the violation was material to payment.

The district court also took a hard look at the evidence in *U.S. ex rel. Scutellaro v. Capitol Supply, Inc.*, declining to grant summary judgment to the relator on the issue of materiality because a government agency had given the defendant “mixed signals” about its compliance—while one agency office warned the defendant of the seriousness of its violations, another largely overlooked the violations and gave the defendant high reviews.¹⁰⁰

Materiality in Criminal Fraud Cases. Finally, in *United States v. Palin*, the Fifth Circuit expressed doubt that *Escobar* overturned the materiality standard that previously applied in criminal fraud cases.¹⁰¹ Yet, the Fifth Circuit upheld the defendants’ convictions on the ground that even if *Escobar* applied, the defendants’ violations were material.

DEVELOPMENTS IN FCA PLEADING STANDARDS

Pleading Details of a Fraudulent Scheme

Whether a relator has pleaded facts with the requisite level of particularity to satisfy Rule 9(b) of the Federal Rules of Civil Procedure is typically a hotly litigated topic, and last year proved to be no exception. Courts generally agree that a relator must plead the “who, what, when, where, and how” of the alleged fraud to state an FCA claim, and courts have continued to scrutinize complaints to determine whether the circumstances of a fraudulent scheme were set forth with sufficient detail.

As in the past, courts continued to require relators to spell out the specifics of the alleged fraudulent scheme. For example, in *U.S. ex rel. Colquitt v. Abbott Laboratories*, the Fifth Circuit affirmed the dismissal of a relator’s complaint alleging that Abbott Labs engaged in an “off-label” promotion scheme.¹⁰² The relator generally described programs providing volume discounts and rebates to hospitals and vascular specialists who received dinners, training and fellowships, but failed to include any specifics about the discounts and rebates provided, or any details showing that the doctors and hospitals who received the ill-defined benefits used the devices for off-label uses. Such allegations, the Fifth Circuit explained, were not enough to make out the fraudulent scheme.

Courts also examined the individual components of the “who, what, when, where, and how” requirement of Rule 9(b).¹⁰³ For instance, in *Hinkle*, the district court determined that the “who” aspect of Rule 9(b) did not require plaintiffs to “name specific physicians” involved in the alleged misconduct when the underlying complaint only asserted FCA claims against

a corporate provider who submitted claims for payment for hospice services based on the doctors’ certifications.¹⁰⁴

As to facts sufficient to plead the “when” element, in *U.S. ex rel. Lord v. Napa Management Services Corp.*, the district court limited the relator’s claims to the time period of his employment with the defendant because his complaint provided specific examples of fraud for only the two-year period of his employment.¹⁰⁵ For the remaining four years of the alleged fraud, the relator relied solely on information-and-belief pleading, which the court found insufficient under 9(b).

Pleading Submission of False Claims

Courts continued to reach different conclusions about the specificity with which plaintiffs must plead that an alleged fraud resulted in the submission of false claims to the government. While certain courts required plaintiffs to identify at least one actual claim submitted to the government as a result of the alleged fraud, most courts allowed a complaint to survive Rule 9(b) if the relator’s allegations provided “reliable indicia” supporting a strong inference that claims were actually submitted.

Pleading Actual Claims

While the Sixth Circuit appeared to adopt a relaxed standard for the first time last year in *U.S. ex rel. Prather v. Brookdale Senior Living Communities, Inc.*,¹⁰⁶ it has yet to apply that standard in any other case, and later decisions from the Sixth Circuit reinforced its application of a “strict standard” for pleading FCA claims.

Indeed, in *U.S. ex rel. Ibanez v. Bristol-Meyers Squibb Co.*, the Sixth Circuit re-emphasized its strict application of Rule 9(b), by requiring that relators attach to the complaint a “specific representative claim” which satisfies each step in the chain of causation ultimately ending in the submission of a false claim to the government.¹⁰⁷ Although the relators alleged that the defendants engaged in an off-label promotion scheme and attached several proposed representative claims, the Sixth Circuit rejected the complaint because none of the allegations or attached claims established a complete causal chain—i.e., that the defendants had illegally promoted their drug to a provider, that the provider in turn prescribed the drug for an off-label use, that the patient filled the prescription, and that the filling pharmacy submitted a claim for reimbursement to the government. The Sixth Circuit also determined that the relators, who were former sales representatives for defendants, were not entitled to the relaxed standard first applied in *Prather* because they had not alleged specific, detailed personal knowledge of the defendants’ billing practices.

100. 2017 WL 1422364 (D.D.C. Apr. 19, 2017).

101. 874 F.3d 418 (5th Cir. 2017).

102. 858 F.3d 365 (5th Cir. 2017).

103. For a detailed analysis of several of these requirements as they apply to an alleged scheme to submit false claims for home health services, see *U.S. ex rel. Wagner v. Care Plus Home Health Care, Inc.*, 2017 WL 6329850 (N.D. Okla. Dec. 11, 2017).

104. 2017 WL 3670652 (E.D. Tenn. May 30, 2017).

105. 2017 WL 2653164 (M.D. Pa. June 20, 2017).

106. 838 F.3d 750 (6th Cir. 2016) (holding that a relator had satisfied Rule 9(b) because her allegations were “based on her personal billing-related knowledge” and supported a “strong inference that specific false claims were submitted for payment”).

107. 874 F.3d 905 (6th Cir. 2017).

Likewise, in *U.S. ex rel. Hirt v. Walgreen Co.*, the Sixth Circuit affirmed the dismissal of AKS claims premised on the distribution of Walgreens gift cards where the relator failed to identify, by name or date, any specific customer who filled a prescription at Walgreens after receiving a gift card.¹⁰⁸ When the relator sought to invoke the relaxed standard applied in *Prather*, the Sixth Circuit explained that its prior use of the word relaxed “runs the risk of misleading lawyers and their clients.” The Sixth Circuit explained that it had no authority to relax Rule 9(b)’s standard, which requires a complaint to include either an actual claim or allegations of detailed personal knowledge of the claims submission process.¹⁰⁹

Alternatives to Pleading Actual Claims

Other circuits appeared more willing to accept allegations of falsely submitted claims without requiring the attachment or identification of an actual claim that was submitted to the government.

Cases Requiring a Strong Inference of Claims Submission. A number of courts held that a relator’s complaint could survive a motion to dismiss so long as it contained the particular details of a scheme to submit false claims, along with “reliable indicia” that lead to a strong inference that claims were actually submitted as a result.

“The Eleventh Circuit’s use of the word “relax,” and our repetition of it in later cases, runs the risk of misleading lawyers and their clients. We have no more authority to ‘relax’ the pleading standard established by Civil Rule 9(b) than we do to increase it.”

U.S. ex rel. Hirt v. Walgreen Co.

For example, in *Colquitt*, the Fifth Circuit found a strong inference that the named hospitals submitted claims to Medicare for certain vascular procedures using biliary stents, reasoning that nearly every hospital in America participates in Medicare and would most likely have billed Medicare had they performed procedures using Abbott’s stents on a person over 65.¹¹⁰

Similarly, in *U.S. ex rel. Wood v. Allergan, Inc.*, the district court declined to dismiss a complaint alleging that Allergan violated the AKS by providing free drug samples and other goods to physicians in exchange for their prescribing Allergan drugs to beneficiaries of the federal healthcare programs.¹¹¹ While acknowledging the absence of allegations relating to actual claims, the district court nonetheless held the complaint survived Rule 9(b) because the relator identified “a defined pool of false claims.” The complaint

identified specific physicians and healthcare centers who received alleged kickbacks, and from that, Allergan was on notice of the claims against it, since it could “connect the dots” to determine which pharmacies ultimately submitted claims to the government as a result of the scheme.

At least one court held that relators need not identify claims actually submitted to the government at the pleading stage when the complaint incorporates patient records that contain allegedly fraudulent notations relevant to Medicare billing. In *U.S. ex rel. Dicken v. Northwest Eye Center, P.A.*, the district court granted the relator’s motion to vacate the dismissal of his FCA claims.¹¹² While the relator’s second amended complaint did not identify any representative examples of allegedly false claims submitted by Northwest Eye Center, it did attach patient charts listing CPT and ICD-9 codes that relator alleged Northwest Eye Center used when submitting fraudulent Medicare claims. Notably, the relator lacked first-hand experience with Northwest’s claim submission process. Quoting the Fifth Circuit’s decision in *U.S. ex rel. Grubbs v. Kanneganti*,¹¹³ the district court found that it would “stretch the imagination” to find that Northwest Eye Center did not actually submit the claims to Medicare given the use of CPT and ICD-9 codes and the relator’s allegations tying the codes to Medicare billing.

Cases Applying a Relaxed Pleading Standard. Some courts have recognized a relaxed pleading standard in cases where the relevant billing information is “peculiarly within the knowledge” of the defendant. For instance, in *U.S. ex rel. Chorches v. American Medical Response, Inc.*, the Second Circuit adopted a “more lenient” pleading standard, reviving a relator’s claims where his complaint alleged on information and belief that specific claims had been submitted to Medicare for payment, but included no details, such as invoice numbers, invoice dates or amounts billed and reimbursed.¹¹⁴ The Second Circuit held that the relator was not required to identify the exact billing numbers, dates or amounts for claims submitted to the government, because that information was “peculiarly within [defendant’s] knowledge” and was not made accessible to employees in relator’s position. Under this standard, not every *qui tam* complaint must be based on personal knowledge or provide specifically-identified false claims submitted to the government, but those who *can* identify examples of actual claims *must* do so at the pleading stage.

Several courts also applied a relaxed standard in cases against defendants who caused third parties to submit false claims. For example, in *U.S. ex rel. Nargol v. DePuy Orthopaedics, Inc.*, the First Circuit the revived relators’ claim that DePuy had “palmed off” defective hip replacement devices to providers, holding that it was sufficient for the relators to allege that over a five-year period, several thousand Medicare and Medicaid recipients received what their doctors understood to be FDA-approved hip replacement devices although more than half of those implants did not meet the FDA requirements, and that the latency of the defect was such

108. 846 F.3d 879 (6th Cir. 2017).

109. Other cases similarly required relators to allege actual claims. See, e.g., *U.S. ex rel. Aquino v. Univ. of Miami*, 250 F. Supp. 3d 1319 (S.D. Fla. 2017) (“Although the [complaint] details questionable internal procedures at the satellite office in Doral, it does not allege with any particularity even one claim for payment to Medicare or any other government program.”); *U.S. ex rel. Quartararo v. Catholic Health Sys. of Long Island, Inc.*, 2017 WL 1239589 (E.D.N.Y. Mar. 31, 2017) (granting motion to dismiss when relator failed to connect alleged fraudulent diversion of funds to the submission of any actual claims for payment).

110. Other courts have resisted this line of reasoning. See, e.g., *U.S. ex rel. Carver v. Physicians’ Pain Specialists of Ala., P.C.*, 2017 WL 4873710 (S.D. Ala. Oct. 27, 2017) (dismissing FCA claims against physician group based on an alleged kickback scheme when relator’s only allegation that false claims were actually submitted to the government was based on the percentage of the group’s patient population that was covered by Medicare).

111. 246 F. Supp. 3d 772 (S.D.N.Y. 2017).

112. 2017 WL 2345579 (D. Minn. May 30, 2017).

113. 565 F.3d 180 (5th Cir. 2009).

114. 865 F.3d 71 (2d Cir. 2017).

that doctors would have had no reason not to submit claims for reimbursement for these non-compliant devices.¹¹⁵ Similarly, in *United States v. Johnson & Johnson*, the relators alleged that Johnson & Johnson used a national sales force to mislead physicians about the effectiveness of two HIV/AIDS drugs and to improperly promote the drugs for off-label use, but did not identify any physician who wrote a prescription that was submitted to the government on the basis of those marketing efforts.¹¹⁶ The district court denied Johnson & Johnson's motion to dismiss, reasoning that the relators' allegations regarding the "nationwide scheme of misbranding and kickbacks" and the "substantial financial success" that followed were sufficient to establish that claims had been submitted to the government as a result of Johnson & Johnson's alleged acts.¹¹⁷

Developments Regarding Falsity

False Certification

While *Escobar* focused on implied certification liability, its guidance as to the FCA's materiality requirement should apply equally to FCA cases where falsity is premised on an express certification.¹¹⁸ In addition, although *Escobar* did not discuss the parameters of the express false certification theory of liability, it did disavow open-ended FCA liability, remarking that "if the Government required contractors to aver their compliance with the entire U.S. Code and Code of Federal Regulations," then "failing to mention noncompliance with any of those requirements would always be material," which is "an extraordinarily expansive view of liability" that the FCA "does not adopt."

But how courts view the scope of the express certification requirement and whether courts apply the materiality requirement as strongly in express certification cases will be important issues to watch moving forward, as they could curtail the import of *Escobar* to the detriment of healthcare providers. For instance, in *U.S. ex rel. Dresser v. Qualum Corp.*, the district court rejected the government's implied certification claim because the government failed to satisfy *Escobar*'s materiality standard by generally alleging that it would not have paid the defendants' claims had it known of the alleged noncompliance with Medicare staffing regulations.¹¹⁹ Yet, the district court allowed the government's express certification claim to proceed where the defendant certified in a CMS-1500 claim form that it had complied with "all applicable Medicare and/or Medicaid laws, regulations, and program instructions for payment." In the context of this broad express certification, the district court found the materiality requirement satisfied—without explanation—by the government's conclusory allegation that it would only pay for sleep tests that complied with the Medicare staffing regulations at issue.

Other courts have denied FCA claims based on broad certifications, like the one at issue in *Dresser*, which did not reference compliance with the particular requirement the defendant allegedly violated. In *U.S. ex rel. Bishop v. Wells Fargo & Co.*, the Second Circuit rejected an attempt by relators to premise FCA liability on the defendant's broad certifications in a lending agreement of compliance with "any laws or regulations" that "could have any adverse effect" with the agreement.¹²⁰ To hold otherwise, the Second Circuit explained, would not "sufficiently cabin" the express certification requirement, as the defendant's banks are "subject to thousands of laws and regulations that could plausibly affect" the terms of the lending agreement.¹²¹ In *U.S. ex rel. Tessler v. City of New York*, the district court similarly held that a certification of compliance with "applicable implementing" statutes and regulations could not form the basis of an express certification claim because "the representation has to refer to compliance with a particular law."¹²²

Courts also closely scrutinized how relators must plead theories of falsity. Generally, relators pleading falsity must allege either factual or legal falsity. The theory of factual falsity is that a claim for government reimbursement 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. Attempting to curb "shotgun pleading" of those falsity theories, the district court in *U.S. ex rel. Sharpe v. Americare Ambulance* dismissed a relator's FCA claim because the relator failed to specify a "theory of falsity" underlying the claim.¹²³ In doing so, the district court chastised the relator for relying on "bare legal conclusions," failing to allege "specific facts or certifications render[ing] ... claims false and why they were false," and incorporating by reference all preceding allegations ("a hallmark of 'shotgun' pleading").

Even when a relator has identified a theory of falsity, courts have become increasingly quick to dismiss reliance on an incorrect theory. In *U.S. ex rel. Schimelpfenig v. Dr. Reddy's Labs. Ltd.*, the relators alleged that the defendants submitted claims for prescription drugs that were illegally packaged and labeled. In doing so, the relators attempted to rely on a theory of factual falsity.¹²⁴ The district court rejected the relators' use of that theory because the relators "neither alleged that [d]efendants dispensed drugs different than that for which [d]efendants sought federal reimbursement, nor do [relators] allege that [d]efendants sought reimbursement for drugs that were not at all provided." Rather, the district court characterized the relators' reliance on factual falsity as an inappropriate attempt to "circumvent the requirements for proving legal falsity under the FCA by repurposing their

115. 865 F.3d 29 (1st Cir. 2017).

116. 2017 WL 2367050 (D.N.J. May 31, 2017).

117. See also *U.S. ex rel. Lupo v. Quality Assurance Servs., Inc.*, 242 F. Supp. 3d 1020 (S.D. Cal. 2017) (finding viable FCA claim based on allegations a company falsified medical device inspection reports, which caused third parties using the devices to file false claims because there was a "strong inference" that claims were actually submitted as a result of the scheme); *U.S. ex rel. Lutz v. Berkeley Heartlab, Inc.*, 247 F. Supp. 3d 724 (D.S.C. 2017) (permitting plaintiff to move forward based on allegations that identified physicians and practices who were induced by co-pay and deductible waivers to refer all of their patients to the defendant's lab clients, who in turn likely billed Medicare for some of those patients).

118. See *U.S. ex rel. Thomas v. Black & Veatch Special Projects Corp.*, 820 F.3d 1162, 1174 (10th Cir. 2016) (pre-*Escobar* decision explaining that "[a]lthough express and implied claims differ, both nonetheless share some common elements, including a materiality requirement"); *United States v. Fulton Cnty., Ga.*, 2016 WL 4158392, at *5 (N.D. Ga. Aug. 5, 2016) (post-*Escobar* decision stating that "[t]he misrepresentation, whether express or implied, must be material to the other party's course of action").

119. 2016 WL 3880763 (N.D. Cal. July 18, 2016).

120. 823 F. 3d 35, 45-46 (2d Cir. 2016).

121. Notably, the Second Circuit distinguished *U.S. ex rel. Lemmon v. Envirocare of Utah, Inc.*, 614 F.3d 1163 (10th Cir. 2010), where the Tenth Circuit found a certification in a payment request that work was performed "in accordance with the specifications, terms and conditions of the contract" to be sufficient, by noting that a contract has limited terms whereas a broad certification with all applicable laws is open-ended.

122. 2016 WL 7335654, at *4 (S.D.N.Y. Dec. 16, 2016).

123. 2017 WL 2840574 (M.D. Fla. July 3, 2017).

124. 2017 WL 1133956 (E.D. Pa. Mar. 27, 2017).

claims as ones for factual falsity” and prohibited the relator from proceeding under a theory of factual falsity.

In *U.S. ex rel. Campie v. Gilead Scis., Inc.*, the relator alleged that the defendant falsely certified that its drug’s active ingredients had been manufactured in FDA-approved facilities.¹²⁵ In contrast to the decision reached in *Schimelpfenig*, the district court in *Campie* held that the relators’ allegations of the defendant’s “misbranding” satisfactorily pleaded a theory of factual falsity. Likewise, in *U.S. ex rel. Groat v. Boston Heart Diagnostics Corp.*, the relator averred that the defendant submitted false claims because the defendant “certified that [certain laboratory] tests it performed were medically necessary even though they were not...”¹²⁶ Despite concluding that the defendant had no independent obligation to certify the medical necessity of its laboratory tests, the district court nonetheless held that the relator sufficiently pleaded legal falsity. According to the district court, the relator had made out sufficient allegations because the relator had alleged that the defendant “engaged in a scheme to encourage ... physicians to order medically unnecessary tests.”

Objective Falsity in Medical Necessity Cases

Courts have continued to consider the showing required to establish falsity in FCA cases concerning allegations of medically unnecessary care. Such cases often involve battles between competing medical experts, with disputes between the parties focusing on the medical industry standards to prove objective falsity. This past year was no different.

As in previous years, courts stressed that parties need something more than a difference of opinion to plead and prove the FCA’s requirement of falsity. In *U.S. ex rel. Polukoff v. St. Mark’s Hosp.*, a relator maintained that a cardiologist performed unnecessary procedures resulting in the submission of false claims.¹²⁷ The relator, himself a cardiologist, alleged that the procedures were unnecessary by reference to professional guidelines from the American Heart Association and the American Stroke Association. The district court rejected the notion that allegations that the cardiologist failed to meet those guidelines could satisfy the relator’s obligation to plead objective falsity. In doing so, the district court rejected the relator’s attempt to “equate” industry standards with the medical necessity standard, reasoning that Medicare “does not require compliance with an industry standard as a prerequisite to payment.”

In *U.S. ex rel. Dooley v. Metic Transplantation Lab, Inc.*, the district court looked to industry standards as a means of demonstrating medical necessity, but declined to accept industry standards as the basis for objective falsity.¹²⁸ The relator claimed that the defendants performed unnecessary antibody screening related to organ transplantation. The district court, however, granted the defendant’s motion for summary judgment, having determined that no issue of fact existed regarding the question of falsity. In reaching that conclusion, the district court cited industry standards supporting the necessity of the defendants’ antibody screening procedures.

While referencing those standards, the district court also observed that tests allegedly not in “compl[iance] with a particular standard of care do[] not amount to” actionable fraud under the FCA.

In *United States v. My Left Foot Children’s Therapy, LLC*, the relator’s complaint alleged that the defendants, a children’s rehabilitation facility and its operators, had policies to recommend the highest frequency of and longest therapy visits.¹²⁹ Those policies were alleged to have resulted in the performance of medically unnecessary therapy. Based on those allegations, the district court denied a motion to dismiss because the district court “could reasonably infer that the [defendants] required therapists to provide information in their progress notes that ensured a higher number of sessions would be authorized by Medicaid ... regardless of the medical needs of the child.” In doing so, the district court explained that “[r]egardless of whether in particular instances [the] policies and directives matched a qualified therapist’s recommendation regarding a particular patient, the policies themselves directed all therapists to recommend services at higher levels or to continue services.”

A number of criminal cases considered opinions from civil FCA cases in evaluating the question of falsity in connection with the sufficiency of the evidence offered by the government in support of conviction. In *United States v. Paulus*, the district court held that the judgment associated with whether to insert cardiac stents was a subjective opinion and not subject to proof or disproof, and therefore, vacated the jury’s verdict against the defendant cardiologist, who allegedly had performed medically unnecessary cardiac stenting procedures.¹³⁰ The medical judgment at issue was the degree of stenosis (i.e., the narrowing of arteries) requiring performance of cardiac procedures. The district court granted the defendant’s motion for judgment of acquittal following a jury’s guilty verdict in reliance on admissions by the government’s medical experts that estimating the degree of stenosis was an “imprecise exercise.” Because the degree of stenosis was not an objective fact, the district court acquitted the cardiologist of healthcare fraud.

In reaching this decision, the district court cited a number of FCA opinions considering the question of falsity, including *Polukoff*. The district court rejected the government’s arguments, explaining that “[n]ot surprisingly, the Government contests the value of these False Claims Act cases, claiming that they are ‘wrongly decided’” and currently on appeal However, the Government’s attempt to distinguish these cases fails. The evidence presented at trial failed to show that the degree of stenosis is an objective fact, subject to proof or disproof. And while these False Claims Act cases involve civil liability, the concepts are equally applicable to criminal statutes that require a false statement.”

In contrast, in *United States v. Bertram*, the district court limited the circumstances under which a medical judgment could be considered a “subjective opinion” not susceptible to proof of objective falsehood.¹³¹ In that case, the government charged the defendants with healthcare

125. 862 F.3d 890 (9th Cir. 2017).

126. 2017 WL 6327540 (D.D.C. Dec. 11, 2017).

127. 2017 WL 237615 (D. Utah Jan. 19, 2017).

128. 2017 WL 4323142 (C.D. Cal. June 27, 2017).

129. 2017 WL 1902159 (D. Nev. May 9, 2017).

130. 2017 WL 908409 (E.D. Ky. Mar. 7, 2017).

131. 2017 WL 4355679 (E.D. Ky. Sept. 29, 2017).

fraud based on their submission of claims for payment for medical tests performed on very aged urine samples. Distinguishing *Paulus*, the district court opined that, while in some cases a medical necessity determination may be too subjective to serve as the basis for a criminal conviction, not every instance of medical necessity judgment is too subjective. As a result, the district court held that the time at which the urine samples became too old for medical testing could be subject to a medical necessity determination supporting a criminal conviction.

Developments Regarding Knowledge/Scienter

Courts continued to consider the FCA's scienter element, issuing a number of significant decisions with respect to this issue. To establish an FCA violation, it must be shown that the defendant had actual knowledge or that the defendant acted with deliberate ignorance or reckless disregard for the falsity of the claims.

Pleading and Proving Knowledge

In *U.S. ex rel. Hall v. LearnKey, Inc.*, the relator alleged that the defendant submitted false invoices to the Department of Veterans Affairs for non-qualifying online courses under the Vocational Rehabilitation and Employment program.¹³² In granting the defendant's motion for partial summary judgment, the Ninth Circuit remarked that the relator's "naked assertions, devoid of any evidence of scienter, cannot survive summary judgment."

Conversely, in *U.S. ex rel. Campie v. Gilead Sciences, Inc.*, the Ninth Circuit held that the relators adequately pleaded that the defendant acted with the requisite intent in a case against a drug manufacturer arising out of alleged regulatory violations during the FDA approval process.¹³³ The Ninth Circuit characterized the defendant's statements to the government as "intentional, palpable lies made with knowledge of the falsity and with intent to deceive" where the defendant manufacturer altered research test results, changed batch and inventory numbers, and misrepresented the facilities where the active drug ingredient came from.

In *U.S. ex rel. Scutellaro v. Capitol Supply, Inc.*, the district court denied the relator's and the government's motions for summary judgment in a case arising out of the sale of allegedly noncompliant office products to government agencies.¹³⁴ Under such sale contracts, products must be manufactured in designated countries. The district court determined that the issue of intent was a question to be decided by the jury to evaluate whether an inference of knowledge should be drawn from the fact that the defendant received mixed signals about compliance with contractual provisions from different government personnel and the fact that it relied on its vendors to supply accurate country of origin information.

Corporate Knowledge

A number of decisions considered the appropriate standard for determining whether a corporation, as a legal entity, possessed the requisite intent for the imposition of FCA liability. No clear consensus emerged on this issue.

The relator's claims in *U.S. ex rel. Worthy v. Eastern Maine Healthcare Systems* arose out of numerous allegedly unlawful Medicare billing practices.¹³⁵ The hospital and revenue management defendants argued that they lacked the requisite knowledge to be held liable under the FCA for any unlawful billing, because the billing defendant acted without their knowledge. The relator argued that the hospital and revenue management defendants were vicariously liable for the billing defendant's actions under principles of agency law. The district court held that the relator's allegations were sufficient to show that the hospital and revenue management defendants acted with reckless disregard for the falsity of potential violations. Even though the defendants may not have had actual knowledge, the relator's allegations that she repeatedly reported the problems to staff members and that they did nothing in response was enough to state a plausible claim that the hospital and revenue management defendants acted knowingly under the FCA.

In *U.S. v. Scan Health Plan*, the government intervened following the filing of the relator's Fourth Amended Complaint on remand from the Ninth Circuit.¹³⁶ The government alleged that the defendants were aware of the limited medical record reviews that had been undertaken in connection with the plans risk adjustment, but took no steps to validate reported diagnosis codes, and thus their own risk adjustment certifications were false. In dismissing the government's complaint, the district court explained that "[f]or scienter to be attributable to a corporation, Plaintiffs must sufficiently plead that at least one of the corporation's officers had the requisite scienter at the time they made the allegedly misleading statements." The district court noted that a complaint cannot rely on the idea of a corporation having collective scienter independent of an individual's scienter, and that the government failed to identify any corporate officer who signed the attestations or to allege that those individuals knew or should have known of the falsity of the attestations.

In *Graves v. Plaza Medical Centers, Corp.*, the district court articulated the Eleventh Circuit standard for imputing the knowledge of an employee to a corporation.¹³⁷ In FCA cases, the district court explained that "the knowledge of an employee is imputed to the corporation when the employee acts for the benefit of the corporation and within the scope of his employment." The district court then left the questions of whether the defendant physician and medical center recklessly disregarded the falsity of diagnosis codes up to the jury, denying summary judgment on the question of intent.

The Fifth Circuit applied a different standard for imputing an employee's knowledge under the AKS in *U.S. ex rel. Vavra v. Kellogg Brown & Root, Inc.*¹³⁸ The allegations at issue related to alleged kickbacks by two Kellogg Brown & Root employees who oversaw subcontracting on certain United States Army contracts. The Fifth Circuit rejected both an apparent authority test and the Limited Liability Act eight-factor balancing test for determining whether an employee's knowledge should be imputed to the corporation. Instead, the Fifth Circuit stated that a corporation can be held liable "only for the knowing violations of those employees whose

132. 2017 WL 1592472 (D. Utah Apr. 28, 2017).

133. 862 F.3d 890 (9th Cir. 2017).

134. 2017 WL 1422364 (D.D.C. Apr. 19, 2017).

135. 2017 WL 211609 (D. Maine Jan. 18, 2017).

136. 2017 WL 4564722 (C.D. Cal. Oct. 5, 2017). Other aspects of this case were discussed above and in Bass Berry & Sims' Healthcare Fraud & Abuse Review for 2016.

137. 2017 WL 1115904 (S.D. Fla. Feb. 27, 2017).

138. 848 F.3d 366 (5th Cir. 2017).

authority, responsibility, or managerial role within the corporation is such that their knowledge is imputable to the corporation.” Using this standard, the Fifth Circuit upheld the district court’s finding that the knowledge of an employee who oversaw the day-to-day performance of the subcontract was imputable to the corporation, even though the employee was not particularly high on the corporate ladder. By contrast, the Fifth Circuit reversed the district court’s conclusion that the knowledge of an employee who was involved in initially awarding the subcontract, but had no further involvement, could be imputed to the corporation.

Ambiguity and Interpretations of Laws, Regulations and Guidance

Courts have continued to consider the significance of a defendant’s interpretations of relevant statutes, regulations, and guidance, as such relate to pleading and proving the requisite level of intent.

In one of the most significant cases considering regulatory ambiguity relative to the FCA’s intent requirement, the Eleventh Circuit held that the relator failed to plead facts that would show that the defendant’s interpretation of the regulation at issue was unreasonable in *U.S. ex rel. Phalp v. Lincare Holdings, Inc.*¹³⁹ There, the Eleventh Circuit rejected the district court’s conclusion that identification of a reasonable interpretation of an ambiguous regulation precludes a finding of scienter. Rather, the Eleventh Circuit explained that the appropriate standard is whether the defendant knew or should have known that its conduct violated a regulation in light of the ambiguity at the time of the alleged violation. The Eleventh Circuit expressed concern that the district court’s formulation would allow defendants to evade liability by relying on a reasonable interpretation manufactured *post hoc*. Even under the more stringent standard it had announced, the Eleventh Circuit affirmed summary judgment for the defendant, because the relator presented nothing more than two unpersuasive emails to prove scienter.

The district court in *U.S. ex rel. Bahnsen v. Boston Scientific Neuromodulation Corp.* cited *Phalp* before denying the defendant’s motion for summary judgment.¹⁴⁰ The district court explained that, although the chapter of the Medicare Program Integrity Manual at issue in the case was arguably ambiguous, the defendant did not point to any evidence supporting its contention that it acted pursuant to a reasonable interpretation of the chapter at the time it actually submitted the claims. The plaintiffs, however, did point to sufficient evidence to create a genuine issue of material fact as to whether the defendant believed it was subject to the requirements of the chapter at the time it submitted the claims.

In an extensive discussion of this issue, the district court in *U.S. v. Quicken Loans Inc.* addressed at least five patterns that gave rise to alleged false claims related to FHA insurance eligibility on home mortgage loans.¹⁴¹ Throughout its opinion, the district court made several observations about the impact of ambiguity, or lack thereof, in the applicable law. One alleged scheme related to the defendant’s internal value appeals process by which employees could request inflated appraisal values in order to make a loan eligible for FHA insurance. Quicken Loans argued that value appeals were not unambiguously prohibited by U.S. Department of Housing and

Urban Development (HUD) at the time, and its interpretation of the regulations as allowing this process was not objectively unreasonable. The government, however, presented FHA guidance letters as well as internal emails that demonstrated that Quicken Loans knew its value appeals process violated FHA requirements, and the district court found that this evidence allowed for a reasonable inference of knowledge. Another alleged scheme related to Quicken Loans’ allegedly ignored “red flags” in loan applications after the application was accepted by the approval software program. Quicken Loans argued that the FHA rules did not unambiguously require a lender to analyze red flags when a loan was approved by the software, and thus the government failed to allege scienter. The government argued, and the district court accepted, that lenders are mandated to exercise “due diligence” as well as follow specific requirements related to some red flags. As a result, the district court held that the government sufficiently stated a claim with respect to this scheme as well.

Knowledge Meets Materiality

While post-*Escobar* materiality decisions are discussed in depth earlier in this publication, it is worth noting that several cases have considered the relationship between knowledge and materiality following *Escobar*.

In *U.S. ex rel. Ruckh v. Salus Rehabilitation LLC*, the district court spoke unequivocally on this issue in an opinion that vacated a nearly \$350 million judgment against a long-term care provider on the grounds of both materiality and scienter. Relying heavily on *Escobar*, the district court explained that “with no evidence that the government regarded the disputed practices as material, establishing the defendants’ knowledge of materiality seems at least impractical, if not impossible...”¹⁴² It relied on this reasoning in overturning the jury verdict, stating that “the False Claims Act requires the relator to prove both that the non-compliance was material to the government’s payment decision *and* that the defendant knew at the moment the defendant sought payment that the non-compliance was material to the government’s payment decision.”

In *U.S. ex rel. Wood v. Allergan, Inc.* the district court quoted *Escobar* in stating “[w]hat matters is ... whether the defendant *knowingly* violated a requirement that the defendant *knows* is material to the Government’s payment decision.”¹⁴³ The claims in this case were premised on alleged AKS violations involving the defendant drug manufacturer providing free drugs to physicians in exchange for prescribing the company’s brand name drugs to government healthcare program beneficiaries. The district court held that “to the extent *Escobar* requires knowledge that a violation of the AKS is material to the Government’s payment decisions,” the relator adequately pleaded as much.

Similarly, in *U.S. v. DynCorp International, Inc.*, the district court articulated a two-prong test for establishing knowledge on the basis of implied certification.¹⁴⁴ Under this test, the plaintiff must prove that the defendant knew: (1) that it violated a contractual obligation; and (2) that compliance with that obligation was material to the government’s payment decision. The allegations in this case centered on a government contractor charging unreasonable rates

139. 857 F.3d 1148 (11th Cir. 2017).

140. 2017 WL 6403864 (D.N.J. Dec. 15, 2017).

141. 239 F. Supp. 3d 1014 (E.D. Mich. 2017).

142. 2018 WL 375720, at *2 (M.D. Fla. 2018).

143. 246 F. Supp. 3d 772, 828 (S.D.N.Y. 2017) (quoting *Escobar*, 136 S. Ct. at 1996 (emphasis supplied)).

144. 253 F. Supp. 3d 89 (D.D.C. 2017).

for accommodations and labor. The district court held that the complaint adequately pleaded scienter by alleging comments from high-level employees about the rates being higher than reasonable (satisfying prong 1) and regulatory provisions, as well as common sense, that indicate the government would refuse to pay unreasonable charges (satisfying prong 2).

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 provider or supplier: (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 any overpayment for more than 60 days after it has been identified.

As we noted in last year’s Healthcare Fraud & Abuse Review, in February 2016, CMS published a final rule clarifying that an overpayment is “identified” when “the person has or should have, through the exercise of reasonable diligence, determined that the person has received an overpayment and quantified the amount of the overpayment” with a reasonable degree of certainty. CMS further explained in the final rule that “reasonable diligence” requires “proactive compliance activities” and investigations to uncover potential overpayments.

While courts have not had much of an opportunity to address CMS’s final rule, there were still noteworthy developments and continued trends in FCA cases involving reverse false claim theories.

Contingent Payment Obligations

Courts consistently have emphasized that “obligation[s]” *contingent* on future acts or events do not support liability under the FCA’s reverse false claims provision. In particular, courts have rejected several claims based on purported violations of CIAs where any potential penalties for such violations had not yet come to fruition.

In *U.S. ex rel. Booker v. Pfizer Inc.*, for example, the First Circuit affirmed the dismissal of relators’ reverse FCA claim based on relators’ failure to allege that Pfizer determined a particular complaint was a “reportable event” under its CIA—the trigger for any potential payment obligation. The district court had dismissed the claim on slightly different grounds—that relators had failed to identify any “obligation” due to the discretionary nature of any penalty to be imposed by HHS-OIG—but both courts’ reasoning focused on the lack of any *present* duty to make a payment to the government.¹⁴⁵ Similarly, in *U.S. ex rel. Keen v. Teva Pharmaceuticals USA Inc.*, the district court dismissed a reverse FCA claim predicated on a purported violation

of a CIA that, in the district court’s description, was “intentionally structured ... to give OIG an opportunity” to determine whether monetary penalties were appropriate. In light of that discretion—which OIG had not yet exercised—the district court determined that “Teva had no ‘obligation’ to pay stipulated penalties,” even if it had violated its CIA.¹⁴⁶

Consistent with the First Circuit’s decision in *Pfizer*, several other appellate courts addressing reverse FCA claims have confirmed that contingent obligations do not suffice in other contexts either. In *U.S. ex rel. Petras v. Simparel, Inc.*, the Third Circuit held that the defendants had not violated the reverse false claims provision by allegedly concealing a company’s deteriorating financial condition in order to avoid paying a dividend to the Small Business Administration (SBA), which was acting as the company’s receiver. The Third Circuit explained that because any duty to pay a dividend was contingent on the occurrence of events yet to occur—such as dissolution or wind-up—there was no present payment “obligation” within the meaning of the FCA.¹⁴⁷

Addressing the post-Fraud Enforcement and Recovery Act (FERA) definition of “obligation” for the first time in *U.S. ex rel. Barrick v. Parker-Migliorini Int’l, LLC*, the Tenth Circuit explained that the new definition did nothing to change its prior view that contingent obligations are not within the scope of the reverse false claims provision. In dismissing relator’s claim alleging that defendants avoided paying inspection fees to the U.S. Department of Agriculture by providing sham destinations for their meat exports, the Tenth Circuit held that any payment obligations were merely “potential and contingent” because they depended on “multiple assumptions” and “future discretionary acts.”¹⁴⁸

Finally, in *U.S. ex rel. Schneider v. JPMorgan Chase Bank*, the D.C. Circuit cited *Simparel* while noting (albeit in dicta) that defendant’s alleged noncompliance with mortgage servicing standards in a settlement agreement did not make out a viable reverse FCA claim. In the D.C. Circuit’s view, this was because any possible payment obligation arising from the noncompliance was, in fact, “nothing more than a contingent possibility,” considering the “series of steps” (e.g., citation, failure to cure, failure of informal dispute resolution) required before any actual penalty could be assessed.¹⁴⁹ As with the Tenth Circuit in *Barrick*, this case marked the first time the D.C. Circuit has addressed the post-FERA definition of “obligation.”

That said, several district courts have clarified that payment obligations are *not* contingent—and thus *may* support liability under the reverse false claims provision—when the violation of a statute or regulation triggers an immediate, *automatic* duty to pay penalties, which are not subject to any intervening exercise of government discretion. As one district court has explained, the key distinction in such cases is between statutes or regulations that “impose only a duty to obey the law,” on the one hand, and those that impose an affirmative “duty to pay regulatory penalties,” on the other.¹⁵⁰

145. 847 F.3d 52, 55-56 (1st Cir. 2017).

146. 2017 WL 36447, at *5-6 (N.D. Ill. Jan. 4, 2017).

147. 857 F.3d 497, 506-07 (3rd Cir. 2017). Notably, the court further held that any such obligation would not involve the “government,” in any event, because the SBA does not function in a governmental capacity when serving as a receiver. *Id.* at 503-04.

148. 2017 WL 6614466, at *7 (10th Cir. 2017).

149. 2017 WL 6543859, at *4 (D.C. Cir. 2017).

150. *U.S. ex rel. Kasowitz Benson Torres LLP v. BASF Corp.*, WL 4803906, at *7 (D.D.C. Oct. 23, 2017) (dismissing reverse FCA claim premised on alleged failure to make a report and pay penalties to the Environmental Protection Agency (EPA) under the Toxic Substances Control Act (TSCA) because the TSCA imposes only a duty to obey the law, not to pay penalties); see also *United States v. Newman*, WL 3575848, at *10 (D.D.C. Aug. 17, 2017) (declining to dismiss reverse FCA claim alleging that the defendants fraudulently avoided repaying a credit to the Federal Communications Commission (FCC) because “the obligation created by the [relevant] regulations [did] not appear to [be] contingent on any act being taken by the government” but rather “simply required Defendants to return the credit under certain circumstances”).

Retention of Overpayments

As in past years, courts considered a number of instances where relators asserted reverse false claims theories based on the retention of purported overpayments, a particularly significant issue for healthcare providers in light of CMS's final rule.

Several of the overpayment cases focused on the effect of recent statutory amendments. For example, in **Taul v. Nagel Enterprises, Inc.**, the district court clarified that Medicare and Medicaid retention-of-overpayment claims should be brought under § 3729(a)(1)(G) of the FCA (the reverse false claims provision), rather than under § 3729(a)(1)(A-C), because PPACA designates overpayments retained for more than 60 days as “obligations”—a term that appears in § 3729(a)(1)(G), but not in the other FCA provisions.¹⁵¹ In **U.S. ex rel. Duffy v. Lawrence Memorial Hospital**, the district court denied defendant's motion for summary judgment while noting that FERA “either change[d] or clarifie[d] the statute to make the knowing retention of an overpayment sufficient to establish an obligation to pay money to the Government.” In the district court's view, “[t]his statutory language appear[ed] consistent with” relator's theory that defendant was “ineligible for any pay-for-reporting payments during years when it falsely certified the accuracy and completeness” of the quality data it submitted to CMS.¹⁵² Finally, two other cases addressed application of the pre- and post-FERA definitions of “obligation,” with the courts agreeing that the standard to be applied depends on *when*, precisely, the defendant's repayment obligation took effect (that is, before or after FERA's enactment).¹⁵³

One other notable overpayment decision was reached in **U.S. ex rel. Wagner v. Care Plus Home Health Care, Inc.** There, relator asserted a reverse FCA claim violation under two distinct theories: (1) defendant's retention of patients allegedly ineligible for home health services; and (2) defendant purportedly making false statements and records in response to additional documentation requests (ADRs) from Medicare. The district court dismissed all FCA claims under the first theory because the relator's pleaded exemplars “belie any indicia of falsity,” as in multiple instances “a physician [had] provided an order for home health service” and in many examples relator “assert[ed] only that the patients left their home to receive medical treatment,” which did not disqualify these patients from needing home health services. As to the relator's second theory, the district court denied defendant's motion to dismiss, finding that the relator pleaded enough specifics regarding the alleged false statements and records made in response to ADRs (e.g., altering records to reflect that home visits had been completed when they had not) to satisfy Rule 9(b).¹⁵⁴

Relationship to Traditional FCA Violations

In a final noteworthy development, district courts agreed in several cases that failing to repay funds obtained through alleged traditional FCA violations cannot—without more—establish a claim under the reverse false claims provision.

In **United States v. Mount Sinai Hospital** and, later, in **U.S. ex rel. Hussain v CDM Smith, Inc.**, district courts held that the receipt of money from traditional false claims does not itself amount to the kind of “obligation” that will separately support liability under the reverse false claims provision. In **Mount Sinai**, the district court noted that to allow such a claim would effectively result in reverse false claims liability *anytime* there is liability under a traditional false claims theory, a notion it flatly rejected.¹⁵⁵ In **CDM Smith**, the district court also rejected the argument that certain legislative history calling for broad construction of the reverse false claims provision should be interpreted to allow such a result.¹⁵⁶

The district court reached the same conclusion in **U.S. ex rel. Scott v. Pacific Architects and Engineers, Inc.**, echoing the admonition that the relator's theory would effectively turn every FCA case into a reverse false claims case.¹⁵⁷ And, in **U.S. ex rel. Groat v. Boston Heart Diagnostics Corp.**, the district court dismissed a reverse FCA claim because the complaint did not allege any payment obligation independent of the conduct giving rise to plaintiff's claims under the other provisions of the FCA.¹⁵⁸

THE FCA'S 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. Cases analyzing the public disclosure bar last year continued to focus primarily on what disclosures are sufficient to trigger the bar and how a relator can qualify for the “original source” exception to the public disclosure bar if the bar is triggered. In addition, courts continued to grapple with what version of the FCA to apply, particularly where the fraudulent conduct is alleged to have occurred both before and after PPACA affected amendments to the FCA in 2010.

151. 2017 WL 432460, at *10-11 (N.D. Ala. Feb. 1, 2017).

152. 2017 WL 2905406, at *10 (D. Kan. July 7, 2017) (denying summary judgment on reverse FCA claim that defendant submitted false data to CMS—specifically, reporting chest pain patients' arrival time in the emergency room—which “affected various measures of inpatient and outpatient care used to calculate incentive payments” from CMS).

153. See *Graves v. Plaza Med. Ctrs.*, 2017 WL 1102908 (S.D. Fla. Mar. 20, 2017) (noting that “liability is triggered at ‘the moment a person comes to know of overpayments it is retaining,’” and thus explaining that reverse false claims liability should be analyzed under the *post*-FERA standard if payments were knowingly retained after that statute was enacted, even if the initial payments were made before); *U.S. ex rel. Salters v. Am. Family Care, Inc.*, 2017 WL 1384381 (N.D. Ala. Apr. 18, 2017) (applying the *pre*-FERA standard to relator's claim concerning alleged Medicare overpayments because all of the relevant conduct, including identification and retention of the alleged overpayments, occurred prior to FERA's enactment). Notably, the district court in *Graves* also rejected defendant's argument that 42 C.F.R. § 422.326 makes only Medicare Advantage Organizations (MAOs), and not providers, potentially liable for reverse false claims.

154. 2017 WL 6329850, at *9-10 (N.D. Okla. Dec. 11, 2017); see also *U.S. ex rel. Gacek v. Premier Medical Mgmt., Inc.*, 2017 WL 2838179 (S.D. June 30, 2017) (denying motion to dismiss reverse false claims action based on defendant having failed to repay funds allegedly obtained in violation of the AKS after relator notified defendant of the scheme by reporting it to his supervising doctor).

155. 256 F. Supp. 3d 443 (S.D.N.Y. May 16, 2017).

156. 2017 WL 4326523 (S.D.N.Y. Sep. 27, 2017).

157. 2017 WL 4075155 (D.D.C. Sep. 13, 2017).

158. 255 F. Supp. 3d 13 (D.D.C. 2017); see also *U.S. ex rel. Stepe v. RS Compounding*, 2017 WL 5178183 (M.D. Fla. Nov. 8, 2017) (dismissing relator's reverse FCA claim in part because she had failed to allege an “obligation” separate from the defendants' failure to return funds they had received through alleged traditional FCA violations).

Whether the Public Disclosure Bar Remains Jurisdictional

Continuing a unanimous trend among federal appellate courts from prior years, the Second Circuit held that the public disclosure bar is no longer jurisdictional after the 2010 PPACA amendments. In *U.S. ex rel. Chorches for Bankr. Estate of Fabula v. Am. Med. Response, Inc.*, the Second Circuit cited Supreme Court precedent for the principle that “[c]ourts must ‘inquire whether Congress has clearly stated that the rule is jurisdictional; absent such a clear statement, [the Supreme Court has] cautioned, courts should treat the restriction as nonjurisdictional in character.’”¹⁵⁹ The Second Circuit reasoned that PPACA’s 2010 amendment to the public disclosure bar deleting the jurisdictional language provided “especially strong” evidence that the public disclosure bar is no longer jurisdictional. The Second Circuit also noted that “‘the FCA clearly states that *other* limitations on *qui tam* actions are jurisdictional, but does not clearly state’ that the public disclosure bar is jurisdictional,” and that the majority of other circuits that have addressed the jurisdictional question have reached the same conclusion.¹⁶⁰

NOTEWORTHY DEVELOPMENT:

District courts agreed in several cases that failing to repay funds obtained through alleged traditional FCA violations cannot—without more—establish a claim under the reverse false claims provision.

Which Version of the FCA Applies?

Where the fraudulent conduct at issue is alleged to have occurred both before and after PPACA’s enactment in 2010, most courts continued to apply the pre-PPACA version of the statute to conduct pre-dating PPACA and the post-PPACA version of the statute to conduct post-dating PPACA.¹⁶¹ In *U.S. ex rel. Denis v. Medco Health Solutions, Inc.*, the district court issued two different opinions in 2017, both of which discussed the applicability of the 2010 PPACA amendments. In its January 5, 2017 opinion

dismissing the relator’s third amended complaint, the district court applied the pre-PPACA version of the FCA’s public disclosure bar to all of the relator’s allegations despite the relator’s argument that both versions should apply because he alleged conduct “over ten years” and that there was “no proof that it has stopped.”¹⁶² The district court reasoned that “all non-conclusory allegations of fraudulent conduct occurred between 2005 and 2007” and that it was not reasonable to infer “that what occurred in 2007 continues indefinitely, until proven otherwise”

based only on conclusory allegations that the conduct “continue[s] to violate” the FCA. In its October 26, 2017 opinion dismissing the relator’s fourth amended complaint, the district court applied the two different, respective versions of the statute to pre-2010 conduct and post-2010 conduct even though it expressly acknowledged that “[f]rom this court’s perspective, the better approach would be to apply the pre-2010 public disclosure bar to the entire continuing fraud claim, because that was the statute in effect at the time the claim accrued, and the statute is not retroactive.”¹⁶³

In *Bellevue v. Universal Health Services of Hartgrove, Inc.*, however, the Seventh Circuit reaffirmed its outlier position that although PPACA’s amendment to what constitutes a public disclosure is not retroactive, the amendment to the definition of original source is retroactive. The Seventh Circuit explained that the change to the definition of public disclosure is not retroactive because it is a substantive change; in contrast, the change to the “original source” definition “is a clarification rather than a substantive change, and therefore is retroactive.”¹⁶⁴

In *U.S. ex rel. Conroy v. Select Med. Corp.*, the district court addressed an interesting constitutional argument raised in light of the new language of the post-PPACA public disclosure bar, which states that a court “shall dismiss an action or claim under this section, unless opposed by the Government, if substantially the same allegations or transactions as alleged” were previously publicly disclosed. The defendants argued that the Executive Branch’s power to oppose dismissal of an FCA claim violates constitutional separation-of-powers principles. The district court rejected that argument, reasoning that it “presupposes the government could override an involuntary dismissal” of an FCA claim, but “courts do not construe Section 3730(b)(1) in this manner; instead, they have consistently understood this provision to require the government’s consent only where the relator seeks a *voluntary* dismissal from the court.”¹⁶⁵ Because the government’s right to object did not equate to a government “veto” of a court’s decision, the district court held that the post-PPACA language does not offend the separation of powers.

When Are Disclosures Sufficient to Bar FCA Allegations?

In determining whether a *qui tam* complaint is “based upon” or “substantially similar to” previous public disclosures, many courts generally view the “substantially similar” test to be a “quick trigger,” moving to the original source analysis if any part of the complaint was based upon public disclosures.¹⁶⁶ Nevertheless, courts have continued to adopt varying approaches to determine whether the scope and specificity of public disclosures are sufficient to bar an FCA

159. 865 F.3d 71, 79 (2d Cir. 2017) (quoting *Sebelius v. Auburn Reg’l Med. Ctr.*, 568 U.S. 145, 153 (2013)).

160. See *id.* at 80 (quoting *U.S. ex rel. Hayes v. Allstate Ins. Co.*, 853 F.3d 80, 86 (2d Cir. 2017)).

161. See, e.g., *Green v. AmerisourceBergen Corp.*, 2017 WL 1209909 (S.D. Tex. Mar. 31, 2017); *U.S. ex rel. Conroy v. Select Med. Corp.*, 2017 WL 468276 (S.D. Ind. Feb. 3, 2017) (reaffirming both the court’s previous dismissal of the relator’s claims arising from conduct occurring before March 23, 2010, for lack of subject matter jurisdiction under the public disclosure bar and the court’s previous holding that claims arising from conduct occurring after March 23, 2010, were not subject to dismissal on jurisdictional grounds).

162. 2017 WL 63006, at *5 (D. Del. Jan. 5, 2017).

163. 2017 WL 4838410, at *4 (D. Del. Oct. 26, 2017).

164. 867 F.3d 712, 718 (7th Cir. Aug. 8, 2017); but see *Prather v. AT&T, Inc.*, 847 F.3d 1097, 1103 (9th Cir. 2017) (“The Supreme Court has determined that the amendments to 31 U.S.C. § 3730(e)(4) are not retroactive.”) (citing *Graham Cty. Soil & Water Conservation Dist. v. U.S. ex rel. Wilson*, 559 U.S. 280, 283 n.1 (2010)).

165. 2017 WL 468276, at *4 (S.D. Ind. Feb. 3, 2017).

166. See *U.S. ex rel. Brown v. BankUnited Trust 2005-1*, 235 F.Supp.3d 1343, 1357-58 (S.D. Fla. 2017) (finding that the complaint was “partially based” upon public disclosures where it had significant numbers of public documents listed as exhibits and lifted nearly 200 paragraphs from a complaint filed in a different jurisdiction); *AmerisourceBergen Corp.*, 2017 WL 1209909, at 8-9 (finding that allegations even “partly based” on public allegations are nonetheless “based upon” such allegations and that allegations are “substantially similar” where they “provide materials elements of the Relator’s claims”).

lawsuit. Specifically, last year saw continued development among courts with respect to what information should be considered “public,” whether previous resolution of substantially similar allegations bars a subsequent suit alleging continued or restarted fraudulent action, and how courts treat similar actions with new defendants.

The Fifth Circuit became the latest appellate court to adopt the “transaction test” for determining whether allegations in an FCA suit are “substantially similar” to public disclosures. That widely-used test uses algebraic terms—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 $X + Y = Z$. A relator’s allegations are “substantially similar” to publicly available information only where, if the allegation of fraud itself (Z) is not in the public domain, both elements X and Y are publicly known.

In *U.S. ex rel. Colquitt v. Abbott Labs*, the relator argued that the defendants had misrepresented the true purpose of certain biliary stents when it applied for approval from the FDA, falsely inducing Medicare to pay for the devices that actually were used for vascular procedures and too small to be used as biliary stents.¹⁶⁷ The Fifth Circuit held that both the misrepresented state of facts (the application for a new biliary device) and the true state of facts (that the stents were incorrectly sized for that purpose) were in the public domain. The Fifth Circuit found that the relator “hoisted himself with his own petard” when he relied on the dimensions of the stents disclosed in the FDA applications and notifications to expose the fraud.

The D.C. Circuit rejected application of the public disclosure bar in *U.S. ex rel. Shea v. Cellco Partnership* using the same test.¹⁶⁸ In *Shea*, the relator alleged that Verizon was improperly charging the government for certain taxes and surcharges on a number of government contracts. The D.C. Circuit found that while the misrepresented state of the facts was publicly disclosed, the true state of the facts—that Verizon was overcharging on its contracts—came from non-public information. The D.C. Circuit held that public disclosures are insufficient to trigger the bar unless they supply the “missing link” in the fraud at hand.

Circuits remain split regarding whether resolution of previous claims bars allegations of subsequent fraud. In *U.S. ex rel. Ibanez v. Bristol-Myers Squibb Co.*, the Sixth Circuit noted that allegations that a pharmaceutical company engaged in a complex, nationwide scheme to improperly promote an antipsychotic drug were previously resolved in an FCA action and CIA with the government.¹⁶⁹ The Sixth Circuit held that allegations that the fraudulent activity continued despite the CIA or restarted after it was executed may not be barred. The district court in *Medco* came to the opposite conclusion.¹⁷⁰ There, the district court barred a claim

because the complaint was based in part on “precisely the same” conduct that led to a CIA with the defendant, even if the relator was not specifically alleging a violation of the CIA. The district court noted that courts are split on this issue and that the Third Circuit has not yet addressed it.¹⁷¹

After the Supreme Court declined to grant certiorari in 2016 in *Cause of Action v. Chicago Transit Authority* to address the issue, appellate courts remained split regarding the circumstances under which certain information is “public” under the public disclosure bar.¹⁷² The Seventh Circuit remains alone in holding that information that is available to government agencies is sufficient in and of itself to trigger the public disclosure bar, a position it reaffirmed in *Bellevue*.¹⁷³ The relator in *Bellevue* alleged that a children’s psychiatric hospital routinely exceeded its 150-bed capacity in violation of federal and state requirements. The defendant hospital argued that both the Illinois Department of Public Health and CMS issued audit letters years before the filing of the FCA lawsuit regarding the precise issue raised, thereby triggering the bar. The Seventh Circuit agreed, finding that the public disclosure bar applies where information available to the government put it in a position to draw the same inferences upon which the relator relied in filing the complaint.¹⁷⁴

Appellate courts also took varying approaches in determining whether public disclosures are “substantially similar” to a relator’s allegations of fraud. Though all circuits essentially rely on whether the disclosures put the government “on notice” of the alleged fraud, the Seventh and Ninth Circuits analyze whether the relator’s complaint adds “genuinely new and material” information to publicly disclosed allegations. The district court in *Lisitza* examined this facet of the “substantially similar” test.¹⁷⁵ There, the relator alleged that a drug manufacturer fraudulently orchestrated a prescription-switching scheme by producing generic drugs in non-standard forms and dosages. The relator previously had filed three *qui tam* actions with identical allegations against pharmacies. The district court held that when the relator merely identifies “another fraudster in the same scheme,” he cannot be said to have brought something “genuinely new and material.”

Other courts have continued to wrestle with how to treat public allegations against new defendants. In *U.S. ex rel. Lager v. CSL Behring*, the Eighth Circuit examined whether prior litigation and government reports may be sufficient to trigger the public disclosure bar, even where the defendant is not named specifically. In that suit, the relator alleged that the defendants conspired with specialty pharmacies to submit false claims by manipulating the average wholesale price (AWP) of drugs to fraudulently increase the cost to the government.¹⁷⁶ The Eighth Circuit noted that public disclosures widely publicized the use of such a “spread”

167. 858 F.3d 365 (5th Cir. 2017).

168. 748 F.3d 338 (D.C. Cir. 2017).

169. 874 F.3d 905, 919 (6th Cir. 2017).

170. 2017 WL 63006, at *8.

171. See also *U.S. ex rel. Graziosi v. Accretive Health, Inc., et al.*, 2017 WL 1079190 (N.D. Ill. Mar. 22, 2017) (finding that disclosures sufficient to trigger the bar where they included an OIG Report, subsequent investigation and settlement and complaint added only the name of a contractor used to execute the scheme).

172. 137 S. Ct. 205 (2016).

173. 867 F.3d at 718-19.

174. See also *U.S. ex rel. Lisitza v. Par Pharmaceutical Co, Inc.*, 2017 WL 3531678 (N.D. Ill. Aug.17, 2017) (analyzing the Seventh Circuit view that disclosures may be public if made solely to the government, only if it was made to an official or body with “direct responsibility” for the claim in question); but see *U.S. ex rel. Quartararo v. Catholic Health System of Long Island, Inc.*, 2017 WL 1239589 at *15 (S.D.N.Y. Mar. 31, 2017) (noting no Second Circuit precedent, but that many other circuits hold that information disclosed during the course of a government audit or investigation, remaining with the government, is not publicly disclosed where it was not also disclosed to the public more broadly); *U.S. ex rel. Ortiz v. Mount Sinai Hospital, et al.*, 2017 WL 2558753 (S.D.N.Y. May 16, 2017) (finding disclosures insufficient where they contain “no suggestion of wrongdoing,” and where the disclosure was only to a government agency).

175. 2017 WL 3531678, at *13-14.

176. 855 F.3d 935 (8th Cir. 2017).

by drug manufacturers both in general and specifically with respect to the two drugs at issue. The Eighth Circuit concluded that to be barred, the disclosures must either “explicitly identify” the defendant as a participant in the scheme or provide enough information such that the defendant is “identifiable,” as they were in this case. The Eighth Circuit also stated where the “essential elements” exposing the fraud are sufficient to put the government on the trail, those disclosures will be sufficient, even where separate disclosures must be “read together” to collectively infer fraud. The Eighth Circuit found that “all elements critical to Lager’s complaint theory were already in the public domain before Lager brought suit.”¹⁷⁷

When Is a Relator an Original Source?

Courts applied relatively stringent interpretations of the original source standard under both the pre- and post-PPACA versions of the original source definition. Courts tended to reject most claims of original source status except where the relator was able to show that he or she had firsthand knowledge of the fraudulent conduct as a result of his or her own interactions with the defendant and/or own access to non-public information—the substance of which must be adequately pleaded in the complaint.¹⁷⁸

Courts often held that a relator did not qualify as an original source where the relator’s information about alleged fraud was secondhand in nature. In *U.S. ex rel. Prather v. AT&T, Inc.*, the Ninth Circuit held that the relator—a former prosecutor who alleged that telephone carriers were overbilling the government for the “reasonable costs” of wiretaps—was not an original source because he had no firsthand knowledge of the true costs of the services provided. The Ninth Circuit further held that because his disclosure to the government before filing his lawsuit had been at the request of his employer—even though his job description did not include a duty to report fraud—it was not a voluntary disclosure.¹⁷⁹ Similarly, citing its earlier decision in *U.S. ex rel. Saldivar v. Fresenius Medical Care Holdings, Inc.*,¹⁸⁰ the Eleventh Circuit affirmed the district court’s determination in *Wilhelm v. Molina Healthcare of Florida, Inc.* that the relator was not an original source because he provided only secondhand information that was insufficient to establish original source status.¹⁸¹

Several other courts rejected claims of original source status because the relators offered only secondhand information such that they could not show “direct and independent knowledge” of the alleged fraud under the pre-PPACA definition.¹⁸² In *Lisitza*, the fourth in a line of *qui tam* actions that raised the same allegations of fraud against different defendants, the district court held that the relator’s awareness of the billing scheme from the earlier cases and his knowledge of fraudulent conduct of the other entities did not establish him as an original source with respect to the claims brought against this defendant.¹⁸³ In *United States v. Durrani*, the relator was a patient who alleged fraud based on the use of a certain medical device in his surgery without his informed consent. The district court held that the relator did not have direct knowledge of the use of the device because he had no knowledge that the device had been used until speaking to his counsel after the surgery and, therefore, could not qualify as an original source.¹⁸⁴

Courts also declined to conclude that a relator was an original source where the relator analyzed, applied expertise to, or offered a general understanding of a business practice in combination with publicly available information.¹⁸⁵ In *Colquitt*, where the relator argued that the defendants had misrepresented the true purpose of certain biliary stents when it applied for approval from the FDA, the Fifth Circuit affirmed the district court’s ruling that the relator was not an original source. The relator alleged that the stents were not the proper size for biliary stents and argued that providing such information qualified him as an original source of the allegations. The dimensions of the stents, however, had been included in FDA filings. The Fifth Circuit held that the relator did not qualify as an original source because the publicly available information was the only information required to discover the fraud.¹⁸⁶

In *Denis*, the district court held that the relator failed to qualify as an original source on three separate grounds, including: (1) a relator cannot qualify as an original source where the information that he provides comes from reviewing documents and having discussions with colleagues about the underlying events and, therefore, is not direct knowledge; (2) a relator was “not an original source where he is simply combining ‘direct and independent knowledge of [a company’s] business strategies’ with ‘an experienced-based belief that misconduct was

177. See also *U.S. ex rel. Rahimi v. Zydus Pharmaceuticals (USA), Inc., et al.*, 2017 WL 1503986 (D.N.J. Apr. 26, 2017) (finding that there was no public disclosure where the publicly disclosed information referred only to industry-wide fraud with a large number of players and where the defendants had not yet entered the business at the time of some of the disclosures); *U.S. ex rel. JDJ & Associates LLP v. Natixis, et al.*, 2017 WL 4357797 (S.D.N.Y. Sept. 29, 2017) (holding that removing a publicly known participant in a widely-publicized fraud and simply identifying an additional participant was insufficient to survive the bar under the “substantial similarity” test).
178. See *Rahimi*, 2017 WL 1503986, at *9-10. In *Rahimi*, the relators alleged Zydus fraudulently inflated prices for generic drugs by reporting inflated AWP that would be used to calculate federal reimbursements even though the drugs were sold to retail at lower prices than reported. The relators were pharmacists who owned or ran pharmacies who purchased drugs from Zydus. The district court found they were an original source because they discovered the fraud in the course of personally ordering the drugs, filling prescriptions, observing Medicaid reimbursements, and being able to determine the spread in pricing based on this non-public information.
179. 847 F.3d 1097 (9th Cir. 2017).
180. 841 F. 3d 927 (11th Cir 2016).
181. 674 F. Appx. 960 (11th Cir. Jan. 18, 2017).
182. In *Brown*, the relator had not been employed by any defendant, but rather by a third party mortgage broker and did not allege any specific information about the fraud gained in the course of his employment there. The court determined he did not have direct and independent knowledge sufficient to be considered an original source under the pre-PPACA definition. 235 F.Supp.3d at 1358-61. In *U.S. ex rel. Amico v Deutsche Bank AG*, the district court similarly found that the relator could not have had direct and independent knowledge because he had never worked for Deutsche Bank. The district court also noted that the relator admitted his allegations were based on “knowledge derived from third party sources, including public records” which precluded original source status under the pre-PPACA definition and that this was “not cured by Amico’s purported invention of the method he used to uncover Defendant’s fraud.” 2017 WL 2266988 (S.D.N.Y. May 8, 2017). In *U.S. ex rel. Urquilla-Diaz v. Kaplan University*, the relator testified that his knowledge came from what he heard others say in meetings. Further, the relator did not work in the billing department and had no direct knowledge of the allegedly fraudulent billing process. The court found he did not have direct and independent knowledge and therefore was not an original source. 2017 WL 2992197 (S.D. Fl. July 13, 2017). In *U.S. ex rel. Solomon v. Lockheed Martin Corporation*, the Fifth Circuit held in a procurement fraud case that the relator could not be an original source because he had conceded that he could only suspect the relationship between cost performance and award fees and only actually recognized the connection by reading the publicly available contract.
183. 2017 WL 3531678 (N. D. Ill. Aug. 17, 2017).
184. 2017 WL 2443405 (S.D. Ohio June 6, 2017).
185. See *U.S. ex rel. Payton v. Pediatric Services of America*, 2017 WL 3910434 (N.D. Ga. Sept. 6, 2017) (holding that relator’s allegations of experience in the healthcare industry and general knowledge of billing practices could not overcome the fact that she lacked actual knowledge of the inappropriate billing); *Natixis*, 2017 WL 4357797 (holding that the relator was not an original source under either definition because all of the materials on which it based its allegations were publicly available, even though they were unintelligible in their public form, and rejecting the relator’s argument that the expertise and analytical methodology that relator applied to decipher them qualified the relator as an original source).
186. 858 F.3d at 375-76.

occurring,” because the relator merely described business practices and asked the court to infer misconduct; and (3) allegations based on information and belief were “categorically insufficient for original source status.”¹⁸⁷

In **U.S. ex rel. Coyne v Amgen, Inc.**, the relator was not considered to be an original source under either the pre-PPACA or post-PPACA definition because his claims were based solely on his alternative interpretation of publicly disclosed data and “[d]isagreements over scientific opinion, methodology, and judgments’ are insufficient to state a claim under the FCA.”¹⁸⁸ The district judge adopted the report and recommendation, agreeing that the “plaintiff’s ‘suspicions and scientific agreement as to the proper interpretation of publicly disclosed data...cannot, as a matter of law, have materially added to the government’s knowledge.”¹⁸⁹

The Seventh and Eighth Circuits addressed cases in which only the post-PPACA definition of original source was applied.¹⁹⁰ In **U.S. ex rel. Ambrosecchia v. Paddock Laboratories, LLC**, the Eighth Circuit affirmed the district court’s ruling that the relator did not qualify as an original source because the information offered as her personal knowledge, without any detail provided as to that information, did not materially add to the publicly disclosed information. Further, the Eighth Circuit found that the single piece of additional information provided—a concrete example of a false claim—did not materially add to the information about how the fraud was perpetrated.¹⁹¹

The Sixth Circuit addressed a case under both the pre- and post-PPACA original source definitions in **United States v. Garman** because the relator alleged fraud that occurred both before and after the PPACA enactment date. The relator—a former employee of a long-term acute care facility owned by the defendant—alleged four theories of FCA liability against the defendants. The district court dismissed the complaint based on a then-pending *qui tam* action alleging Medicare reimbursement fraud against the defendant that owned the facility in question. The Sixth Circuit held that the relator was not an original source under the pre-PPACA definition because he did not disclose to the government his knowledge that pre-dated PPACA’s enactment until after the other, pending case addressing the same fraud had been filed. Further, he failed to meet the post-PPACA definition because none of the additional details that he provided were “significant or essential” to the alleged fraud that already was disclosed in the other lawsuit.¹⁹²

FCA’S STATUTE OF LIMITATIONS

There were a number of FCA decisions considering application of the FCA’s statute of limitations. In **Taul v. Nagel Enterprises, Inc.**, the district court applied the U.S. Supreme

Court’s ruling in **Kellogg Brown & Root Services, Inc. v. U.S. ex rel. Carter**, and held that the Wartime Suspension of Limitations Act, 18 U.S.C. § 3287, applies only to criminal cases.¹⁹³ Accordingly, the district court barred the plaintiff’s FCA claims that occurred more than six years before the initial complaint was filed pursuant to the time bar provisions under 31 U.S.C. § 3731(b)(1). Additionally, in **Scan Health Plan**, the district court interpreted the FCA’s statute of repose, barring FCA claims brought “more than 10 years after the date on which the violation [was] committed,” as precluding any of the alleged violations that occurred a decade preceding the filing of the government’s complaint-in-intervention.¹⁹⁴ To support that ruling, the district court relied on congressional testimony emphasizing that the “10-year repose provision was meant as an ultimate cutoff date to protect defendants from litigation of stale issues from the distant past.”

Not all statute of limitation-related rulings benefited defendants. In **U.S. ex rel. Vavra v. Kellogg Brown & Root Services, Inc.**, the Fifth Circuit, in a case of first impression, upheld the district court’s decision that rejected the defendant’s statute of limitations argument in connection with allegations that the defendant had violated the AKS.¹⁹⁵ The relators had filed their *qui tam* complaint in January 2004, but the government did not intervene and file its complaint asserting AKS violations until August 2010, more than six years later. The defendant asserted that § 3731(c) (the subsection of the FCA providing for relation back to the original complaint) only permits relation back for FCA claims, and therefore, the government’s AKS claims should have been time barred. In determining that the government’s AKS claims were timely, the Fifth Circuit broadly construed § 3731(c) and concluded that the government’s AKS claims related back to the allegations contained in the original complaint.

Similarly, in **U.S. ex rel. Gohil v. Aventis, Inc.**, the district court held that the government’s FCA claims sufficiently related back to a previously-filed complaint to survive the defendant’s motion for partial judgment on the pleadings.¹⁹⁶ That ruling, however, rested on the district court’s application of the relation back provision under Rule 15(c), which, in the Third Circuit, liberally favors amendment of pleadings. Upon considering whether the facts and claims of the amended pleadings were “a natural outgrowth of the original pleading,” thereby placing the defendants on notice of potential liability, the district court concluded that the later pleadings were “natural offshoots” of the plaintiff’s original allegations. Accordingly, the district court determined that the defendant was on “fair notice” of the claims, suffering no prejudice from their prosecution.

187. 2017 WL 63006, at *8-9.

188. 229 F.Supp.3d 159 (E.D.N.Y. Jan. 17, 2017) (quoting *U.S. ex rel. Harris v. Bernad*, 275 F.Supp.2d 1, 6 (D.D.C. 2003)).

189. *U.S. ex rel. Coyne v. Amgen, Inc.*, 243 F. Supp. 3d 295, 298 (E.D.N.Y. 2017), *aff’d sub nom. Coyne v. Amgen, Inc.* 2017 WL 6459267 (2d Cir. Dec. 18, 2017).

190. In *Bellevue*, the Seventh Circuit noted that since the district court had ruled, a Seventh Circuit case made clear that the post-PPACA definition of original source applies, even if the alleged conduct occurred before 2010. The Seventh Circuit held that the relator did not meet the new definition of original source because his allegations did not materially add to the publicly disclosed allegations. 867 F.3d at 720-21.

191. 855 F.3d 949 (8th Cir. 2017).

192. 2017 WL 6209641 (6th Cir. Dec. 8, 2017).

193. 2017 WL 432460 (N.D. Ala. Feb. 1, 2017); see also 135 S. Ct. 1970 (2015).

194. 2017 WL 4564722, (C.D. Cal. Oct. 5, 2017).

195. 848 F.3d 366, 381-84 (5th Cir. 2017).

196. 2017 WL 85375, at *4-9 (E.D. Pa. Jan. 10, 2017).

DEVELOPMENTS REGARDING RELATORS

First-to-File Bar

The FCA's first-to-file bar limits the rights of the public to bring an action premised on facts that are already at issue in another pending FCA matter.¹⁹⁷ Courts continue to disagree about the application of the first-to-file bar, including the impact of the 2015 Supreme Court case, **Kellogg Brown & Root Services, Inc. v. U.S. ex rel. Carter**, which held that a *qui tam* action ceases to be pending under the FCA's first-to-file bar once the suit is dismissed.¹⁹⁸ Once the matter is dismissed, a subsequent action on the same facts will not be barred under this section of the FCA.¹⁹⁹

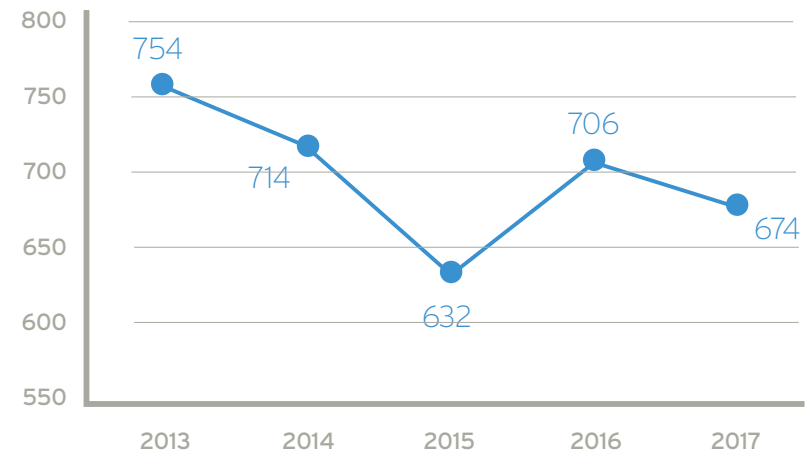
In **U.S. ex rel. Carter v. Halliburton Co.**, the Fourth Circuit articulated its understanding of **Kellogg Brown**, by holding that a later-filed suit that violates the first-to-file bar cannot be "cured" with the dismissal of the first suit. The later-filed suit must still be dismissed.²⁰⁰ In examining **Kellogg Brown**, the Fourth Circuit noted that the Supreme Court's decision "did not reject, or even comment on, this Court's holding that a court must look at the facts as they existed when the claim was brought to determine whether an action is barred by the first-to-file rule." Consequently, in the Fourth Circuit, later-filed cases may not continue simply because the earlier case was dismissed.

Another circuit court similarly developed its understanding of the first-to-file bar in light of **Kellogg Brown** when the D.C. Circuit decided **Shea**.²⁰¹ In **Shea**, the D.C. Circuit held that simply amending the later-filed complaint would not cure the first-to-file defect, and the later-filed FCA action must be dismissed.²⁰² The D.C. Circuit held that the action must be dismissed even if re-filing would be an issue due to statutes of limitations; to hold otherwise would disregard the language of the statute which forbids the *bringing* of another action and not simply the *continuing* of another action.

This issue otherwise remains undecided across federal circuits. A district court recently certified two unanswered questions to the Second Circuit: (1) "whether a violation of the FCA's 'first to file' rule compels dismissal or can be cured through the filing of a new pleading" and (2) "[i]f a violation of the first to file bar is curable, whether the FCA's limitations period is measured from the date of the relator's curative pleading . . . or the original complaint."²⁰³ Considering some courts have previously held that a first-to-file defect can be cured by amending the later-filed complaint after the first-filed complaint is dismissed,²⁰⁴ it will remain to be seen how courts, including the Second Circuit, decide the issue.

In **U.S. ex rel. Hayes v. Allstate Insurance Company**, the Second Circuit deepened a circuit split on a *different* first-to-file issue when it followed the D.C. Circuit and held that the first-to-file

NUMBER OF NEW QUI TAM LAWSUITS FILED BY YEAR (FY 2013-2017)



bar, 31 U.S.C. § 3730(b)(5), is non-jurisdictional. This holding differs from the Fourth, Fifth, and Sixth Circuits, which have all "stated or assumed that the first-to-file rule is jurisdictional."²⁰⁵ The Second Circuit reviewed the language of the statute and found that it did "not speak in jurisdictional terms or refer in any way to the jurisdiction of the district courts," which was in "sharp contrast to other provisions of the FCA that *do* explicitly invoke the jurisdiction of the district courts." Consequently, the Second Circuit determined that the first-to-file rule "bears only on whether a *qui tam* plaintiff has properly stated a claim" and the court did not "lack subject matter jurisdiction over an action that may be barred on the merits by the first to file rule."

Finally, in **U.S. ex rel. Carson v. Manor Care, Inc.**, the Fourth Circuit considered "a novel argument" made by a relator who argued that because his *qui tam* action was consolidated with a previously-filed action, and because the government intervened in that consolidated action, the relator's action could not be dismissed pursuant to the first-to-file rule, even though his later-filed complaint contained factually similar allegations to the previously-filed complaint.²⁰⁶ The Fourth Circuit, however, held that this argument "has no merit" and that "the first-to-file

197. 31 U.S.C. § 3730(b)(5).

198. 135 S. Ct. 1970 (2015).

199. *United States v. AstraZeneca Biopharmaceuticals, Inc.*, 2017 WL 1378128 (E.D.N.Y. Apr. 17, 2017) (holding that an administrative stay placed on the first suit is *not* equivalent to a dismissal and that the first case must be dismissed before it ceases to be pending).

200. 866 F.3d 199, 20708 (4th Cir. 2017).

201. 863 F.3d 923 (D.C. Cir. 2017).

202. *Shea*, 863 F.3d at 929 ("Although Shea's first-filed suit is no longer pending, a supplemental *complaint* cannot change when Shea brought his second *action* for purposes of the statutory bar.").

203. *U.S. ex rel. Wood v. Allergan, Inc.*, 2017 WL 1843288 (S.D.N.Y. May 4, 2017).

204. See, e.g., *U.S. ex rel. Gadbois v. PharMerica Corp.*, 809 F.3d 1 (1st Cir. 2015).

205. 853 F. 3d 80, 85 (2d Cir. 2017).

206. 851 F. 3d 293, 305 (4th Cir. 2017) (internal quotations omitted).

rule is an absolute, unambiguous exception-free rule” that “does not make an exception . . . for consolidated complaints.” Consequently, relator’s later-filed complaint was dismissed, despite the district court’s consolidation of the two complaints and the government’s intervention.

Relators’ Identity

When filing a *qui tam* action, some relators wish to remain unknown even after a case is unsealed. Federal Rule of Civil Procedure 10(a), however, “requires that the names of all the parties be included in the complaint,” and courts are generally reluctant to allow a relator to proceed with a case while concealing her identity—such as by using a “Jane Doe” pseudonym.

In ***U.S. ex rel. Doe v. Lincare Holdings, Inc.***, relator “John Doe” alleged that Lincare committed fraud by improperly inflating its medical equipment sales to Medicare Part B patients. The district court granted Lincare’s motion and dismissed all of John Doe’s claims except for his retaliation claim.²⁰⁷ “Generally, a plaintiff may not proceed anonymously unless he can demonstrate a substantial privacy right that outweighs the customary presumption of openness in judicial proceedings.” Because John Doe had “cited no facts, circumstances, or legal authority” that showed he was entitled to anonymity, the district court ordered that he disclose his identity to continue with the retaliation claim.

In ***United States v. UCB, Inc.***, the district court refused to allow the plaintiff either to keep the complaint under seal indefinitely or to proceed as a “John Doe” upon the complaint being unsealed.²⁰⁸ The relator, who had filed the action against his former employer, argued that either one of these two steps was necessary due to: (1) possible retaliation by his *current* employer; and (2) his choice to “forego an individual right of action for wrongful termination against his former employer,” and instead, filing the *qui tam* action. The district court stated a fear of retaliation is simply not enough to overcome the presumption that judicial documents be publicly accessible; the FCA contains a method of recourse for the relator if this were to happen—the anti-retaliation provision. Regarding the relator’s second argument, the district court simply stated that his choice to forego a wrongful termination action did not “ha[ve] any bearing on the presumption of public access to judicial documents.” The district court, however, did allow the relator to amend his complaint to redact the identity of his current employer.

Similarly, fear of harm to one’s reputation is not enough to allow the relator to continue under anonymity. In ***United States v. Apothetech RX Specialty Pharmacy Corp.***, the relators argued that continuing under seal was “the only way to avoid damaging their hard earned reputations within the healthcare industry and protect themselves and their families from retaliatory action.”²⁰⁹ The district court rejected such “generalized apprehensions of future retaliation,” because the relators had failed to show with any specificity how they would lose future employment opportunities if the complaint were not sealed or amended to remove

all personally identifying information. Again, the relators were not without options if such unspecified retaliation did occur, as they could bring a retaliation claim.

Overall, courts have balanced the competing interests of having information available to the public against quelling the relator’s fears of being identified as the plaintiff bringing the allegations. So far, courts have prioritized making information available to the public, and this seems at least partially due to the additional remedy afforded by the FCA’s anti-retaliation provision.

Relators’ Share

A successful *qui tam* action generally entitles the relator to a share of the proceeds of the action, whether or not the government intervenes.²¹⁰ Questions arise, however, when relators pursue a share under 31 U.S.C. § 3730(c)(5), which allows a district court to award a relator a share when the government pursues an “alternate remedy” against the defendant in the relator’s *qui tam* action. Courts recently have struggled with determining the exact parameters of what constitutes an “alternate remedy” that might entitle a relator to payment or recovery.

For example, courts have held that in order for the government’s action to be considered an alternate relative to the relator’s *qui tam* action, the *qui tam* action must have been ongoing at the time the government initiated the other action. In ***United States v. L3 Communications EOTech, Inc.***, a nonparty claimed that he was entitled to a share of the government’s settlement with the defendants, because it was an “alternate remedy” to the previous *qui tam* action the nonparty had filed against the same defendants.²¹¹ But, the district court stated that because the nonparty had dismissed his action before the government filed the current action, the government’s current action did not constitute an *alternate* remedy, but the only one the government could choose. Therefore, the nonparty was not entitled to a share of the settlement.

Similarly, in ***United States v. Sprint Communications, Inc.***, the Ninth Circuit held that because the relator’s previously dismissed *qui tam* complaint was barred by jurisdictional considerations such as the public disclosure bar, a later settlement between the government and the defendants was not an alternative remedy to the relator’s previous complaint. The relator “would have had *no* right to recovery, and so cannot recover here under the ‘alternate remedy’ provision of the statute.”²¹²

Courts also have been asked to decide whether criminal proceedings constitute alternate remedies, as relators have been asking for shares of the government’s restitution and forfeiture awards in separate criminal proceedings against the same defendants in the relator’s *qui tam* action. So far, courts have not reached a definitive conclusion on this issue. For example, in ***United States v. Van Dyck*** a relator moved to intervene in a criminal forfeiture proceeding against her former employer—the same defendant she had previously filed a *qui tam* action

207. 2017 WL 752288, at *8 (S.D. Miss. Feb. 27, 2017).

208. 2017 WL 838198 (S.D.N.Y. Mar. 3, 2017).

209. 2017 WL 1100818, at *1 (S.D. Miss. Mar. 20, 2017).

210. 31 U.S.C. § 3730(d)(1) & (2); see also 31 U.S.C. § 3730(c)(5).

211. 232 F. Supp. 3d 58 (S.D.N.Y. 2017); see also *N.Y. ex rel. Khurana v. Spherion Corp.*, 2017 WL 1169632, at *4 (S.D.N.Y. Mar. 28, 2017) (applying the reasoning in *L3 Communications EOTech* to the New York FCA, similarly stating that “if there is no valid *qui tam* action for the government to take over, then any remedial option that the government might pursue is not, in fact, an ‘alternate’ to taking over a *qui tam* action”).

212. 855 F.3d 985, 995 (9th Cir.2017).

CAN A RELATOR REMAIN ANONYMOUS IN A QUI TAM CASE?

When filing a *qui tam* action, some relators wish to remain unknown even after a case is unsealed. Federal Rule of Civil Procedure 10(a), however, “requires that the names of all the parties be included in the complaint,” and courts are generally reluctant to allow a relator to proceed with a case while concealing her identity—such as by using a “Jane Doe” pseudonym.

against. The Ninth Circuit noted that “it is an open question as to whether a criminal proceeding constitutes an ‘alternate remedy’ under the False Claims Act[.]”²¹³ but then stated that they “need not reach” that issue “because the sole issue before [the Court] is whether Relators are entitled to intervene in the criminal proceeding,” and the relator was not entitled to do so.

N.Y. ex rel. Khurana v. Spherion Corp. concerned claims under the New York City and state FCA statutes. There, the district court analyzed the claims through the lens of federal FCA case law, considering the statutes to be “mirrors” of each other.²¹⁴ The relator had filed his *qui tam* action three months after the government unsealed a criminal complaint against the same defendant. The government entered a deferred prosecution agreement with the defendant where the defendant agreed to pay \$500 million in a settlement, and the relator moved for a share of this settlement, arguing that it was an alternate remedy. After moving for his share, however, the relator’s claims were dismissed on public disclosure concerns. The district court summarized the status of current case law on the issue, noting that “lower courts appear divided on the question of whether a proceeding with criminal dimensions constitutes an ‘alternative remedy.’” It ultimately decided the issue on different grounds, however, stating that because the relator ceased to have a valid *qui tam* action when his claims were dismissed on public disclosure grounds, he was not entitled to a share.

Conversely, in **U.S. ex rel. Brown v. Celgene Corporation**, there was no dispute about whether the government’s settlement with Celgene was an alternate remedy, but instead the dispute concerned the percentage of that settlement to which relator was entitled. In 2010, the relator filed a *qui tam* action against Celgene and continued to litigate the case after the government declined to intervene. When the government and Celgene later settled for \$259 million the relator argued she was entitled to the maximum 30%, while the government countered with 25%. Awarding the relator 28%, the district court cited the significant work relator did in the case, which included “collecting thousands of documents and emails from her work at Celgene, and wearing a wire to a multi-day national meeting for Celgene,” reporting the fraud to her superiors and consequently opening herself up to potential retaliation, successfully with her attorney defeating a summary judgment motion, and helping achieve a large settlement.²¹⁵

Attorneys’ Fees

Under the FCA, courts will award relators attorneys’ fees for successful *qui tam* actions, whether or not the government intervenes.²¹⁶ Depending on the extent of plaintiff’s success, however, these attorneys’ fees may be limited. Likewise, a court may award attorneys’ fees to a successful *defendant*, but only in limited circumstances. Specifically, 31 U.S.C. § 3730(d)(4) allows an award of attorneys’ fees to a defendant if: (1) the government decides not to intervene; (2) the relator continues with the action; (3) the defendant prevails in the action; and (4) the district court finds the relator’s claim was “clearly frivolous, clearly vexatious, or brought primarily for the purposes of harassment.”²¹⁷

213. 866 F.3d 1130 (9th Cir. 2017).

214. 2017 WL 1169632, at *4.

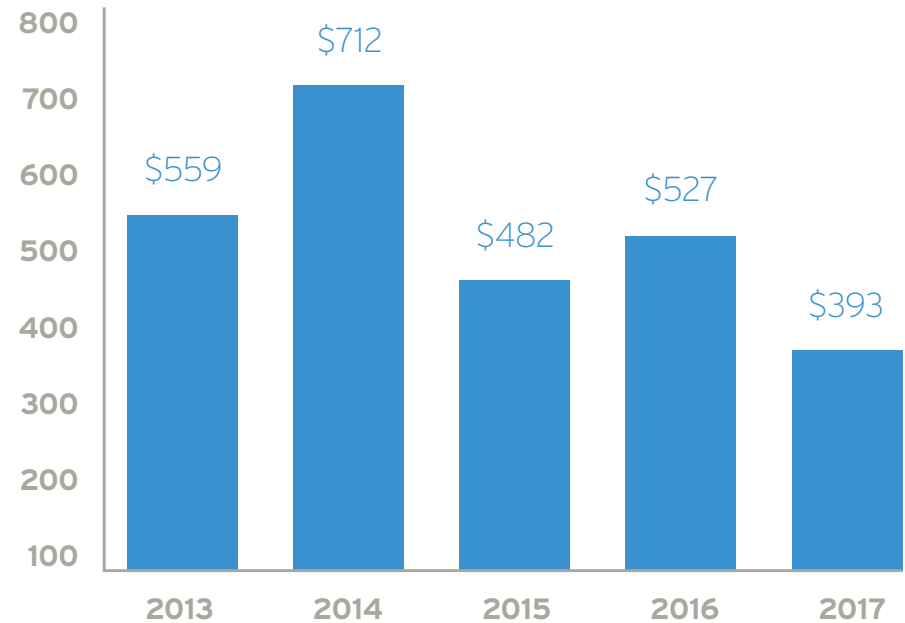
215. *U.S. ex rel. Brown v. Celgene Corporation*, 10-cv-03165-RGK-SS (C.D. Cal. Dec. 15, 2017).

216. 31 U.S.C. § 3730(d)(1) & (2).

217. 31 U.S.C. § 3730(d)(4).

218. 855 F.3d 1279, 1292 (11th Cir. 2017).

RELATOR SHARE AWARDS 2013-2017 (\$ IN MILLIONS)



Relators’ Attorneys’ Fees

The FCA entitles a relator to attorneys’ fees for a successful action; however, the Eleventh Circuit recently held that courts have discretion over the amount of attorneys’ fees to award. In **United States v. Everglades College, Inc.**, the Eleventh Circuit determined that the Hensley-Farrar principle—which allows for the reduction in attorneys’ fees when the plaintiff wins only nominal damages—is applicable not only to private party claims, but also to claims involving the government.²¹⁸ When a plaintiff obtains a nominal or “technical” win, such as by proving a legal violation but suffering no actual damages, the district court’s ability to reduce awards of attorneys’ fees appropriately “highlights the plaintiff’s failure to prove actual, compensable injury.”

For example, in *Everglades College*, the relators originally alleged that the defendant submitted over 230,000 false claims to the government for a total of \$1.2 billion of improperly received financial aid. The district court, however, found that the defendant actually only submitted two false certifications to the government, and the defendant was only required to pay \$11,000 as a penalty. Citing this nominal award, along with the “encouragement of whistle-blowers, the costs incurred by [defendants] of defending the lawsuit and considerations of judicial economy,” the district court awarded the relators \$60,000 in attorneys’ fees when they had requested more than \$1 million. The Eleventh Circuit affirmed this award, explaining that courts have discretion to award attorneys’ fees, even in situations where the relator prevails, and the statute states that courts “shall” award fees.

Defendants’ Attorneys’ Fees

Until recently, prior Ninth Circuit case law held “that when a defendant wins because the action is dismissed for lack of subject matter jurisdiction he is never a prevailing party.”²¹⁹ That prior case law, however, was called into question in a Supreme Court case decided in 2016, and in *Amphastar Pharmaceuticals, Inc. v. Aventis Pharma SA*, the Ninth Circuit determined that the Supreme Court’s ruling “effectively overruled” the older case law. Consequently, the Ninth Circuit held that courts have subject matter to determine attorneys’ fees if the defendant prevails on jurisdictional grounds *as long as the statute contains an independent grant of jurisdiction to do so*. Following the Tenth Circuit, the Ninth Circuit found that 31 U.S.C. § 3730(d)(4) contains an independent grant of subject matter jurisdiction to award attorneys’ fees.

Still, courts continue to find that § 3730(d)(4) presents a high bar to overcome, and have been hesitant to award prevailing defendants attorneys’ fees when it’s not completely clear that the relator’s claims were frivolous, vexatious or intended to harass. In *United States v. Muskingum Watershed Conservancy District*, the defendant met the first three requirements listed above and subsequently filed for attorneys’ fees, arguing that the relator’s claims were not only frivolous, but also vexatious and intended to harass. The district court, however, determined that the relator’s claims were not frivolous because they were decided on an issue of first impression in the Sixth Circuit. Further, although the relator did file two separate lawsuits that covered the same factual transaction, the court refused to find this was vexatious or with intent to harass: “there was at least some authority arguably supporting relators’ position” that a second suit was required in light of the FCA’s sealing requirements.²²⁰

Retaliation

The FCA protects whistleblowers from adverse employment actions related to their whistleblowing activities.²²¹ To establish that an employer retaliated against an employee in violation of § 3730(h), an employee must demonstrate that: (1) the employee engaged

in protected activity; (2) the employer knew that the employee was engaged in protected activity (the notice element); and (3) as a result, the employee was discriminated against.²²²

Last year, courts addressed a number of pleading issues that are unique to retaliation-as opposed to fraud-based-FCA claims. In addition, courts continued to consider the type of conduct that constitutes “protected activity” and provides “notice” to employers under the FCA’s retaliation provision.

Pleading Standard

Most jurisdictions have concluded that FCA retaliation claims are not subject to the heightened pleading standards required to prove a typical FCA fraud claim.²²³ Motions to dismiss, therefore, are evaluated on the more lenient Rule 8(a) plausibility standard, which may permit retaliation claims to survive even when the accompanying FCA fraud claims have been dismissed, or when such claims are not even alleged.

For example, in *U.S. ex rel. Gacek v. Premier Medical Management, Inc.*, the district court granted dismissal of two counts of FCA fraud due to failure to meet the heightened pleading standard for those claims, but refused to dismiss the plaintiff’s remaining FCA retaliation claim based on similar facts.²²⁴ The district court noted that the plaintiff had met the Rule 8(a) pleading standard by “plead[ing] a short and plain statement showing a plausible claim for retaliation under § 3730(h). Nothing further was required.”

Similarly, in *Rodriguez v. Reston Hospital Center, LLC*, the district court refused to dismiss a FCA retaliation claim in a case where the plaintiff did not separately allege substantive FCA claims.²²⁵ In moving to dismiss the retaliation claim, the defendant hospital argued that the complaint “relie[d] upon too many inferential leaps” to support a finding that the hospital acted fraudulently and subsequently terminated the plaintiff for whistleblowing conduct. The district court noted that, at the pleading stage, “a plaintiff need not prove an underlying FCA violation because, as the Supreme Court has explained, § 3730(h) protects an employee’s conduct even if the target of an investigation or action to be filed was innocent.” Accordingly, under the Rule 8(a) pleading standard, the hospital’s arguments in support of its motion to dismiss “miss[ed] the mark, [] as they focus[ed] on whether RHC committed an actual FCA violation, rather than whether Plaintiff sufficiently” alleged an FCA retaliation claim. *Rodriguez* provides a recent example of courts permitting FCA retaliation claims to proceed even when a plaintiff does not bring an accompanying FCA fraud claim.

Proper Defendants

Courts also considered whether FCA retaliation claims could proceed against certain types of defendants. Courts specifically addressed the potential for exposure when: (1) individual

219. 856 F.3d 696, 710 (9th Cir. 2017).

220. 2017 WL 4102360, at *6 (N.D. Ohio Sept. 15, 2017).

221. See 31 U.S.C. § 3730(h).

222. See, e.g., *Carlson v. DynCorp Int’l LLC*, 2016 WL 4435515, at *2 (4th Cir. Aug. 22, 2016).

223. See, e.g., *U.S. ex rel. Chorches v. Am. Med. Response*, 865 F.3d 71, 96 (2d Cir. 2017) (“The particularity requirement of Rule 9(b) does not apply to retaliation claims under the FCA.”).

224. 2017 WL 2838179, at *10-11 (S.D. Ala. June 30, 2017).

225. 2017 WL 772348 (E.D.Va. Feb. 28, 2017). The complaint also alleged wrongful discharge and interference under the FMLA, but did not allege FCA fraud.

defendants, *i.e.* supervisors within a terminating employer, are named as defendants in an FCA retaliation claim; and (2) the company sued for retaliation was not the company accused of having submitted false claims under the FCA.

In 2010, Congress amended § 3730(h) to expand the scope of potential FCA retaliation plaintiffs. Importantly, the amended statute also removed language expressly providing that retaliation claims could only be brought against a retaliating employer. As a result, relators have attempted to expand potential FCA retaliation liability beyond employers to include individual supervisors, but with limited success. A majority of district courts across jurisdictions have regularly dismissed FCA retaliation claims brought against individuals.

For example, in **Staley v. Gila Regional Medical Center**, the district court rejected the plaintiff's argument that her claim against individual defendants was proper because the language of

Relators have attempted to expand potential FCA retaliation liability beyond employers to include individual supervisors, but with limited success. A majority of district courts across jurisdictions have regularly dismissed FCA retaliation claims brought against individuals.

§ 3730(h) does not explicitly require that an action be brought solely against an "employer."²²⁶ Instead, the district court considered the legislative history of the 2010 amendment to § 3730(h) and held that Congress did not evince an intent to "expand the scope of liability to individuals."²²⁷

In **Diffley v. Bostwick Laboratories, Inc.**, the district court employed similar reasoning in dismissing an FCA retaliation claim brought against a former employer's CEO.²²⁸ While noting that district courts in the Second Circuit are split on the issue of whether FCA retaliation claims can be brought against individual defendants, the district court in **Diffley** concluded that, had Congress intended to widen the class of potential defendants in amending the retaliation statute, it would have included explicit language to that effect.

Similarly, in **Roberto v. Kent State University**, the district court dismissed FCA retaliation claims against

individual defendants, whom the plaintiff had named as parties presumably as an attempt to get around her employer's Eleventh Amendment sovereign immunity.²²⁹ In dismissing the action, the district court noted it had elected to "join[] the growing majority of courts" by concluding the FCA retaliation provision "does not permit a cause of action against individual supervisors."

Notably, in **Andrews v. City of Norfolk**, the district court held that § 3730(h) permits actions against retaliating employers even when the employer itself is not the party that has allegedly committed fraud.²³⁰ The district court reasoned that, "where an employer acts on behalf of a third party who is alleged to have violated the FCA," that employer may be liable for retaliation. According to the district court, "[t]his is true even where there is no alleged coordination between the employer and the third party." In reaching this decision, the district court rejected the defendants' argument that the Fourth Circuit's language in **Carlson v. DynCorp International LLC**,²³¹ stating that an employee must believe its "employer is violating, or soon will violate, the FCA."²³² The district court held that **Carlson** "is not on point to the issue at bar because it dealt with alleged retaliation involving an employee who believed that his own employer was violating the FCA."²³³

Definition of "Protected Activity"

The current statutory definition of "protected activity," enacted in 2010, covers: (1) employee "conduct in furtherance of an action under this section;" or (2) "other efforts to stop 1 or more violations of this subchapter."²³⁴ For the former, "such action minimally requires that a plaintiff be investigating matters that could reasonably lead to a viable FCA case."²³⁵ For the latter, courts generally require that a plaintiff maintain an "objectively reasonable belief that the conduct she opposes violates the FCA." In practice, courts have continued to employ a fact-intensive, case-by-case analysis to determine whether a specific plaintiff-employee had alleged sufficient conduct aimed at uncovering or stopping fraud on the government.

The Second Circuit, in **U.S. ex rel. Chorches v. American Medical Response, Inc.**, reversed a district court decision dismissing an FCA retaliation claim for failure to establish that the plaintiff engaged in protected activity.²³⁶ The Second Circuit held that the plaintiff's claims that he refused a request to falsify a single report for submission to the government demonstrated that he "prevent[ed] or hinder[ed] at least one [FCA] violation" and thus were sufficient to establish at the pleading stage that he engaged in protected activity. The Second Circuit found this allegation, combined with allegations concerning his subsequent email to a supervisor stating that he did not "feel comfortable" making those alterations, to be "functionally equivalent" to raising the issue internally in effort to stop an FCA violation.

In contrast, in **U.S. ex rel. Booker v. Pfizer, Inc.**, the First Circuit upheld the district court's grant of the defendant's motion for summary judgment in an action alleging that Pfizer terminated a sales representative in response to whistleblowing activities.²³⁷ The First Circuit held that the plaintiff's deposition testimony stating that he objected on two occasions to requests from superiors to promote a drug's off-label use did not rise to the level of activity that "reasonably

226. 2017 WL 3602057, at *3 (D.N.M. Feb. 21, 2017).

227. *Id.* at *4. The district court reiterated that the 2010 amendments were intended to expand the scope of plaintiffs who could bring FCA retaliation cases, not the universe of potential defendants.

228. 2017 WL 6948353, Dkt. 28 (S.D.N.Y. Dec. 6, 2017).

229. 2017 WL 1155563 (N.D. Ohio Mar. 28, 2017).

230. 2017 WL 4837707, at *11 (E.D.Va. Oct. 23, 2017).

231. 657 Fed. App'x 168 (4th Cir. 2016).

232. 2017 WL 4837707, at *11.

233. *Andrews*, 2017 WL 4837707, at *11.

234. 31 U.S.C. § 3730(h)(1) (emphasis supplied).

235. *Armstrong v. Arcanum Grp.*, 2017 WL 4236315, at *5 (D. Colo. Sept. 25, 2017) (collecting cases).

236. 865 F.3d 71, 98 (2d Cir. 2017).

237. 847 F.3d 52, 60 (1st Cir. 2017).

could lead to an FCA action.” The First Circuit explained that such objections could not support a claim for retaliation on summary judgment “absent any evidence that those objections or reports concerned FCA-violating activity such as the submission of false claims.”

In **Malanga v. NYU Langone Medical Center**, the district court denied the defendants’ motion for summary judgment in a case alleging that the plaintiff, a former director of research administration at NYU’s School of Medicine, was retaliated against for objecting to, and investigating, hospital billing practices.²³⁸ At summary judgment, the defendants argued that the plaintiff failed to establish that she engaged in protected activity because investigating fraud was part of her job. According to the defendants, employees that investigate fraud against the government as part of their job responsibilities should be required to “make clear [their] intentions of bringing or assisting in an FCA action” in order to “overcome the presumption that [they were] merely acting in accordance with [their] employment obligations.”

The district court disagreed, refusing “to adopt a higher standard to plead protected conduct for employees . . . whose jobs encompass investigating fraud.” Instead, the district court explained that an employee satisfies the protected activity requirement when she “engages in activity that [leads] to the distinct **possibility of evidence** that an FCA violation occurred.” While an employee’s job responsibilities can impact this analysis, the district court held that the plaintiff here satisfied this standard by demonstrating that, among other actions, the plaintiff identified and followed-up on fraudulent billing practices for government-funded projects and reported her attempts to stop fraudulent billing to the human resources department.

Notice to Employers

The notice element of a *prima facie* FCA retaliation claim requires that a plaintiff-employee put the terminating employer on notice of the “distinct possibility” of FCA litigation.²³⁹ This element is required to establish that an employer knew of an employee’s whistleblowing activities, and therefore could have acted out of a related desire to retaliate. In general, courts agree that “[m]ere complaints about job dissatisfaction or regulatory violations generally are not sufficient to put an employer on notice.” Instead, an employee’s conduct must raise the issue of fraud or illegal behavior to the employer. While there is no bright-line test as to establish notice, courts routinely consider the plaintiff-employee’s former job duties to determine whether the employee’s conduct sufficiently notified the employer of the possibility of FCA litigation.²⁴⁰

In **U.S. ex rel. Campie v. Gilead Sciences, Inc.**, the Ninth Circuit reversed the district court’s dismissal of the plaintiff’s FCA retaliation claim. The relator, a former quality assurance professional at Gilead, alleged that Gilead terminated him in retaliation for reporting that Gilead was falsely certifying FDA compliance in order to receive government reimbursement.²⁴¹ In reversing the dismissal of the case, the Ninth Circuit recognized that “when an employee is tasked with [quality insurance] investigations [as part of his job description], it takes more than

an employer’s knowledge of” such investigations to put the employer on notice of a potential *qui tam* suit. While noting that the “monitoring and reporting activities outlined by relator[] are by-and-large the types of activities [the relator] was required to undertake as part of his job,” the court held that the operative complaint nevertheless pleaded an adequate retaliation claim. Specifically, the complaint contained additional factual allegations beyond the relator’s traditional reporting duties, including that the relator: (1) informed his employer that he was going to report the non-compliance to government officials, (2) was thereafter “selectively circumvent[ed]’ and ‘excluded’ from the regulatory review process,” and (3) was expressly told by supervisors that such compliance concerns were “not in his job description.”

In contrast, in **Jamison v. Fluor Federal Solutions**, the district court held that an employee failed to adequately allege notice in a retaliation claim, even when the employee had both: (1) filed a *qui tam* action under seal, and (2) issued an internal report to the employer’s human resources department requesting an internal investigation regarding certain problematic conduct.²⁴² With respect to the allegations in the *qui tam* action, the complaint alleged that a coworker told the plaintiff that employees were instructed “not give any information to Plaintiff and that there was every indication [of] a Qui Tam filing.” The district court found this allegation insufficient to plead notice, explaining that “there are any number of plausible reasons why” the employer may have wanted to wall off the plaintiff from information. Regarding the internal report, the district court recognized the tension between competing requirements that an employee must “specifically tell the employer that [s]he is concerned about possible fraud,” but that “no magic words—such as illegal or unlawful—are necessary to place the employer on notice of protected activity.” The district court explained that “an internal report must concern possible fraud against the government, but need not mention fraud.” By contrast, the plaintiff’s report requested an internal investigation and did not mention fraud or litigation, thereby making “it unreasonable [for the employer] to expect something more in the form of *qui tam* litigation. Put another way, some words, such as express requests for discrete forms of relief that do not involve litigation, might make it less reasonable for an employer to expect *qui tam* litigation.”

Similarly, in **Hernandez v. Hernandez**, the district court dismissed the plaintiff’s FCA retaliation claim due to failure to adequately plead notice.²⁴³ Plaintiff claimed that his employer had knowledge of his activity investigating and reporting alleged Medicare fraud because employer “personnel were recording or viewing Plaintiff’s work activity [] while Plaintiff was viewing fraudulent medical records.” The district court noted that the plaintiff’s job responsibilities gave him access to patient billing activity and medical records. Accordingly, even if the plaintiff’s activities were monitored, the employer would have “no way to distinguish whether Plaintiff was engaged in a protected activity or merely conducting ordinary business.” In addition, the district court noted that the plaintiff “specifically did not raise the Medicare fraud issues because he knew he would be terminated immediately,” and found that an allegation that a facility doctor asked another physician whether plaintiff was an FCA

238. 2017 WL 4466612, at *6 (S.D.N.Y. Oct. 5, 2017).

239. See, e.g., *Reid v. Temple Univ. Hosp. Episcopal Campus*, 2017 WL 5157620, at *4 (E.D.Pa. Nov. 7, 2017).

240. See, e.g., *U.S. ex rel. Campie v. Gilead Sciences, Inc.*, 862 F.3d 890, 908 (9th Cir. 2017) (explaining that “an allegation of knowledge is not a high bar” and the mere “reference to ‘civil violations’ can be” sufficient to establish notice).

241. 862 F.3d at 909-10.

242. 2017 WL 3215289, at *11 (N.D. Tex. July 28, 2017).

243. 2017 WL 2557066, at *3 (M.D. Fla. June 6, 2017).

whistleblower “demonstrates nothing more than [that physician’s] *lack* of knowledge regarding whether Plaintiff was engaged in protected activities.” Both of these facts further supported that the plaintiff could not demonstrate the requisite notice to the employer.

DISCOVERY DEVELOPMENTS IN FCA CASES

Waiver of Attorney-Client Privilege

A handful of cases highlighted the risk of privilege waiver that defendants face in denying scienter based on an assertion of its intent to comply with relevant regulations. In ***U.S. ex rel. Lutz v. Berkeley Heartlab, Inc.***, the defendants asserted an affirmative defense of good faith reliance on advice of counsel in response to allegations that it violated the AKS and FCA. In their answer, the defendants specifically referenced memos from two attorneys—and attached one of the memos—as well as advice received from a third attorney. When the government argued the defendants had waived privilege regarding “all” information on the alleged schemes, the defendants argued that they had not waived privilege with regard to advice received during an OIG investigation. Finding a broader waiver, the district court explained that “when a party asserts an advice of counsel defense[,] the privilege waiver applies to advice received during the entire period the misconduct is alleged to have been ongoing—even up to and during trial.” The district court concluded the defendants “placed their communications with counsel at issue,” and thus, “waived the attorney client privilege as to all information relating to their communications with counsel during the OIG investigation about the conduct at issue in this case.”²⁴⁴

In contrast, one defendant managed to avoid placing communications with counsel at issue by relying on its employees’ understanding of applicable regulations, but explicitly disavowing a good faith reliance on advice of counsel defense. In ***U.S. ex rel. Garbe v. Kmart Corp.***, Kmart made various statements about its employees’ beliefs with regard to the impact of certain discount programs and prices on its usual and customary (U&C) prices for its drugs in connection with its summary judgment motion. It explicitly represented, however, that it did not intend to rely on an “advice of counsel” or “good faith defense” at trial. Nevertheless, the relator argued that “these statements, indicating Kmart employees acted on the ‘good faith’ belief their conduct was within the bounds of applicable regulations, implicitly waives the attorney-client privilege because the truthful resolution of these statements requires the examination of confidential communications.” The district court disagreed. Because Kmart had not “affirmatively placed its communications with counsel at issue,” it was not using the attorney-client privilege as both a sword and a shield, such that the attorney-client privilege was not waived.²⁴⁵

Notwithstanding the decision reached in ***Garbe***, significant risks exist in articulating a defense based on the intent to comply with applicable law. As covered in our **Healthcare Fraud & Abuse**

Review for 2016, another district court reached a conclusion opposite from that reached in ***Garbe***, finding that the defendant waived the attorney-client privilege when it asserted that it acted “in compliance with all applicable legal requirements” because “knowledge about the law is vital, and the advice of counsel is highly relevant to the legal significance of [its] conduct.”²⁴⁶

Discovery Issues in Intervened FCA Cases

Defendants continued to make headway in discovering pre-indictment and pre-intervention materials from the government. For instance, in ***U.S. ex rel. Lutz v. Berkeley Heartlab, Inc.***, the defendants successfully sought the production of witness statements, memoranda of interviews, notes of interviews, and FBI 302 reports relating to witnesses to the case. The government claimed that all such materials were either privileged or protected by the work-product doctrine, but the district court disagreed, explaining that in *qui tam* actions, fairness dictates that both sides have equal access to relevant witness statements, which are often given early on in the investigation and shed light on how testimony may have changed over time. The district court held that because substantially verbatim witness statements contained in notes, memoranda, and other documents are considered “fact work product,” they are discoverable under Rule 26(b).²⁴⁷

But, as in years past, defendants’ requests for internal government communications were frequently met with claims of deliberative process and irrelevance. In ***Lutz***, the defendants sought documents in which any attorney, law firm or government agency had “opined on the legality” of the payment of fees to physicians by the laboratories at issue. The defendants maintained that such communications would be relevant to proving that their belief that the payments were legal was reasonable in light of the AKS’s ambiguity. The government claimed that those communications were privileged and irrelevant. The district court agreed with the government, holding that the defendants had failed to make a compelling case for why the government’s internal communications were relevant to the defendants’ state of mind at the time of the conduct at issue.²⁴⁸

Similarly, the defendants in ***Lutz*** requested all documents relied upon or considered by the OIG in determining whether to issue a Special Fraud Alert. The government objected and submitted an affidavit in support of withholding that information based on the deliberative process privilege. Though the district court recognized that such an affidavit will often be procedurally ineffective if it claims that every single potentially responsive document is protected by the privilege, it held that in this instance, the defendants had crafted their discovery requests to specifically target only predecisional deliberations regarding whether to issue a Special Fraud Alert. Accordingly, it denied the motion to compel without prejudice.

244. 2017 WL 1533434, at *1-2, 4 (D.S.C. Apr. 5, 2017).

245. 2017 WL 3034342, at *1-3 (S.D. Ill. July 17, 2017).

246. *U.S. ex rel. Calilung v. Ormat Industries, Ltd.*, 2016 WL 4107682, at *4 (D. Nev. Aug. 1, 2016).

247. 2017 WL 1533434, at *4 (D. S.C. Apr. 27, 2017).

248. *Id.* at *5. The court’s decision was in response to the defendants’ scienter argument. It is worth noting that other post-*Escobar* decisions have reached a different conclusion based on arguments of materiality.

INTERVENTION AND SETTLEMENT

Several decisions addressed the standards courts should apply when reviewing the government's decision to intervene in and settle *qui tam* actions.

When the government initially declines to intervene in a *qui tam* action, the FCA permits the government to intervene later upon a showing of "good cause" pursuant to § 3730(c)(3). In ***U.S. ex rel. Drennen v. Fresenius Med. Care Holdings, Inc.***, the district court granted the government's request to intervene despite the fact that it was made nearly six years after the relator had filed his complaint and after the relator and defendant had already completed discovery.²⁴⁹ The district court found the government possessed good cause to intervene because the government sought to defeat the defendant's public disclosure bar argument against the relator. As explained by the district court, because the government is the real party in interest, it is appropriate for the government to intervene to avoid application of the public disclosure bar, which applies only to private plaintiffs. The district court also found good cause satisfied because the government recently had received new, important evidence. While the defendant had produced this evidence to the relator much earlier, it was "new" to the government because the government had not previously received it. Though the district

court permitted the government to intervene, it prohibited the government from seeking additional fact discovery from the defendant, yet permitted the defendant to serve discovery requests on the government.

[U]nder the plain language of § 3730(b)(1), the Attorney General possesses an absolute veto power over voluntary settlements in FCA *qui tam* actions.

U.S. ex rel. Michaels v. Agape Senior Community, Inc.

the dismissal and their reasons for consenting." Recognizing that this provision imposes no standard for reviewing the government's decision, the Fourth Circuit held that the government's veto authority over settlements is absolute. In so ruling, the Fourth Circuit joined the Fifth and Sixth Circuits, which have reached the same conclusion, but disagreed with a prior Ninth Circuit ruling.

In ***U.S. ex rel. Shepard v. Grand Junction Reg'l Airport Auth.***, the district court was asked to review the government's proposed settlement in an intervened case where the relators objected

that the settlement amount was too low.²⁵¹ Under § 3730(c)(2)(B), the government may settle a *qui tam* action over the relator's objection if the settlement is "fair, adequate, and reasonable." The district court rejected the relator's argument that the court should apply the stringent standards governing review of class action settlements, and instead found it appropriate to apply a "highly deferential" standard of review, under which the government must show only a rational relationship between dismissal and an identified, valid government purpose. The district court had little difficulty finding this standard met where the government thoroughly investigated and found the claims largely meritless and the damages difficult to prove.

U.S. ex rel. Christiansen v. Everglades College, Inc. presented an interesting situation where the government intervened to settle a case while the relators' appeal from final judgment was pending before the Eleventh Circuit.²⁵² The relators had initially sought billions of dollars for an alleged scheme concerning improper requests for student financial aid, but only recovered \$11,000. While the relators' appeal was pending before the Eleventh Circuit, the government agreed to settle with the defendants for \$335,000. The Eleventh Circuit held that when the government intervenes only to settle and dismiss the case, it need not satisfy the good-cause intervention requirement under § 3730(c)(3). Further, the Eleventh Circuit held that the government's settlement decision should be reviewed with deference to determine only "whether the government has advanced a reasonable basis for concluding the settlement is in the best interest of the United States, and whether the settlement unfairly prejudices the relator's potential *qui tam* recovery." Applying this standard, the Eleventh Circuit found the settlement was reasonable because it was significantly larger than the relators' recovery at trial, and because the government had an interest in avoiding potential adverse precedent should the relators lose on appeal. The Eleventh Circuit further held that a relator is not entitled to an evidentiary hearing or discovery related to the fairness of the government's settlement, but that the district court possesses equitable powers to convene a hearing or require discovery, if the relator were to show a substantial and particularized need.

249. 2017 WL 1217118 (D. Mass. Mar. 31, 2017).

250. 848 F.3d 330 (4th Cir. 2017).

251. 2017 WL 749070 (D. Colo. Feb. 27, 2017).

252. 855 F.3d 1279 (11th Cir. May 3, 2017).

STARK LAW/ ANTI-KICKBACK STATUTE

The past year saw a number of notable statutory developments affecting both the AKS and Stark Law and numerous cases and settlements explored a variety of important principles related to these statutes and the broad scope of potential liability under both.

Developments in Illegal Remuneration

Courts continued to explore the contours of what constitutes illegal remuneration. In *United States v. Addus HomeCare Corp.*, the complaint alleged, in part, that Addus accepted false Medicare certifications of home health eligibility from a physician services group, HPG, in exchange for referrals to HPG.²⁵³ Addus argued that certifying compliance with Medicare requirements could not be illegal remuneration because the certifications had no value and brought Addus “only the mere expectation (or possibility) of payment.” The district court rejected this argument and held that the false certifications made it possible for the provider to bill Medicare for the patients in question, which was enough to constitute actionable remuneration as “anything of value” to the recipient.

The complaint in *U.S. ex rel. Wood v. Allergan, Inc.*, alleged that Allergan provided ophthalmologists illegal remuneration in the form of free surgical kits, drug samples and office supplies in order to induce them to prescribe Allergan’s drugs.²⁵⁴ Allergan argued the free drug samples and kits containing free drug samples could not constitute remuneration given the language of the Prescription Drug Marketing Act, which authorizes free drug samples under certain conditions. The district court acknowledged this argument, but noted Allergan “ultimately goes too far.” Because Medicare reimburses ophthalmologists using a flat rate per surgery, Allergan’s provision of the samples (specifically, eye drops that are administered prior to surgery and thus not reimbursable under Medicare), could plausibly have subsidized surgical costs, increasing ophthalmologists’ profit per surgery, and “[s]uch profit maximization can constitute remuneration under the AKS.” The district court also held that the patient instruction sheets and prescription pads could constitute illegal remuneration because the

complaint plausibly alleged the instruction sheets were regarded as a necessity, which raised the inference that the physicians would otherwise have had to cover printing and shipping themselves. Further, allegations that various physicians consistently ordered customizable prescription pads from Allergan for over a decade showed that they had more than nominal value to the physicians. The case is currently on appeal in the Second Circuit and the United States, though it declined to intervene, has filed an amicus brief and petitioned for leave to participate in the scheduled oral argument.

In one of the largest single federal FCA recoveries in FY 2017, Shire Pharmaceuticals LLC and related entities agreed to pay \$350 million to resolve federal and state FCA allegations that Shire paid kickbacks and used other unlawful methods to induce clinics and physicians to use its bioengineered human skin substitute, Dermagraft.²⁵⁵ Shire allegedly induced clinics and physicians to use or overuse Dermagraft with lavish dinners; drinks; entertainment; and travel; along with free medical equipment and supplies; unwarranted payments for purported speaking engagements and sham case studies; and cash; credits; and rebates. The six relators involved continue to litigate the appropriate apportionment of whistleblower shares to be awarded.

In *U.S. ex rel. Rembert v. Bozeman Health Deaconess Hosp.*, the complaint alleged Bozeman exchanged patient referrals for remuneration related to the formation and operation of an imaging center.²⁵⁶ Specifically, the complaint alleged Bozeman received majority ownership and control in the imaging center, large cash distributions pursuant to its ownership interest, free services from the center in its radiology department, and non-compete agreements from radiologists working in the center. The district court upheld the complaint against a Rule 9(b) challenge, finding it adequately alleged particulars regarding the joint venture, how the market for radiology services was impacted by the scheme, the valuation process, and the allegedly false claims that resulted.

Evidentiary Developments Related to AKS

In a recent opinion bearing on proof in AKS cases, in *U.S. ex rel. Cairns v. D.S. Medical L.L.C.*, the district court allowed the government to introduce evidence related to the medical necessity of defendant physician’s surgeries, including statistical and anecdotal evidence regarding comparative usage of implant devices by the physician and his peers, to support the government’s allegations that the physician selected his co-defendant distributor’s medical devices based on illegal kickbacks.²⁵⁷ The district court called the issue a “close question” but agreed with the government that the evidence would be probative of the physician’s intent and would not be unfairly prejudicial.

In *United States v. Moshiri*, the Seventh Circuit affirmed the district court’s decision to permit expert testimony relevant to the fair market value (FMV) of a teaching contract that defendant podiatrist allegedly received as a vehicle to pay him for patient referrals.²⁵⁸ Rather than render an opinion about the FMV of the contract at issue, the government’s expert testified to the

253. 2017 WL 467673 (N.D. Ill. Feb. 3, 2017).

254. 246 F. Supp. 3d 772 (2017).

255. <https://www.justice.gov/opa/pr/shire-plc-subsidiaries-pay-350-million-settle-false-claims-act-allegations>.

256. 2017 WL 514205 (D. Mont. Feb. 7, 2017).

257. 2017 WL 1304947 (E.D. Mo. Apr. 7, 2017).

258. 858 F.3d 1077 (7th Cir. 2017).

value of the contract compared to “industry norms,” noting he had never heard of an attending physician being paid as much for teaching as the defendant was under his contract. The Seventh Circuit acknowledged that the lack of nationwide “empirical analysis” of similar contracts was relevant to the weight of the expert’s testimony but not fatal to its admissibility, and upheld the physician’s conviction.

Perennial Scrutiny of Physician Compensation Arrangements

Physician employment arrangements with hospitals continued to garner significant scrutiny. In *U.S. ex rel. Holden v. Mercy Hosp. Springfield*, two Mercy affiliates agreed to pay \$34 million and enter a five-year CIA to resolve FCA allegations that compensation paid to employed medical oncologists was based in part on a formula that took into account the volume or value of referrals to the hospital’s infusion center, in violation of the Stark Law.²⁵⁹ Mercy indicated the payment arrangement resulted from an oversight when it converted a freestanding oncology clinic to a provider-based outpatient department in 2009 in order to participate in a federal drug pricing program. Mercy allegedly used work relative value unit (wRVUs) not based on physician work but instead as a proxy for keeping newly-employed oncologists’ compensation at the same level as when they owned the clinic.

In *U.S. ex rel. Scott v. Pine Creek Med. Ctr., LLC*, a physician-owned hospital agreed to pay \$7.5 million to resolve claims that it violated the FCA by paying physicians kickbacks in the form of marketing services in exchange for surgical referrals.²⁶⁰ The hospital paid for a variety of such services, including local and regional print, radio, and television advertisements; website upgrades; billboards; business cards; and brochures.

In *U.S. ex rel. Mason v. HMA* and *U.S. ex rel. Miller v. HMA*, two physician groups, EmCare, Inc. and Physician’s Alliance Ltd. (PAL), agreed to pay \$29.6 million and \$4 million, respectively, to resolve FCA allegations that they received illegal remuneration in exchange for referring patients to hospitals owned by the now-defunct Health Management Associates (HMA).²⁶¹ HMA allegedly provided EmCare “lucrative contracts and cash” to induce physicians to recommend unnecessary testing and inappropriate inpatient admissions, and allegedly paid kickbacks to PAL physicians in the form of excessive compensation and “bogus” co-management or medical directorship fees. Three hospital executives also are contributing to the PAL settlement, confirming the continued relevance of the Yates Memo.

In *United States v. Nagelvoort*, the Seventh Circuit affirmed the criminal conviction of a hospital administrator who caused his employer to pay kickbacks to physicians in return for patient referrals.²⁶² The Seventh Circuit found the evidence was sufficient for the jury to conclude that the hospital’s leases, personal services contracts, and teaching agreements with physicians took into account the physicians’ potential referrals, thereby placing the agreements outside the bounds of the AKS’ safe harbors. In so ruling, the Seventh Circuit declined to strike down the

“one purpose test” as unconstitutionally vague, upholding a jury instruction that allowed the jury to find an AKS violation if “any part or purpose” of the payments was to induce referrals.

Stark Law’s “Signed Writing” Requirement Material to Payment?

In October 2015, CMS clarified that the “in writing” requirement found in many of the Stark Law’s exceptions could be met through a collection of documents, even in the absence of a formal contract.²⁶³ *U.S. ex rel. Emanuele v. Medicor Assocs.* explored the parameters of this flexibility and reiterated the importance of strict adherence to the writing requirement. The operative portion of the complaint alleged that certain medical directorship arrangements failed to satisfy the signed writing requirement in the Stark Law’s personal services or FMV exceptions during various periods of time, resulting in FCA violations. For six arrangements, the district court found that despite the fact that the agreements had expired by their terms, there was sufficient documentation evidencing the course of conduct of the parties for the time in between the expiration and subsequent documentation, including invoices and checks consistent with the terms of the original agreement. The district court, however, found insufficient evidence

of a writing for other agreements where the collection of documents did not address identifiable services, a timeframe, or a rate of compensation, nor have a signature.

Even an innocent failure to discover and disclose technical Stark violations can result in the difficult choice between a high-risk trial or an expensive FCA settlement.

In a matter of first impression, the district court purported to apply the rigorous materiality standard espoused in *Escobar* and held “it is clear” that violations of the written agreement requirement could be material to the government’s payment decision for purposes of the FCA. On this basis, the court denied summary judgment, and the defendants subsequently resolved the allegations for \$20.75 million.²⁶⁴ This result is a discouraging reminder that even an innocent failure to discover and disclose technical Stark violations can result in the difficult choice between a high-risk trial or an expensive FCA settlement.

Notable Statutory Developments

HHS-OIG implemented final rules effective January 6, 2017, that adopted changes to the AKS safe harbors and exceptions to the Civil Monetary Penalties (CMP) statute. Updates were made to the safe harbors related to referral services, cost-sharing waivers for pharmacies and ambulance service providers, Medicare Coverage Gap Discount Program, and local transportation.²⁶⁵ CMP

259. <https://www.justice.gov/opa/pr/missouri-hospitals-agree-pay-united-states-34-million-settle-alleged-false-claims-act>.

260. <https://www.justice.gov/opa/pr/dallas-based-physician-owned-hospital-pay-75-million-settle-allegations-paying-kickbacks>.

261. <https://www.justice.gov/opa/pr/two-physician-groups-pay-over-33-million-resolve-claims-involving-hma-hospitals>.

262. 856 F.3d 1117 (7th Cir. 2017).

263. See 42 C.F.R. § 411.357 (requiring arrangements be set forth in writing to meet various exceptions to the Stark Law).

264. <http://www.post-gazette.com/business/healthcare-business/2017/11/09/upmc-hamot-whistleblower-lawsuit-settlement-erie-pennsylvania-20-7-million/stories/201711090158>.

265. See 42 C.F.R. § 1001.952(f), 952(k), 952(aa), and 952(bb), respectively.

regulations were expanded to include guidelines for assessment and exclusion under the CMP statute, Stark Law and the Emergency Medical Treatment and Labor Act (EMTALA); and additional exceptions were established to the CMP's definition of "remuneration," including an exception for co-payment waivers for the first fill of generic drugs and certain remuneration that poses a low risk of harm and promotes access to care.²⁶⁶

CMS also finalized revisions to its Voluntary Self-Referral Disclosure Protocol, requiring that all voluntary Stark Law self-disclosures made on or after June 1, 2017, (with limited exceptions) must be submitted using new forms and a financial worksheet.²⁶⁷ Key changes include:

- 1) the requirement for a physician information form for each physician implicated,
- 2) narrative information regarding the noncompliant conduct, and
- 3) information regarding the pervasiveness of the non-compliance.

The revisions also acknowledge the lookback period is expanded to six years and runs from the date when the disclosing entity identified the overpayment.

266. See 42 C.F.R. § 1003.110.

267. https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Self_Referral_Disclosure_Protocol.html.

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, including their marketing practices, resulting in several significant FCA settlements.

The government also aggressively targeted defendants for allegedly prescribing medically unnecessary drugs, with a particular emphasis on opioids and other narcotics. Additionally, DOJ ramped up its scrutiny of pharmaceutical manufacturer donations made to charitable patient assistance programs, indicating increased risk of FCA liability and underscoring the importance of compliance.

Renewed Focus on Marketing of Medical Devices and Pharmaceutical Products

Three settlements in 2017 involving Shire Pharmaceuticals LLC and subsidiaries of Shire PLC, Celgene Corp., and Novo Nordisk Inc. demonstrated the continuing risk of marketing efforts that can result in AKS and FCA exposure. In January 2017, Shire reached a \$350 million settlement to resolve allegations of FCA violations stemming from marketing and sales of “Dermagraft,” a skin treatment used to treat diabetic foot ulcers, in the largest FCA recovery related to kickbacks associated with a medical device.²⁶⁸ Shire and ABH, a company Shire acquired in 2011, allegedly offered kickbacks, including, among others, expensive dinners, drinks, entertainment and travel, cash, rebates and cash equivalents, medical equipment, and unjustified speaker fees, to clinics and physicians to encourage the use of Dermagraft. The settlement also resolved allegations of unlawful marketing of the product by Shire and ABH for unapproved uses, as well as making false statements to increase the price of the product and improperly coding or certifying claims.

Similarly, in July 2017, Celgene agreed to pay \$280 million to resolve allegations related to improper promotion of Thalomid and Revlimid, two cancer drugs, for uses that were not approved by the FDA and not reimbursable under federal healthcare programs and the state healthcare programs of 28 states and the District of Columbia.²⁶⁹ The related *qui tam* action filed by a Celgene sales manager raised allegations that Celgene employed false and misleading statements to promote the two cancer-related drugs for unapproved uses and paid kickbacks to physicians to incentivize prescriptions for the medications. According to the *qui tam* action, Celgene allegedly encouraged physicians to “substitute its untried remedies for treatments proven to be safe and effective in desperately ill patients.”²⁷⁰ The Celgene settlement involves one of the largest improper marketing settlements in the context of cancer treatment, an area in which drugs are often prescribed for off-label uses to serve a vulnerable patient population.²⁷¹

In September 2017, pharmaceutical manufacturer Novo Nordisk reached a \$58.65 million settlement to resolve allegations under the FCA, state false claims acts and the U.S. Federal Food, Drug, and Cosmetic Act (FDCA) that the company did not satisfy the FDA’s requirements for the Risk Evaluation and Mitigation Strategy (REMS) for Type II diabetes medication, Victoza.²⁷² The government alleged that Novo Nordisk did not adhere to the REMS requirement to accurately convey risk information related to the potential risk of development of Medullary Thyroid Carcinoma (MTC), a rare cancer associated with use of Victoza. The settlement resolves allegations that Novo Nordisk provided its sales force with misleading information that falsely downplayed the risk of MTC and encouraged the use of Victoza for unapproved use in patients without Type II diabetes, leading to the submission of false claims under the FCA and state false claims acts. Novo Nordisk sales representatives allegedly provided misleading information to physicians, which instilled an inaccurate perception that the Victoza REMS-required message related to the risk of MTC was “erroneous, irrelevant, or unimportant.” As a result, certain physicians were allegedly not fully apprised of Victoza’s potential risk of MTC to patients. Despite modification to the REMs required by the FDA to address this risk, Novo Nordisk allegedly instructed its sales representatives to provide deceptive information to physicians on the risk of MTC related to Victoza contrary to the REMS modification and the FDCA.

Usual and Customary Pricing

Government scrutiny of pharmaceutical companies’ “usual and customary” (U&C) pricing continued in 2017. Mylan Inc. and Mylan Specialty L.P. agreed to pay the government \$465 million to resolve allegations brought by a corporate whistleblower, Sanofi-Aventis US LLC, that Mylan intentionally misclassified the EpiPen as a generic drug to circumvent payment of rebates owed primarily to Medicaid under the Medicaid Drug Rebate Program in violation of the FCA.²⁷³ To protect Medicaid programs from arbitrary increases in drug prices, price increases on single-source, brand name drugs result in higher rebates to Medicaid depending on the price increase

268. <https://www.justice.gov/opa/pr/shire-plc-subsidiaries-pay-350-million-settle-false-claims-act-allegations>.

269. <https://www.justice.gov/usao-cdca/pr/celgene-agrees-pay-280-million-resolve-fraud-allegations-related-promotion-cancer-drugs>.

270. See Third Amended Complaint at 2, *U.S. ex rel. Brown v. Celgene Corp.*, No. 10-cv-03165 (C.D. Cal. Feb. 5, 2014).

271. <https://www.justice.gov/usao-cdca/pr/celgene-agrees-pay-280-million-resolve-fraud-allegations-related-promotion-cancer-drugs>.

272. See <https://www.justice.gov/opa/pr/novo-nordisk-agrees-pay-58-million-failure-comply-fda-mandated-risk-program>.

273. See <https://www.justice.gov/opa/pr/mylan-agrees-pay-465-million-resolve-false-claims-act-liability-underpaying-epipen-rebates>.

as compared to inflation. Until recently, generic drugs manufactured by multiple companies involved lower rebates to Medicaid as they were not adjusted for inflation. The government alleged that Mylan incorrectly reported EpiPen as a generic drug to Medicaid, although it was a single-source, brand drug without a therapeutic equivalent. According to the government, Mylan sharply increased the price of EpiPen by 400% in the private market between 2010 and 2016 and avoided the full extent of its Medicaid rebate obligations based upon the incorrect generic classification despite Mylan's knowledge that EpiPen was not generic. As part of the settlement, Mylan entered into a CIA with HHS-OIG, requiring, in part, annual review by an independent review organization (IRO) of its practices and activities related to the Medicaid Drug Rebate Program.

In December 2017, Kmart Corporation agreed to pay \$58 million to resolve FCA allegations that its in-store pharmacies failed to report discounted prescription drug prices to Medicare Part D, Medicaid, and TRICARE.²⁷⁴ The underlying *qui tam* action alleged that Kmart pharmacies offered discounted generic drug prices to cash-paying customers but failed to disclose those prices in connection with its reporting of U&C pricing to the federal healthcare programs. This conduct allegedly resulted in inflated U&C pricing and increased reimbursement to Kmart for generic drugs.

Patient Assistance Programs Closely Scrutinized

DOJ continued its extensive review of multiple pharmaceutical manufacturers and charitable patient assistance programs (PAPs) that provide funding to assist financially needy patients with obtaining prescription medications for chronic illnesses. Underscoring the need for compliance related to charitable PAPs, in an unusual move, HHS-OIG rescinded retroactively its 2006 Advisory Opinion No. 06-04 (AO 06-04) issued to Caring Voice Coalition (CVC).²⁷⁵ In its November 28, 2017 rescission, HHS-OIG declared that the "public interest" required the rescission because CVC allegedly did not: (1) fully and accurately disclose "all relevant and material facts" to HHS-OIG; and (2) comply with several of the certifications of facts that CVC had made to HHS-OIG and were relied upon in AO 06-04. HHS-OIG concluded that CVC provided at least one of its donors with patient-specific information that would allow the donors to link the amount and frequency of their donations with the total number of subsidized prescriptions for their products and permitted donors to have direct or indirect influence on the structuring of CVC's disease categories. CVC did not challenge these determinations, but instead proposed to further update AO 06-04 to include provisions related to CVC's new compliance program.

HHS-OIG declined to modify AO 06-04, contending that CVC's prior factual certifications were material to its determination that CVC qualified as an independent, *bona fide* charitable organization operating between donors and patients. Specifically, HHS-OIG raised concerns

related to the steering of patients toward more expensive drugs sold by a manufacturer donor and reimbursed by a federal healthcare program. In response to the rescission of AO 06-04, CVC announced that it would no longer provide financial assistance to patients in 2018.²⁷⁶ On January 14, 2018, HHS-OIG advised the Pharmaceutical Research and Manufacturers of America (PhRMA) that it will not impose administrative sanctions under the AKS against any company that manufactures, sells or distributes outpatient prescription drugs for providing free drugs during 2018 to patients covered by federal healthcare programs who were receiving financial support for those drugs from CVC provided certain safeguards are instituted.²⁷⁷

In December 2017, pharmaceutical manufacturer United Therapeutics Corp. (UT) agreed to pay \$210 million to resolve allegations that it violated the FCA by using a charitable PAP to channel its donations to cover Medicare copays of patients using UT's pulmonary arterial hypertension drugs to encourage use of these drugs.²⁷⁸ The government alleged that UT used data obtained from the PAP related to use of donations for UT's drugs to inform UT's future donations to the

PAP. Additionally, the settlement resolves the allegation that UT did not provide free drugs to financially needy Medicare patients as it did to non-Medicare patients, but instead referred these Medicare patients to the charitable PAP, which resulted in reimbursement from Medicare. UT also entered into a five-year CIA with HHS-OIG requiring, among other things, implementation of compliance measures related to external PAPs and review by an IRO.

To protect Medicaid programs from arbitrary increases in drug prices, price increases on single-source, brand name drugs result in higher rebates to Medicaid depending on the price increase as compared to inflation. Until recently, generic drugs manufactured by multiple companies involved lower rebates to Medicaid as they were not adjusted for inflation.

274. See <https://www.justice.gov/opa/pr/kmart-corporation-pay-us-323-million-resolve-false-claims-act-allegations-overbilling-federal>.

275. <https://oig.hhs.gov/fraud/docs/advisoryopinions/2006/AdvOpn06-04A.pdf>; see also https://oig.hhs.gov/fraud/docs/advisoryopinions/2015/AdvOpn06-04_mod.pdf; <https://oig.hhs.gov/fraud/docs/advisoryopinions/2017/AdvOpnRescission06-04.pdf>.

276. <http://www.caringvoice.org/decision-2018-financial-assistance/>.

277. <https://oig.hhs.gov/compliance/alerts/guidance/stansel-letter.pdf> (To avoid administrative sanctions for provision of free drug, OIG recommended the following safeguards: (1) provide free drugs in a consistent manner to federal healthcare program patients who were receiving financial support from CVC for the same drugs as of November 28, 2017 and have been impacted by CVC's decision to cease providing support; (2) award free drugs regardless of the patient's choice of provider, practitioner, supplier or health plan; (3) the free drugs should not be billed to any federal healthcare program or third party payor, resold or counted towards the Medicare Part D true-out-of-pocket costs; (4) the provision of free drugs should not be reliant upon any future purchases or orders for other items or services; and (5) the drug company should maintain complete, accurate and contemporaneous records of any free drug provided to federal healthcare program patients.)

278. <https://www.justice.gov/opa/pr/drug-maker-united-therapeutics-agrees-pay-210-million-resolve-false-claims-act-liability>.

APPENDIX - 2017 NOTABLE SETTLEMENTS

FCA SETTLEMENTS CHART

HOSPITALS AND HOSPITAL SYSTEMS

| DATE | ENTITY | FCA ALLEGATIONS | SETTLEMENT AMOUNT |
|------------------|---|--|-------------------|
| January 19, 2017 | University of Pennsylvania Health System (UPHS) | UPHS agreed to pay \$845,000 to resolve FCA allegations that it billed Medicare for medically unnecessary stent procedures performed by two interventional cardiologists at Pennsylvania Hospital. UPHS voluntarily disclosed the allegations, from which the government started an investigation. UPHS cooperated with the government's investigation, and implemented a new quality assurance plan for procedures performed in the Pennsylvania Hospital cardiac catheterization lab. In addition, UPHS notified potentially affected patients of its internal review of stent procedures and offered free evaluations by UPHS' cardiologists. UPHS also voluntarily disclosed the allegations to state regulators. ¹ | \$845,000 |
| January 27, 2017 | Vanderbilt University | Vanderbilt University agreed to pay \$6.5 million to resolve FCA allegations in a <i>qui tam</i> action styled U.S. ex rel. D'Alessio, et al. v. Vanderbilt University, et al. (M.D. Tenn.), in which the government declined to intervene, that the medical center billed a federal healthcare program for certain operating room physician services, intensive care unit physician services, anesthesia services, and surgeries in violation of Medicare billing regulations. ² | \$6.5 million |
| February 6, 2017 | TeamHealth Holdings (successor in interest to IPC Healthcare Inc. f/k/a IPC The Hospitalists, Inc.) | TeamHealth, as successor in interest to IPC, a national physician group practice, agreed to pay \$60 million to resolve FCA allegations that it billed federal healthcare programs for higher and more expensive levels of medical service than were actually performed by pressuring hospitalists to maximize their billings and "catch up" with higher-billing peers. As part of the settlement, TeamHealth and certain subsidiaries entered into a five-year CIA with HHS-OIG. ³ | \$60 million |
| February 9, 2017 | University Behavioral Health of El Paso, LLC | A psychiatric hospital agreed to pay \$860,000 to resolve FCA allegations that one of its personal services agreements with a physician constituted illegal remuneration under the AKS and Stark Law. The government alleged the physician was paid above FMV, or for services not rendered, in exchange for referrals of Medicare-reimbursed services to the hospital. ⁴ | \$860,000 |

1. <https://www.justice.gov/usao-edpa/pr/university-pennsylvania-health-system-agrees-settle-voluntary-disclosure-improper>.
2. <https://www.tennessean.com/story/money/industries/health-care/2017/07/26/vumc-pay-millions-over-medicare-fraud-allegations/505862001>.
3. <https://www.justice.gov/opa/pr/healthcare-service-provider-pay-60-million-settle-medicare-and-medicaid-false-claims-act>.
4. <https://www.justice.gov/usao-wdtx/pr/el-paso-behavioral-health-facility-pays-860000-resolve-false-claims-act-allegations>.

| DATE | ENTITY | FCA ALLEGATIONS | SETTLEMENT AMOUNT |
|----------------|---|---|-------------------|
| April 11, 2017 | Norman Regional Hospital Authority d/b/a Normal Regional Health System; Greg Terrell; Chadwick Webber, M.D.; Merl Kardokus, M.D.; Rick Wedel, M.D.; Gautham Dehadrai, M.D.; Barbara Landaal, M.D.; Sanjay Narotam, M.D. | Norman Regional, a former administrator of the hospital, and six radiologists employed by the hospital agreed to pay \$1,618,750 to resolve FCA allegations that they submitted, or caused to be submitted, false claims for payment to Medicare for radiological services performed by radiological practitioner assistants (RPA) that required “personal” supervision, but a physician was not in the room supervising the RPA when the service was performed. ⁵ | \$1,618,750 |
| April 27, 2017 | Indiana University Health, Inc. (IU Health); HealthNet, Inc. | IU Health and HealthNet agreed to pay \$18 million to resolve FCA allegations that they engaged in an illegal kickback scheme whereby IU Health provided HealthNet with an interest-free line of credit without the expectation that a substantial portion of the loan be repaid, in order to induce the referral of HealthNet’s OB/GYN patients to IU Health’s Methodist Hospital. ⁶ | \$18 million |
| May 1, 2017 | Poplar Healthcare, PLLC; Poplar Healthcare Management, LLC (Poplar) | Poplar agreed to pay \$897,640 to resolve FCA allegations that it directly, and through a subsidiary known as GI Pathology, promoted and billed the government for diagnostic tests that were not consistent with FDA approval and not supported by adequate scientific evidence. ⁷ | \$897,640 |
| May 18, 2017 | Mercy Hospital Springfield f/k/a St. John’s Regional Health Center; Mercy Clinic Springfield Communities f/k/a St. John’s Clinic (Mercy) | Two hospitals agreed to pay \$34 million to resolve FCA allegations that they submitted false claims to Medicare for chemotherapy services rendered to patients referred by oncologists whose compensation was based, in part, on a formula that improperly took into account the value of their referrals of patients to the infusion center operated by Mercy, in violation of the Stark Law. As part of the settlement, Mercy and its affiliates entered into a five-year CIA with HHS-OIG. ⁸ | \$34 million |
| June 13, 2017 | University of Rochester | A university operating a teaching hospital agreed to pay \$113,722 to resolve self-disclosed FCA allegations that it improperly used an Evaluation and Management (E&M) billing modifier for certain ophthalmologic services claims which resulted in the university receiving overpayments to which it was not entitled. The government commended the university for self-disclosing the conduct prior to learning about a related, previously filed, <i>qui tam</i> lawsuit. ⁹ | \$113,722 |

5. <https://www.justice.gov/usao-wdok/pr/oklahoma-hospital-former-hospital-administrator-and-physicians-agree-pay-1618750-settle>.
6. <https://www.justice.gov/opa/pr/indiana-university-health-and-healthnet-pay-18-million-resolve-allegations-false-claims>.
7. <https://www.justice.gov/usao-ri/pr/poplar-healthcare-pay-nearly-900000-resolve-false-claims-act-allegations>.
8. <https://www.justice.gov/opa/pr/missouri-hospitals-agree-pay-united-states-34-million-settle-alleged-false-claims-act>.
9. <https://www.justice.gov/usao-ndny/pr/university-rochester-pay-more-100000-resolve-false-claims-act-lawsuit>.

| DATE | ENTITY | FCA ALLEGATIONS | SETTLEMENT AMOUNT |
|--------------------|---|--|-------------------|
| June 28, 2017 | PAMC, Ltd.; Pacific Alliance Medical Center, Inc. (PAMC) | The owners and operators of an acute care hospital agreed to pay \$42 million to resolve FCA allegations in a <i>qui tam</i> action styled U.S. ex rel. Chan v. PAMC, Ltd., et al. (C.D. Cal.), in which the government declined to intervene, that they billed Medicare and Medi-Cal for services rendered to patients referred by physicians with whom the defendants had improper financial relationships in the form of (1) arrangements under which the defendants allegedly paid above-market rates to rent office space in physicians' offices; and (2) marketing arrangements that allegedly provided undue benefit to physicians' practices, in violation of the AKS and the Stark Law. As part of the settlement, PAMC entered into a five-year CIA with HHS-OIG. ¹⁰ | \$42 million |
| June 30, 2017 | Carolinas HealthCare System | Carolinas HealthCare System agreed to pay \$6.5 million to resolve FCA allegations that it billed for urine tests as if they were of higher complexity than they actually were. ¹¹ | \$6.5 million |
| August 3, 2017 | The Medical Center of Central Georgia, Inc., d/b/a The Medical Center, Navicent Health (Navicent) | Navicent agreed to pay \$2,549,742 to resolve FCA allegations that it submitted bills for emergency ambulance transports that were either inflated or medically unnecessary. As part of the settlement, Navicent, which was already subject to a CIA prior to this settlement, agreed to have its CIA heightened and expanded to address the newly-resolved conduct. ¹² | \$2,549,742 |
| August 23, 2017 | St. Agnes Healthcare | St. Agnes Healthcare agreed to pay \$122,928 to resolve FCA allegations that it billed Medicare for E&M services—provided by 12 employed cardiologists—at a higher reimbursement than Medicare allowed. ¹³ | \$122,928 |
| September 1, 2017 | CHRISTUS St. Vincent Regional Medical Center; CHRISTUS Health | CHRISTUS St. Vincent Medical Center and CHRISTUS Health agreed to pay \$12.24 million to resolve FCA allegations that they made non-bona fide donations to county governments, used to fund the state share of Medicaid payments to the hospital under New Mexico's Sole Community Provider program, and thus causing the presentment of false claims by the state to the federal government under Medicaid. ¹⁴ | \$12.24 million |
| September 13, 2017 | MediSys Health Network, Inc. | The owner and operator of two hospitals agreed to pay \$4 million to resolve FCA allegations that it billed Medicare for services rendered to patients referred by physicians with whom the defendants had improper financial relationships in the form of compensation and office lease arrangements in violation of the Stark Law. ¹⁵ | \$4 million |

10. <https://www.justice.gov/opa/pr/los-angeles-hospital-agrees-pay-42-million-settle-alleged-false-claims-act-violations-arising>.
11. <https://www.justice.gov/usao-wdnc/pr/carolina-healthcare-system-agrees-pay-65-million-settle-false-claims-act-allegations>.
12. <https://www.justice.gov/usao-mdga/pr/navicent-settles-ambulance-fraud-claims-over-25mm>.
13. <https://www.justice.gov/usao-md/pr/st-agnes-healthcare-agrees-resolve-false-claims-act-allegations-overbilling-medicare>.
14. <https://www.justice.gov/opa/pr/christus-st-vincent-regional-medical-center-and-christus-health-pay-1224-million-settle>.
15. <https://www.justice.gov/opa/pr/new-york-hospital-operator-agrees-pay-4-million-settle-alleged-false-claims-act-violations>.

| DATE | ENTITY | FCA ALLEGATIONS | SETTLEMENT AMOUNT |
|--------------------|--|--|-------------------|
| September 27, 2017 | ANMED Health | A hospital agreed to pay \$7 million to resolve FCA allegations that it billed for: (1) radiation oncology services for Medicare patients when a qualified practitioner was not immediately available to provide assistance and direction throughout the radiation procedure, as required by Medicare regulations; (2) a minor care clinic as if it was an Emergency Department; and (3) for Emergency Department services as if they were provided by a physician when, in fact, the services were rendered by mid-level providers. ¹⁶ | \$7 million |
| October 4, 2017 | Bayshore Medical Center; Clear Lake Regional Medical Center; West Houston Medical Center; East Houston Regional Medical Center | Four hospitals agreed to pay \$8.6 million to settle FCA allegations that they received kickbacks in “swapping” arrangements with various ambulance companies, whereby the hospitals’ patients received free or heavily discounted ambulance transports in exchange for rights to the hospitals’ more lucrative Medicare and Medicaid transport referrals. ¹⁷ | \$8.6 million |
| October 30, 2017 | Catholic Health System (CHS) | CHS agreed to pay \$6 million to resolve FCA allegations that its subsidiary, Home & Community Based Care (f/k/a Continuing Care), billed Medicare for rehabilitation therapy services at Ultra High RUG levels that were unreasonable, not medically necessary, and unsupported by the medical records. In addition, CHS entered into a five-year CIA with HHS-OIG. ¹⁸ | \$6 million |
| November 1, 2017 | Mercy Hospital | Mercy Hospital agreed to pay \$1.514 million to resolve FCA allegations that it overbilled Medicare and Medicaid for urinalysis drug screening tests by using a billing modifier code to receive payment for multiple same-day urinalysis drug screening tests that did not arise from separate, medically necessary encounters with the same patients on the same days. ¹⁹ | \$1.514 million |
| November 17, 2017 | Meadows Regional Medical Center | Meadows Regional agreed to pay \$12.875 million to resolve FCA allegations that it submitted claims for services referred by physicians with whom Meadows Regional had improper compensation agreements, violating the Stark Law and AKS. Additionally, as part of the settlement, Meadows Regional entered into a five-year CIA with HHS-OIG. ²⁰ | \$12.875 million |
| December 1, 2017 | Pine Creek Medical Center LLC | A physician-owned hospital agreed to pay \$7.5 million to resolve FCA allegations that it paid physicians kickbacks in the form of marketing services in exchange for surgical referrals. As part of the settlement, Pine Creek agreed to enter into five-year CIA with HHS-OIG. ²¹ | \$7.5 million |

16. <https://www.justice.gov/usao-ndga/pr/anmed-health-agrees-pay-7-million-settle-false-claims-act-allegations>.
17. <https://www.justice.gov/usao-sdtx/pr/four-area-hospitals-pay-millions-resolve-ambulance-swapping-allegations>.
18. <https://www.justice.gov/usao-wdny/pr/catholic-health-pay-6000000-settle-false-claims-act-allegations>.
19. <https://www.justice.gov/usao-me/pr/mercy-hospital-pays-1514000-settle-false-claims-act-allegations>.
20. <https://www.justice.gov/usao-sdga/pr/meadows-regional-medical-center-inc-and-affiliates-pay-12875-million-resolve-alleged>.
21. <https://www.justice.gov/opa/pr/dallas-based-physician-owned-hospital-pay-75-million-settle-allegations-paying-kickbacks>.

HOSPICE

| DATE | ENTITY | FCA ALLEGATIONS | SETTLEMENT AMOUNT |
|----------------|--|--|-------------------|
| April 18, 2017 | International Tutoring Services, LLC, f/k/a International Tutoring Services, Inc., d/b/a Hospice Plus; Goodwin Hospice, LLC; Phoenix Hospice, LP; Hospice Plus, L.P.; and Curo Health Services, LLC f/k/a Curo Health Services, Inc. | Curo Health Services and hospice affiliates agreed to pay \$12.21 million to resolve FCA allegations that they paid kickbacks to a physician housecall company and medical providers in exchange for referrals to the hospice companies. The kickbacks to the physician housecall company came in the form of sham loans, a free equity interest in another entity, stock dividends, and free rental space; and, as to the medical providers, allegedly took the form of cash, gift cards, and other items of value. In addition to settling with these defendants, the government intervened and is litigating the FCA claims against two former executives in a <i>qui tam</i> action styled U.S. ex rel. Capshaw, et al. v. Bryan K. White, et al. (N.D. Tex.). ²² | \$12.21 million |
| June 16, 2017 | Genesis Healthcare, Inc. | Genesis Healthcare agreed to pay \$53.6 million to globally resolve FCA allegations regarding Genesis-acquired entities from three <i>qui tam</i> lawsuits and a separate government investigation. The government alleged that Creekside Hospice, Skilled Healthcare Group, Inc., and Skilled Healthcare, LLC submitted or caused to be submitted false claims to Medicare for services performed at Creekside by: (1) billing for hospice services for patients who were not terminally ill and so were not eligible for the Medicare hospice benefit; (2) billing for hospice services when certain Medicare conditions of payment were not satisfied; and (3) billing inappropriately for certain physician evaluation management services. The settlement resolved three other alleged schemes concerning skilled rehabilitation and nursing facilities acquired by Genesis (see SNFs Section below). ²³ | \$53.6 million |
| July 6, 2017 | Compassionate Care of Gwynedd, Inc.; Compassionate Care Hospice Group, Inc. | A hospice provider agreed to pay \$2 million to resolve FCA allegations that it admitted patients who did not qualify for hospice care and provided unneeded services to them on the basis of a medically unjustified diagnosis of "debility." ²⁴ | \$2 million |
| July 6, 2017 | Compassionate Care Hospice Group, Inc.; Compassionate Care Hospice of Atlanta, LLC (CCH Atlanta) | A hospice group agreed to pay \$2.4 million to resolve FCA allegations that it paid illegal remuneration to five contracted physicians—in the form of payments to a medical director and sham contracts with associate medical directors, in exchange for referrals—in order to induce the providers to refer patients to CCH Atlanta for hospice services and certify individuals as eligible for hospice services. ²⁵ | \$2.4 million |

22. <https://www.justice.gov/usao-ndtx/pr/hospice-companies-pay-122-million-settle-kickback-claims>.

23. <https://www.justice.gov/opa/pr/genesis-healthcare-inc-agrees-pay-federal-government-536-million-resolve-false-claims-act>.

24. <https://www.justice.gov/usao-nj/pr/hospice-company-pay-2-million-resolve-alleged-false-claims-related-unnecessary-hospice>.

25. <https://www.justice.gov/usao-ndga/pr/hospice-pay-24-million-resolve-false-claims-act-allegations>.

| DATE | ENTITY | FCA ALLEGATIONS | SETTLEMENT AMOUNT |
|-------------------|--|--|-------------------------|
| July 6, 2017 | Matthew Kolodesh; Malvina Yakobashvili; Alex Pugman; Svetlana Ganetsky | Owners of a now-defunct hospice facility agreed to turn over an estimated \$9 million in assets to resolve civil FCA allegations that they, through their former hospice, submitted false claims and records (including fabricated records) to Medicare for: (1) purported hospice care for patients who were not terminally ill; and (2) crisis care services that were not necessary or not actually provided. ²⁶ | \$9 million (estimated) |
| July 17, 2017 | Tridia Hospice Care, Inc. | A hospice provider agreed to pay \$3.104 million to resolve FCA allegations that it billed Medicare for services provided to patients who were ineligible for the Medicare hospice benefit because Tridia failed to conduct proper certifications or medical examinations necessary to certify those patients either for initial or continuing hospice eligibility. ²⁷ | \$3.104 million |
| October 30, 2017 | Chemed Corporation; Vitas Hospice Services; Vitas Healthcare Corporation | Chemed, owner and operator of Vitas Hospice Services and Vitas Healthcare, agreed to pay \$75 million to resolve FCA allegations that they billed Medicare for: (1) services to hospice patients who were not terminally ill; and (2) continuous home care services that were not necessary, not actually provided, or not performed in accordance with Medicare requirements. The government alleged that the defendants rewarded employees with bonuses for the number of patients receiving hospice services, without regard to whether they were actually terminally ill and whether they would have benefited from continuing curative care, and used aggressive marketing tactics and pressured staff to increase the volume of continuous home care claims, without regard to whether the patients actually required this level of crisis care. In addition to the settlement, Vitas entered into a five-year CIA with HHS-OIG. ²⁸ | \$75 million |
| December 21, 2017 | Haven Hospice | Haven Hospice agreed to pay \$5.085 million—based on the hospice’s ability to pay—to resolve FCA allegations that it billed Medicare and Medicaid for medically unnecessary hospice care for at least 63 patients who had lengths of stay greater than three years. The government alleged that for those patients, (1) Haven either knowingly or recklessly failed to document a valid basis for the initial start of hospice care and/or subsequent hospice coverage; (2) Haven’s diagnoses were not adequately supported, or were supported only with inconsistent practitioner information; (3) many patients failed to demonstrate objective indications of decline throughout their time in the company’s care, despite some being in hospice for nearly six years; and (4) some patients had their hospice diagnoses changed after several years when they did not show decline under their original “terminal” diagnosis. ²⁹ | \$5.085 million |

26. <https://www.justice.gov/usao-edpa/pr/defunct-philly-hospice-s-ownersoperators-pay-millions-settle-civil-false-claims-suit>.

27. <https://www.justice.gov/opa/pr/three-companies-and-their-executives-pay-195-million-resolve-false-claims-act-allegations>.

28. <https://www.justice.gov/opa/pr/chemed-corp-and-vitas-hospice-services-agree-pay-75-million-resolve-false-claims-act>.

29. <https://www.justice.gov/usao-mdfl/pr/united-states-settles-false-claims-allegations-against-haven-hospice-more-5-million>.

HOME HEALTH

| DATE | ENTITY | FCA ALLEGATIONS | SETTLEMENT AMOUNT |
|-------------------|--|--|-------------------|
| January 5, 2017 | Ultimate Nursing Services of Iowa, Inc.; Steven Tucker Anderson | A home health agency and its president agreed to pay \$1 million to settle FCA allegations that they submitted cost reports improperly, resulting in payment for non-reimbursable travel and entertainment expenses, and for non-reimbursable costs associated with services provided to the home health company by other entities owned by the president or a family member. ³⁰ | \$1 million |
| January 12, 2017 | Family Care Visiting Nurse and Home Care Agency; David A. Krett; Rita C. Krett | A home health agency and its owners agreed to pay \$5.25 million to resolve FCA allegations that the agency, at the direction of its owners, billed Medicaid for (1) 60-day assessments knowing a registered nurse had not performed the assessments as required by Medicaid; and (2) patients who were or may have been dually eligible for Medicare and Medicaid, without first adhering to required procedures for submitting claims to Medicare. As part of the settlement, the agency and its owners entered into a five-year CIA with HHS-OIG. ³¹ | \$5.25 million |
| May 26, 2017 | Abington Memorial Hospital (AMH) | AMH agreed to pay \$491,672 to resolve self-disclosed FCA allegations that an employee in its affiliated home care agency forged required physician signatures on Medicare claims for home health services. In addition to reversing and repaying certain claims, AMH took corrective measures to prevent such conduct from recurring, including terminating the employee and installing a computer program that requires physicians' electronic signatures, eliminating the need for AMH to obtain physical signatures. ³² | \$491,672 |
| July 21, 2017 | Charter Home Health, LLC; Wandell Ray Rogers; Jo Allyson Williams | A home health company agreed to pay \$1.7 million to resolve FCA allegations that, through its officers, it paid individuals for patient referrals in violation of the AKS. As part of the settlement, the company and its officers also entered into a five-year CIA with HHS-OIG. ³³ | \$1.7 million |
| September 5, 2017 | Home Health Care of East Tennessee, Inc; Home Health Care of West Tennessee, Inc.; Home Health Care Services, Inc.; Home Health Care Services II, Inc.; Health Care Staffing of Tennessee, Inc.; Home Health Care Support Services, Inc. (Home Health) | Home Health agreed to pay \$1.8 million to resolve FCA allegations that it: (1) improperly billed Medicare for home health services and, in some instances, hospice services due to compensation or other financial arrangements with certain referring physicians which either violated or failed to meet the requirements of the Stark Law; and (2) billed other services that failed to meet Medicare coverage and payment requirements due to false or invalid certifications. In 2010, Home Health voluntarily disclosed potential Stark Law violations and subsequently made additional disclosures as an internal investigation continued, concluding with this settlement. ³⁴ | \$1.8 million |

30. <https://www.justice.gov/usao-ndia/pr/iowa-home-health-company-and-its-president-agree-pay-1000000-resolve-allegations-they>.

31. <https://www.justice.gov/usao-ct/pr/connecticut-home-health-agency-and-its-owners-pay-525-million-settle-false-claims-act>.

32. <https://www.justice.gov/usao-edpa/pr/abington-memorial-hospital-pay-491672-settle-false-claims-act-liability-improper>.

33. <https://www.justice.gov/usao-mdia/pr/baton-rouge-home-health-company-settles-false-claims-act-case-17-million>.

34. <https://www.justice.gov/usao-edtn/pr/east-tennessee-based-home-health-providers-agree-pay-us-18-million-settle-false-claims>.

| DATE | ENTITY | FCA ALLEGATIONS | SETTLEMENT AMOUNT |
|------------------|---|---|-------------------|
| December 5, 2017 | Centrus Premier Home Care, Inc. d/b/a Maxim Healthcare Services, Inc. (Maxim) | Maxim agreed to pay \$14 million to resolve allegations that it improperly billed and received overpayments for services from the Massachusetts Medicaid program for home health services without a “medically predictable recurring need for nursing services or therapy services,” in violation of MassHealth home health regulations. MassHealth referred the matter to the state Medicaid Fraud Division after a voluntary provider overpayment disclosure. ³⁵ | \$14 million |

SNFs AND NURSING HOMES

| DATE | ENTITY | FCA ALLEGATIONS | SETTLEMENT AMOUNT |
|------------------|---|---|-------------------|
| February 1, 2017 | The Abbey of Le Mars, Inc.; Leo Lenaghan; John Florina, Jr.; Janet Howe; Don Butcher; Donna Stuhrenberg | A nursing facility, its owner, its president, its former director of nursing, and a paid consultant agreed to pay \$100,000 to resolve FCA allegations related to billing Medicaid for worthless nursing services. As to 16 residents, the government alleged that the facility: (1) failed to provide residents adequate nourishment or bathing and toiletry care, leading to infections that necessitated emergent care; (2) failed to address fractures, leading to more expensive care; and (3) used restraints or anti-psychotic medications to numb and sedate residents so as to decrease residents’ needs. The settlement released only Medicaid-related claims. ³⁶ | \$100,000 |
| April 10, 2017 | Prestige Administrative Services, LLC d/b/a Prestige Healthcare (Prestige) | Prestige, a nursing home operator, agreed to pay \$995,500 to resolve FCA allegations that it billed Medicare for medically unnecessary genetic testing. Specifically, the government alleged that, after Prestige provided a genetic testing company with insurance and personal medical information, as well as access to patients in its nursing homes: (1) it failed to ensure that physician orders were obtained before the testing was conducted; (2) its physicians were not aware of and did not agree with the medical necessity of the testing; and (3) it failed to ensure that its patients (or their family members, when applicable) were appropriately informed of the testing and given the opportunity to decline the testing. The government is continuing to investigate the genetic company and other related individuals. ³⁷ | \$995,500 |

35. <https://www.mass.gov/news/ag-secures-more-than-14-million-from-home-health-agency>.

36. <https://www.justice.gov/usao-ndia/pr/iowa-nursing-facility-its-ownership-and-its-management-agree-pay-100000-resolve>.

37. <https://www.justice.gov/usao-wdwi/pr/prestige-healthcare-agrees-pay-nearly-1-million-role-alleged-false-billing-genetic>.

| DATE | ENTITY | FCA ALLEGATIONS | SETTLEMENT AMOUNT |
|---------------|--|--|-------------------|
| May 31, 2017 | Andover Subacute and Rehab Center Services Two, Inc. | Andover, a skilled nursing facility agreed to pay \$888,000 to resolve federal and state FCA allegations that it provided materially substandard or worthless nursing services to certain patients that failed to meet federal standards of care and federal statutory and regulatory requirements. As part of the settlement, Andover entered into a five-year CIA with HHS-OIG. ³⁸ | \$888,000 |
| June 16, 2017 | Genesis Healthcare, Inc. | Genesis Healthcare agreed to pay \$53.6 million to globally resolve FCA allegations regarding Genesis-acquired entities from three <i>qui tam</i> lawsuits and a separate government investigation. The government alleged that (1) SunDance Rehabilitation Agency and related entities submitted or caused the submission of false claims to Medicare Part B by billing for outpatient therapy services that were not medically necessary or unskilled in nature; (2) SKG, Skilled Healthcare and/or Hallmark Rehabilitation GP, LLC, submitted or caused to be submitted false claims to federal healthcare programs-for patients spending 30 days at certain facilities and who were classified at the Ultra High RUG level for at least 65% of their rehabilitation time during their stay-by assigning a higher RUG level than necessary to patients, providing therapy to patients longer than medically necessary, and/or billing for more therapy minutes than the patients actually received; (3) Skilled Healthcare billed Medicare and Medi-Cal for services that were not rendered, grossly substandard, and/or worthless, particularly as a result of failing to provide sufficient nurse staffing to meet residents' needs; and (4) a hospice facility and related entities improperly billed Medicare for certain services (see Hospice Section above). ³⁹ | \$53.6 million |
| July 5, 2017 | Reliant Care Group, LLC; Reliant Care Management Company, LLC; Reliant Care Rehabilitative Services, LLC; various skilled nursing facilities (Reliant) | Reliant and its affiliates, including 13 skilled nursing facilities, agreed to pay \$8.3 million to resolve FCA allegations that it: (1) billed Medicare for unnecessary therapy provided to nursing home residents who had a relatively high level of independence and who were residing in a skilled nursing facility primarily because of a psychiatric condition; and (2) pressured therapists to provide therapy to residents even when the therapists believed that the therapy was medically unnecessary. As part of the settlement, Reliant and its affiliates entered into a five-year CIA with the HHS-OIG. ⁴⁰ | \$8.3 million |

38. <https://www.justice.gov/usao-nj/pr/skilled-nursing-facility-pay-888000-resolve-alleged-false-claims-related-materially>.

39. <https://www.justice.gov/opa/pr/genesis-healthcare-inc-agrees-pay-federal-government-536-million-resolve-false-claims-act>.

40. <https://www.justice.gov/usao-edmo/pr/us-reaches-83-million-civil-settlement-reliant-care-group-and-reliant-affiliated>.

| DATE | ENTITY | FCA ALLEGATIONS | SETTLEMENT AMOUNT |
|-------------------|--|---|--|
| July 17, 2017 | Foundations Health Solutions, Inc. (FHS); Olympia Therapy Inc. (Olympia); Brian Colleran; Daniel Parker | The corporate successor to FHS, a SNF management company, and Olympia, a rehab therapy services provider, agreed to pay \$15,527,844 to resolve FCA allegations that: (1) Olympia and FHS submitted or caused the submission of false claims to Medicare for medically unnecessary rehabilitation therapy services at 18 skilled nursing facilities; and (2) two partial owners (Colleran and Parker) solicited and received kickbacks to refer patients from the SNFs to an unaffiliated home healthcare provider. Colleran and Parker agreed to pay \$895,830 to resolve the matter. As part of the settlement, FHS and Colleran entered into a five-year CIA with HHS-OIG. ⁴¹ | \$16.423 million |
| October 19, 2017 | Health Services Management, Inc. (HSM) | HSM, a nursing home operator, agreed to pay \$5 million to resolve FCA allegations that it billed Medicare for services that were not provided or which were so substandard and deficient that they were worthless and potentially harmful to specific patients. As part of the settlement, HSM entered into a five-year CIA with HHS-OIG. ⁴² | \$5 million |
| November 16, 2017 | Point Loma Convalescent Hospital; Brighton Place-San Diego; Brighton Place- Spring Valley; Amaya Springs Health Care Center | Four skilled nursing facility operators agreed to pay up to \$6.9 million to resolve civil FCA allegations involving employees' payment of kickbacks to discharge planners at a hospital for patient referrals through the use of corporate credit cards to pay for gift cards, massages, tickets to sporting events, and a cruise. As part of the settlement, the nursing homes entered into five-year CIAs with HHS-OIG. The nursing homes previously entered into deferred prosecution agreements (DPAs) in 2016 to resolve related criminal allegations. ⁴³ | \$2.026 million (guaranteed) \$4.9 million (contingent) |
| November 16, 2017 | Hyperion Foundation (Hyperion); AltaCare Corp. (AltaCare); Long Term Care Services Inc.; Sentry Healthcare Acquirors, Inc.; Julie Mittleider; Douglas Mittleider | Hyperion—a nursing home operator—and its former president, AltaCare—a nursing home management company—and its CEO, and related companies agreed to pay \$1.25 million to resolve FCA allegations related to Hyperion's submission of claims to Medicare and Medicaid for grossly substandard care provided to residents at a skilled nursing facility managed by AltaCare. The allegations included failure to meet the nutritional needs of residents, overmedication of certain residents, and insufficient staffing and building operations, which resulted in physical, mental, and emotional harm to the facility's residents. ⁴⁴ | \$1.25 million |

41. <https://www.justice.gov/opa/pr/three-companies-and-their-executives-pay-195-million-resolve-false-claims-act-allegations>.

42. <https://www.justice.gov/usao-sdtx/pr/huntsville-nursing-home-pays-united-states-and-state-texas-5-million-settle-claims>.

43. <https://www.justice.gov/usao-cdca/pr/san-diego-nursing-homes-owned-la-based-brius-management-pay-69-million-resolve-kickback>.

44. <https://www.justice.gov/opa/pr/mississippi-skilled-nursing-facility-related-companies-and-executives-agree-pay-125-million>.

PHARMACEUTICAL AND DEVICE

| DATE | ENTITY | FCA ALLEGATIONS | SETTLEMENT AMOUNT |
|------------------|--|---|---|
| January 11, 2017 | Shire Holdings US AG; Shire Pharmaceuticals LLC; Shire Regenerative Medicine LLC (Shire) | Shire, a biotech company, and its subsidiaries agreed to pay \$350 million to globally resolve FCA allegations stemming from six <i>qui tam</i> lawsuits that Shire and a company it acquired (Advanced BioHealing (ABH)) employed kickbacks and other unlawful marketing methods to induce clinics and physicians to use or overuse its product "Dermagraft," a skin substitute that treats diabetic foot ulcers. The government also alleged that Shire and ABH unlawfully marketed Dermagraft for uses not approved by the FDA; made false statements to inflate Dermagraft's price; and caused improper coding, verification, or certification of Dermagraft claims and related services. Shire has been operating under a CIA since late 2014, after the alleged conduct resolved by this settlement occurred. ⁴⁵ | \$350 million |
| January 12, 2017 | Baxter Healthcare Corporation (Baxter) | Baxter agreed to pay \$2.158 million to resolve civil FCA allegations that it failed to follow current Good Manufacturing Practices (cGMP) when manufacturing sterile drug products. To resolve related criminal allegations, Baxter agreed to a resolution including a DPA and penalties and forfeiture totaling \$16 million. ⁴⁶ | \$2.158 million (civil) \$16 million (criminal penalties and forfeiture) |
| April 25, 2017 | Braden Partners, L.P. d/b/a Pacific Pulmonary Services (PPS) | A medical equipment vendor agreed to pay \$11.4 million to resolve FCA allegations that it and its general partner: (1) billed government healthcare programs for home oxygen supplies and equipment without first obtaining the required physician authorization; and (2) agreed to make patient referrals to sleep testing clinics in exchange for the clinics' agreement to refer patients to PPS for sleep therapy equipment. As part of the settlement, PPS entered into a five-year CIA with HHS-OIG. ⁴⁷ | \$11.4 million |
| May 8, 2017 | Pos-T-Vac, Inc. | Pos-T-Vac, a medical equipment supplier, agreed to pay \$1 million to resolve FCA allegations that it billed Medicare for male vacuum erection supplies that were not medically necessary, lacked documentation of medical necessity, and/or were not properly ordered by a physician. ⁴⁸ | \$1 million |

45. <https://www.justice.gov/opa/pr/shire-plc-subsiidiaries-pay-350-million-settle-false-claims-act-allegations>.

46. <https://www.justice.gov/opa/pr/baxter-healthcare-corporation-pay-more-18-million-resolve-criminal-and-civil-liability>.

47. <https://www.justice.gov/opa/pr/oxygen-equipment-provider-pays-114-million-resolve-false-claims-act-allegations>.

48. <https://www.justice.gov/usao-ks/pr/kansas-medical-supplier-pay-1-million-settle-false-claim-allegations>.

| DATE | ENTITY | FCA ALLEGATIONS | SETTLEMENT AMOUNT |
|---------------|--|--|-------------------|
| June 15, 2017 | MAK Healthcare PC d/b/a Multicare Plus; Dr. Magdiel Garcia | A DME company and its owner agreed to pay \$225,000 to resolve FCA allegations that the owner and the medical providers employed by him improperly referred Medicare beneficiaries for services and equipment to the DME company, in violation of the Stark Law. ⁴⁹ | \$225,000 |
| June 19, 2017 | James O' Connor | A DME store owner agreed to pay \$898,523 to resolve civil FCA allegations that he billed Medicare and Medicaid for more expensive models of DME than what he actually provided. The store owner also pleaded guilty to a related criminal charge. ⁵⁰ | \$898,523 |
| June 27, 2017 | Linde AG; Lincare | An oxygen and respiratory therapy services and equipment provider agreed to pay \$20 million to resolve FCA allegations in a consolidated <i>qui tam</i> action styled U.S. ex rel. Robins v. Lincare, Inc. (D. Mass), in which the government declined to intervene, that it: (1) billed federal healthcare programs for oxygen equipment and tanks, even when customers did not use or require them; (2) fabricated customer oxygen orders; and (3) improperly waived customer co-payments and deductibles. ⁵¹ | \$20 million |
| June 29, 2017 | Innovative Therapies, Inc. (ITI) | A DME manufacturer and its parent company agreed to pay \$2.715 million to resolve FCA allegations that ITI marketed certain models of their devices as DME, despite knowing that the devices did not have the expected life of a durable device, and thus caused DME suppliers to bill the devices as DME when they did not meet the standards for a durable device. A global healthcare company acquired ITI after the alleged misconduct occurred, and the government noted that it took the necessary steps to resolve this matter. ⁵² | \$2.715 million |
| July 24, 2017 | Celgene Corp. | Celgene Corp., a pharmaceutical manufacturer, agreed to pay \$280 million to resolve FCA allegations in a <i>qui tam</i> action styled U.S. ex rel. Brown v. Celgene Corp. (C.D. Cal.), in which the government declined to intervene, that it (1) promoted two cancer drugs for uses that were not FDA-approved and not covered by federal healthcare programs; (2) made or caused to be made false and misleading statements about the two drugs; and (3) paid kickbacks (e.g., speaker programs, clinical trials, advisory boards) to physicians to induce them to prescribe the drugs, in violation of the AKS. ⁵³ | \$280 million |

49. <https://www.justice.gov/usao-edpa/pr/magdiel-garcia-and-mak-healthcare-pc-dba-multicare-plus-agree-settlement-stark-law>.

50. <https://www.justice.gov/usao-ndia/pr/west-des-moines-man-pleads-guilty-providing-false-documents-during-civil-false-claims>.

51. <https://www.reuters.com/article/us-linde-lawsuit/linde-lincare-settles-u-s-whistleblower-case-for-20-million-idUSKBNI9I2GX>.

52. <https://www.justice.gov/usao-mdtn/pr/durable-medical-equipment-manufacturer-agrees-pay-2715-million-resolve-false-claims>.

53. <https://www.justice.gov/usao-cdca/pr/celgene-agrees-pay-280-million-resolve-fraud-allegations-related-promotion-cancer-drugs>.

| DATE | ENTITY | FCA ALLEGATIONS | SETTLEMENT AMOUNT |
|--------------------|---|---|-------------------|
| August 17, 2017 | Mylan, Inc.; Mylan Specialty L.P. (Mylan) | Two subsidiaries of Mylan N.V. agreed to pay \$465 million to resolve FCA allegations that Mylan knowingly misclassified EpiPen as a generic drug to Medicaid despite the absence of any therapeutically equivalent drugs, enabling it to demand massive price increases in the private market while avoiding paying a higher rebate to Medicaid. As part of the settlement, Mylan entered into a five-year CIA with HHS-OIG. ⁵⁴ | \$465 million |
| September 5, 2017 | Novo Nordisk, Inc. | Drug manufacturer Novo Nordisk agreed to pay \$46.5 million to resolve FCA allegations stemming from seven <i>qui tam</i> lawsuits that it caused the submission of false claims by (1) arming its sales force with messages that could create a false or misleading impression with physicians that the FDA-mandated Risk Evaluation and Mitigation Strategy (REMS) message for its Type II diabetes medication Victoza about the potential risk of a rare cancer associated with the use of the drug was erroneous, irrelevant, or unimportant; and (2) encouraging the sale to and use of Victoza by adult patients who did not have Type II diabetes. ⁵⁵ | \$46.5 million |
| September 8, 2017 | Galena Biopharma, Inc. (Galena) | Galena agreed to pay \$7.55 million to resolve FCA allegations that it: (1) paid multiple types of kickbacks to induce doctors to prescribe its fentanyl-based drug, Abstral; and (2) paid doctors to refer patients to the company's RELIEF patient registry study, which was nominally designed to collect data on patient experiences with Abstral, but acted as a means to induce the doctors to prescribe Abstral. Two doctors who received remuneration from Galena previously were sentenced to prison in a criminal trial in which Galena cooperated. ⁵⁶ | \$7.55 million |
| September 20, 2017 | Victor Saul | The former owner of a DME company (R&V Medical Supplies LLC (R&V)) agreed to pay \$220,000 to resolve FCA allegations that he caused false claims to be submitted to Medicare by acting in reckless disregard of several billing schemes by R&V, including directing individuals who worked at doctors' offices to write prescriptions and to prepare medical authorizations and/or physician orders that were not ordered or authorized by a physician. R&V and Saul's brother previously were convicted for related criminal charges. ⁵⁷ | \$220,000 |

54. <https://www.justice.gov/opa/pr/mylan-agrees-pay-465-million-resolve-false-claims-act-liability-underpaying-epipen-rebates>.

55. <https://www.justice.gov/opa/pr/novo-nordisk-agrees-pay-58-million-failure-comply-fda-mandated-risk-program>.

56. <https://www.justice.gov/opa/pr/galena-biopharma-inc-pay-more-755-million-resolve-alleged-false-claims-related-opioid-drug>.

57. <https://www.justice.gov/usao-edpa/pr/former-owner-durable-medical-equipment-supplier-pay-220000-resolve-civil-false-claims>.

| DATE | ENTITY | FCA ALLEGATIONS | SETTLEMENT AMOUNT |
|--------------------|--|--|---|
| September 22, 2017 | Aegerion Pharmaceuticals Inc. (Aegerion) | Aegerion agreed to pay \$28.8 million to resolve civil FCA allegations that it caused the submission of false claims for its drug, Juxtapid, as a result of (1) its promotion of the drug for patients without a diagnosis of, or consistent with, HoFH; (2) false and misleading statements to doctors that the use of Juxtapid was appropriate in patients with symptoms including high cholesterol, irrespective of whether such patients had a diagnosis of HoFH, and despite counter-indications to a diagnosis of HoFH; and (3) alteration or falsification of statements of medical necessity and prior authorizations that were submitted to federal healthcare programs. The government further contended that Aegerion covered patients' copayment obligations for Juxtapid, in violation of the AKS, by siphoning funds through an entity that claimed to be a nonprofit patient assistance organization. As part of the settlement, Aegerion entered into a five-year CIA with HHS-OIG. Aegerion also agreed to plead guilty to related criminal allegations and pay a fine and forfeiture of \$7.2 million. ⁵⁸ | \$28.8 million (civil) \$7.2 million (criminal fines and forfeiture) |
| December 20, 2017 | United Therapeutics Corp. (UT) | UT agreed to pay \$210 million to resolve FCA allegations it used a nonprofit foundation as a conduit to pay the copays of Medicare patients taking its pulmonary arterial hypertension drugs, in violation of the AKS. UT allegedly made donations to the foundation, which then used the donations to pay copays for the drugs to induce patients to purchase the drugs. UT routinely obtained usage data from the foundation to determine how much needed to be donated. As part of the settlement, the company entered into a five-year CIA with HHS-OIG. ⁵⁹ | \$210 million |

PHARMACY SERVICES

| DATE | ENTITY | FCA ALLEGATIONS | SETTLEMENT AMOUNT |
|------------------|--------------------------|--|---------------------|
| January 19, 2017 | Walgreen Co. (Walgreens) | Walgreens agreed to pay \$50 million to settle FCA allegations that it provided government beneficiaries with discounts and other monetary incentives under its Prescription Savings Club (PSC) program, to induce them to fill all their prescriptions at Walgreens pharmacies, in violation of the AKS. The government also alleged that Walgreens, despite knowing that government beneficiary participation in the PSC program was an AKS violation, nevertheless marketed the program to government beneficiaries and paid its employees bonuses for each customer they enrolled in the program, without verifying whether the customers were government beneficiaries. ⁶⁰ | \$50 million |

58. <https://www.justice.gov/opa/pr/drug-maker-aegerion-agrees-plead-guilty-will-pay-more-35-million-resolve-criminal-charges-and>.

59. <https://www.justice.gov/opa/pr/drug-maker-united-therapeutics-agrees-pay-210-million-resolve-false-claims-act-liability>.

60. <https://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-announces-50-million-settlement-walgreens-paying-kickbacks-induce>.

| DATE | ENTITY | FCA ALLEGATIONS | SETTLEMENT AMOUNT |
|-----------------|---|--|-------------------|
| April 20, 2017 | Walgreen Co. (Walgreens) | Walgreens agreed to pay \$9.86 million to resolve FCA allegations that it billed the Medi-Cal program for prescriptions for which it (1) had failed to confirm and document applicable diagnoses and/or (2) did not collect and submit documentation for non-approved diagnoses. ⁶¹ | \$9.86 million |
| May 16, 2017 | Omnicare, Inc. | Omnicare agreed to pay \$8 million to resolve FCA allegations that it designed and implemented an automated label verification system to increase business efficiency and profit that utilized a less specific drug code than the more specific National Drug Code (NDC), resulting in: (1) the submission of claims for generic drugs different from those actually dispensed to government beneficiaries; and (2) the dispensing of drugs with patient-specific labels that displayed an incorrect manufacturer or NDC. The government alleged these inaccuracies affected Omnicare's ability to properly track and, if necessary, conduct patient-level recalls of certain drugs. ⁶² | \$8 million |
| June 13, 2017 | Rhine Drug Company; Andrew "Carter" Clements, Jr. | A drug company and its pharmacist agreed to pay \$2.175 million to resolve FCA allegations that they: (1) billed Medicare for drugs that the company did not dispense to patients; and (2) violated the Controlled Substances Act by negligently failing to make, keep, or furnish certain records as required by federal law. As part of the settlement, Rhine Drug Company and Clements entered into a three-year Integrity Agreement with HHS-OIG. ⁶³ | \$2.175 million |
| July 7, 2017 | Wal-Mart Stores, Inc. | Wal-Mart paid \$1.65 million to resolve FCA allegations that it billed the Medi-Cal program for drug prescriptions on the Medi-Cal formulary for which it had (1) failed to confirm and document applicable diagnoses and/or (2) did not collect and submit documentation for non-approved diagnoses. ⁶⁴ | \$1.65 million |
| August 23, 2017 | U.S. Bioservices Corporation | A specialty pharmacy agreed to pay \$13.4 million to resolve FCA allegations that it participated in an arrangement with Novartis Pharmaceuticals to receive additional patient referrals and related benefits in exchange for refilling a higher percentage of Novartis' drug Exjade in its facilities than two other pharmacies that also dispensed Exjade, in violation of the AKS. ⁶⁵ | \$13.4 million |
| October 4, 2017 | Med-Fast Pharmacy, Inc. (Med-Fast); Med-Fast Pharmacy, LP; A Jane K, LLC; Douglas Kaleugher | A pharmacy chain, its owner, and other related entities agreed to pay \$2.67 million to resolve FCA allegations that Med-Fast submitted false claims to Medicare and Medicaid for drugs it had either recycled from long-term care facilities serviced by its institutional pharmacy or that otherwise differed from the medications identified in its claims. The government also alleged that the defendants billed Medicaid and Medicaid for the retail-packaged version of diabetes testing strips, while actually supplying patients with a cheaper mail-order-packaged version of the same strips. ⁶⁶ | \$2.67 million |

61. <https://www.justice.gov/usao-edca/pr/walgreen-co-pays-986m-settle-allegations-improper-medi-cal-billings>.

62. <https://www.justice.gov/usao-nj/pr/omnicare-inc-agrees-8-million-settlement-false-claims-act-case>.

63. <https://www.justice.gov/usao-sdga/pr/dodge-county-pharmacy-and-pharmacist-agree-pay-over-2-million-resolve-false-claims-act>.

64. <https://www.justice.gov/usao-edca/pr/wal-mart-pays-165m-settle-false-claims-act-allegations-improper-medi-cal-billings>.

65. <https://www.bizjournals.com/philadelphia/news/2017/08/24/amerisourcebergen-pharmacy-bioservices-exjade.html>.

66. <https://www.justice.gov/usao-wdpa/pr/med-fast-pharmacy-inc-and-former-exec-agree-resolve-criminal-and-civil-charges>.

| DATE | ENTITY | FCA ALLEGATIONS | SETTLEMENT AMOUNT |
|-------------------|----------------------------|---|-------------------|
| November 30, 2017 | Express Plus Pharmacy, LLC | A pharmacy agreed to pay \$170,000—based on the pharmacy’s ability to pay—to resolve FCA allegations that it billed Tricare for compounded medications prescribed by one physician that were not reimbursable because (1) they were not issued pursuant to valid physician-patient relationships; (2) the prescriptions were issued after brief phone calls with patients that violated applicable law on telemedicine; (3) the prescriptions were medically unnecessary; and/or (4) the prescriptions were tainted by kickbacks to marketers. ⁶⁷ | \$170,000 |
| December 14, 2017 | DaVita Rx LLC | A nationwide pharmacy specializing in serving patients with severe kidney disease agreed to pay \$63.7 million to resolve FCA allegations—stemming from the pharmacy’s own self-disclosures and a subsequent <i>qui tam</i> lawsuit—that the pharmacy billed federal programs for prescribed medications that never shipped, shipped but were later returned, and prescriptions that did not comply with documentation requirements such as proof of delivery, refill requests, or patient consent. The settlement also resolves alleged AKS violations that involved accepting manufacturer copayment discount cards in lieu of collecting copayments from Medicare beneficiaries, routinely writing off unpaid beneficiary debt, and extending discounts to beneficiaries who paid for their medications by credit card. The pharmacy already repaid \$22.2 million of the \$63.7 million following its self-disclosures. ⁶⁸ | \$63.7 million |
| December 18, 2017 | Glades Drugs | A pharmacy agreed to pay \$300,000 to resolve FCA allegations that it waived or failed to collect required copayments from Medicare and Tricare beneficiaries. ⁶⁹ | \$300,000 |
| December 22, 2017 | Kmart Corporation | Kmart agreed to pay \$59 million to settle FCA allegations in a <i>qui tam</i> action styled U.S. ex rel. Garbe v. Kmart Corp. (S.D. Ill.), in which the government declined to intervene, that its stores failed to report discounted prescription drug prices to Medicare Part D, Medicaid, Tricare, and certain private insurers. The lawsuit alleged the stores offered discounted generic drug prices to cash-paying customers through various club programs, but knowingly failed to disclose those prices when reporting its usual and customary prices in order to receive higher reimbursement from government healthcare programs. ⁷⁰ | \$59 million |

67. <https://www.justice.gov/usao-sdfl/pr/florida-pharmacy-and-owner-agree-pay-170000-resolve-allegations-fraudulent-claims>.

68. <https://www.justice.gov/opa/pr/davita-rx-agrees-pay-637-million-resolve-false-claims-act-allegations>.

69. <https://www.justice.gov/usao-sdfl/pr/glades-drugs-agrees-pay-united-states-300000-settle-allegations-fraudulent-claims>.

70. <https://www.justice.gov/opa/pr/kmart-corporation-pay-us-323-million-resolve-false-claims-act-allegations-overbilling-federal>.

MANAGED CARE/INSURANCE

| DATE | ENTITY | FCA ALLEGATIONS | SETTLEMENT AMOUNT |
|-------------------|--|--|-------------------|
| May 30, 2017 | Freedom Health, Inc.; Siddhartha Pagidipati; various related entities | A provider of managed care services and its related corporate entities agreed to pay \$31.695 million to resolve FCA allegations that they: (1) submitted or caused others to submit unsupported diagnosis codes to CMS, which resulted in inflated reimbursements in connection with two of their Medicare Advantage plans; and (2) made material misrepresentations to CMS regarding the scope and content of their network of providers in their application to CMS to expand into new counties in Florida and in other states. The former COO of Freedom Health agreed to pay \$750,000 to resolve his alleged role in the second scheme. In addition, Freedom Health and Optimum Health entered into a five-year CIA with HHS-OIG. ⁷¹ | \$32.5 million |
| July 17, 2017 | Visiting Nurse Service of New York; VNS Choice | A managed care plan and its nursing service agreed to pay \$4.4 million to resolve FCA allegations in a <i>qui tam</i> action, styled U.S. ex rel. Heisler v. VNS Choice, et al. (S.D.N.Y.), that they knowingly retained over \$1.6 million in Medicaid overpayments by failing to identify and disenroll certain VNS Choice members in a timely manner pursuant to a state contract; consequently continued to receive monthly capitation payments to which it was not entitled; and then, after disenrolling the members, did not repay Medicaid for the funds it had improperly received. In 2014, the government partially intervened in the same <i>qui tam</i> action to settle separate allegations against VNS Choice and initially declined to intervene as to these allegations. ⁷² | \$4.4 million |
| November 7, 2017 | Humana, Inc. | Humana agreed to pay \$1.375 million to resolve FCA allegations in a <i>qui tam</i> action styled U.S. ex rel. Graves v. Plaza Medical Centers, Corp., et al. (S.D. Fla.), in which the government declined to intervene, that Humana and co-defendants, Plaza Medical Centers and related individuals, (1) submitted false claims for payment to Medicare resulting from purportedly unsupported diagnosis codes that the defendants submitted or caused to be submitted to Medicare for Medicare Advantage members; and (2) failed to timely return overpayments to Medicare. Plaza agreed to pay \$1.625 million to resolve the allegations (see Specialty Care section below). Humana and Plaza remain in litigation with the relator regarding her request for nearly \$6.3 million in attorneys' fees and expenses. ⁷³ | \$1.375 million |
| November 14, 2017 | Progressive Casualty Insurance Co.; Progressive Garden State Insurance Co. | Two insurance companies agreed to pay \$2 million to resolve allegations that "health first" automobile insurance plans they offered improperly pushed first payer status to Medicare and Medicaid in violation of the Medicare Secondary Payer Act and Medicaid regulations. ⁷⁴ | \$2 million |

71. <https://www.justice.gov/opa/pr/medicare-advantage-organization-and-former-chief-operating-officer-pay-325-million-settle>.

72. <https://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-announces-44-million-settlement-civil-lawsuit-against-vns-choice>.

73. *U.S. ex rel. Graves v. Plaza Medical Centers, Corp., et al.*, No. 1:10-cv-23382 (S.D. Fla.), Dkt. Nos. 909, 915, 916.

74. <https://www.justice.gov/usao-nj/pr/two-insurance-companies-agree-pay-more-2-million-resolve-false-claims-act-allegations>.

LABORATORY, PATHOLOGY, RADIOLOGY AND DIAGNOSTICS

| DATE | ENTITY | FCA ALLEGATIONS | SETTLEMENT AMOUNT |
|-------------------|--|--|-------------------|
| March 13, 2017 | Charles River Laboratories International, Inc. | A laboratory services provider agreed to pay \$1.8 million to resolve self-disclosed FCA allegations that it improperly charged for labor and other associated costs that were not actually provided on certain National Institutes of Health contracts. ⁷⁵ | \$1.8 million |
| April 28, 2017 | Quest Diagnostics, Inc. (Quest) | Quest agreed to pay \$6 million to resolve FCA allegations in a <i>qui tam</i> action styled U.S. ex rel. Mayes v. Berkeley HeartLab, Inc., et al. (D. S.C.), that a subsidiary (Berkeley HeartLab), which conducts tests on blood samples, paid kickbacks to referring physicians disguised as “process and handling” fees and to patients through co-payment waivers to induce the physicians and patients to choose Berkeley over other laboratories. The government further alleged that these schemes resulted in medically unnecessary cardiovascular tests being billed to federal healthcare programs. Quest acquired Berkeley in 2011 and stopped the conduct at issue in the settlement. The government is continuing to litigate against the remaining defendants in this <i>qui tam</i> suit. ⁷⁶ | \$6 million |
| June 26, 2017 | AMI Monitoring Inc. (a/k/a Spectacor); Joseph Bogdan; Medi-Lynx Cardiac Monitoring (Medi-Lynx); Medicalgorithmics SA | Spectacor, a medical device company, and its owner agreed to pay \$10.56 million to resolve FCA allegations that they billed Medicare for more expensive levels of cardiac monitoring services than requested by ordering physicians, as a result of an enrollment procedure that only allowed the physician to enroll in the monitoring service which provided the highest rate of reimbursement. Medi-Lynx, a related company that allegedly adopted a similar enrollment procedure, and Medicalgorithmics, which subsequently acquired a controlling interest in Medi-Lynx, agreed to pay \$2.89 million to resolve these allegations. ⁷⁷ | \$13.45 million |
| December 21, 2017 | Dominion Diagnostics, Inc. | Dominion Diagnostics, a drug monitoring and screening company, agreed to pay \$815,000 to resolve FCA allegations that it billed Medicare and Medicaid for urine specimen validity testing pursuant to standing orders that did not consider whether referring physicians had actually ordered the validity testing. In addition, the government contended that Dominion adopted a new U&C rate for certain claims and impermissibly applied the rate retroactively for Medicaid claims. ⁷⁸ | \$815,000 |

75. <https://www.justice.gov/opa/pr/charles-river-laboratories-international-inc-agrees-pay-united-states-18-million-settle-false>.

76. <https://www.justice.gov/opa/pr/blood-testing-laboratory-pay-6-million-settle-allegations-kickbacks-and-unnecessary-testing>.

77. <https://www.justice.gov/opa/pr/cardiac-monitoring-companies-and-executive-agree-pay-1345-million-resolve-false-claims-act>.

78. <https://www.justice.gov/usao-vt/pr/dominion-diagnostics-pays-815000-united-states-and-state-vermont-resolve-allegations>.

SPECIALTY CARE AND OTHER PROVIDER ENTITIES

| DATE | ENTITY | FCA ALLEGATIONS | SETTLEMENT AMOUNT |
|-------------------------|--|--|------------------------|
| January 9, 2017 | MB2 Dental Solutions (MB2); Dr. Christopher Steven Villanueva; Dr. Trung Minh Tang; Dr. Mauricio Dardano; Dr. Gabriel Shahwan; Dr. Akhil Reddy; Frank Villaneuva | A dental management firm, 19 affiliated pediatric dental practices, their owners, and their head of marketing agreed to pay \$8.45 million to resolve FCA allegations that they: (1) billed Medicaid for single-surface fillings in children that were not provided; (2) paid kickbacks to Medicaid beneficiaries and their families, as well as marketers and marketing entities; and (3) used false Medicaid provider numbers to misrepresent which dentists were performing specified pediatric procedures. The owners agreed to each individually pay \$250,000, and the marketing chief agreed to pay \$100,000. As part of the settlement, MB2 and the owners entered into a five-year CIA with HHS-OIG. ⁷⁹ | \$8.45 million |
| January 13, 2017 | Medstar Ambulance, Inc.; Medstar EMS, Inc.; MetroWest Emergency Medical Services, Inc.; Pioneer Valley EMS, Inc.; Critical Systems, Inc.; Nicolas Melehov; Gregory Melehov (Medstar) | An ambulance provider, its two owners, and various subsidiaries and affiliated companies agreed to pay \$12.7 million to resolve FCA allegations that Medstar billed for: (1) services not qualified for reimbursement because the transports were not medically reasonable and necessary; (2) higher levels of services than required by patients' conditions; and (3) higher levels of services than were actually provided. As part of the settlement, Medstar agreed to a five-year CIA with HHS-OIG. ⁸⁰ | \$12.7 million |
| February 8, 2017 | Comprehensive Health Services, Inc. | A provider of workforce medical services agreed to pay \$3.818 million to resolve FCA allegations that it: (1) knowingly double-billed the United States for vision screenings, resting electrocardiograms, and blood specimen collections provided to IRS agents when those costs were already included in the bundled price for IRS new applicant exams; and (2) mischarged the government for annual full physical exams for IRS agents that were either not medically indicated or were never performed. ⁸¹ | \$3.818 million |
| May 9, 2017 | Valley Tumor Group | A radiation therapy center agreed to pay \$3 million to resolve FCA allegations that it billed federal healthcare programs for radiation oncology treatments performed by technicians when no doctor was on-site at the center. ⁸² | \$3 million |

79. <https://www.justice.gov/usao-ndtx/pr/texas-dental-management-firm-19-affiliated-dental-practices-and-their-owners-and>.

80. <https://www.justice.gov/opa/pr/medstar-ambulance-pay-127-million-resolve-false-claims-act-allegations-involving-medically>.

81. <https://www.justice.gov/usao-md/pr/health-services-contractor-agrees-pay-3818-million-settle-false-claims-act-allegations>.

82. <https://www.justice.gov/usao-cdca/pr/oncology-therapy-center-high-desert-pays-3-million-resolve-allegations-providing>.

| DATE | ENTITY | FCA ALLEGATIONS | SETTLEMENT AMOUNT |
|---------------|--|--|-------------------|
| May 30, 2017 | Complementary Support Services (CSS); Teri Dimond; Herbert Stockley | A mental health provider and its owners agreed to pay \$4.52 million to resolve FCA allegations that they improperly billed Medicaid for in-home services while knowingly violating state clinical supervision requirements and for time completing paperwork. Dimond and Stockley agreed to pay \$400,000 and \$120,000, respectively. The government also retained an additional \$1.75 million in a separate negotiated civil forfeiture settlement involving Dimond's purported transfer of \$2 million in Medicaid reimbursement out-of-state for personal use. As part of the settlement, CSS was permanently excluded from participating in federal and state health programs, and Dimond and Stockley agreed to eight-year and five-year exclusions, respectively. ⁸³ | \$4.52 million |
| June 2, 2017 | Fredericksburg Hospitalist Group, P.C. | A hospitalist group agreed to pay \$4.2 million to resolve FCA allegations that it knowingly upcoded E&M codes to the highest code levels, resulting in increased reimbursement from federal healthcare payors. ⁸⁴ | \$4.2 million |
| June 13, 2017 | Atlantic Spine & Joint Institute; Robert Claude McGrath, D.O.; Robert Christopher McGrath | A doctor, his chiropractor son, and their practice agreed to pay \$1.78 million to resolve FCA allegations that they billed Medicare for physical therapy services claiming that the physician provided the therapy even though it was in fact administered by unqualified and unlicensed employees, at times when the doctor was not even in the office to supervise. The McGraths each pleaded guilty to a related criminal charge. ⁸⁵ | \$1.78 million |
| June 15, 2017 | Wolf and Yun, P.S.C.; Dr. Bruce Wolf; Dr. Kiro John Yun | Two allergists and their practice agreed to pay \$740,578 to resolve FCA allegations that the practice improperly billed federal healthcare programs by overstating units used in allergy injections and billing for unallowable investigational allergy immunotherapy procedures. ⁸⁶ | \$740,578 |
| June 22, 2017 | Dr. James M. Crumb; Mobility Metabolism and Wellness, P.C. (MMW); Coastal Neurological Institute, P.C. | A physician and his practice agreed to pay \$980,000, and the physician's former employer—a neurosurgeon physician group—agreed to pay \$420,000, to resolve FCA allegations that they: (1) billed for medically unreasonable and unnecessary ultrasound guidance used with routine lab blood draws, and with Botox and trigger point injections; (2) manipulated billing codes to circumvent safeguards implemented by Medicare's National Correct Coding Initiative in order to duplicate bill certain ultrasound guidance codes; (3) falsified patient diagnoses in order to ensure payment; and (4) ordered inflated dosages of Botox medications that were not medically necessary and were not used on the patients for whom the medication was prescribed. As part of the settlement, Dr. Crumb entered into a three-year Integrity Agreement with HHS-OIG. ⁸⁷ | \$1.4 million |

83. <https://www.justice.gov/usao-mn/pr/minnesota-mental-health-nonprofit-and-its-leaders-pay-45-million-resolve-fraud>.

84. <https://www.justice.gov/usao-edva/pr/fredericksburg-hospitalist-group-pays-42-million-settle-civil-fraud-case>.

85. <https://www.justice.gov/usao-nj/pr/cherry-hill-doctor-and-son-admit-defrauding-medicare-agree-178-million-settlement>.

86. <https://www.justice.gov/usao-wdky/pr/kentucky-allergists-agree-pay-740578-resolve-false-claims>.

87. <https://www.justice.gov/usao-sdal/pr/local-physician-dr-james-m-crumb-and-mobile-based-physician-group-coastal-neurological>.

| DATE | ENTITY | FCA ALLEGATIONS | SETTLEMENT AMOUNT |
|-----------------|---|--|-------------------|
| June 27, 2017 | Orthopedic and Sports Medicine Center – Norman, P.C.; Dr. Mark Moses; Dr. David Bobb; Dr. William Harris; Dr. Vytautas Ringus; Dr. Steven Schultz; Dr. Brad Vogel | An orthopedic practice and its owners agreed to pay \$1.537 million to resolve FCA allegations that they billed federal healthcare programs for physician extenders, DME, physical therapy, and E&M services related to hospital consults, where documentation did not support the medical necessity and/or delivery of the same. The practice voluntarily disclosed the allegations following an internal review and audit. ⁸⁸ | \$1.537 million |
| July 14, 2017 | Narco Freedom, Inc. (Narco); Joining Hands Management, Inc. (Joining Hands); Devorah Haigler | Narco—a former operator of outpatient chemical dependency clinics, Joining Hands—an operator of short-term residences, and the co-owner of Joining Hands admitted to FCA allegations involving: (1) a kickback scheme, where Narco made monthly cash payments to Joining Hands in exchange for Haigler and others referring residents of Joining Hands' residences to Narco outpatient programs and enforcing attendance at those programs, for which Narco billed Medicaid; (2) a kickback scheme whereby Narco provided below-cost housing in its own residences to induce residents to enroll in and attend Narco's outpatient programs, and then evicted the residents as soon as Narco had collected the maximum available Medicaid funds; and (3) Narco and others directing and paying employees of its outpatient program to create false treatment records for certain patients and to backdate records. Pursuant to a court-approved consent order, the government received a \$50.5 million claim in the Narco Freedom bankruptcy proceeding, and Joining Hands and Haigler will pay \$300,000. As part of the settlement, Narco agreed to be excluded from all federal healthcare programs for 50 years. ⁸⁹ | \$50.5 million |
| July 24, 2017 | Pain Management Group P.C. (PMG) | PMG agreed to pay \$312,000 to resolve FCA allegations that it caused the submission of false claims for medically unnecessary urine drug tests and for non-FDA approved Botox, Supartz, and Eufflexa, which PMG purchased from foreign-based suppliers. ⁹⁰ | \$312,000 |
| August 2, 2017 | Atlanta Medical Clinic; Dr. Timothy Dembowski | A pain management clinic and its owner agreed to pay \$250,000 to resolve FCA allegations that the clinic billed Medicare for (1) services performed by a physician suspended from the Medicare program, but falsely described as having been performed by another physician; and (2) the administration of an unapproved knee treatment drug. ⁹¹ | \$250,000 |
| August 21, 2017 | Sightpath Medical, Inc. (n/k/a Sightpath Medical, LLC); TLC Vision Corporation (n/k/a TLC Vision (USA LLC)); James Tiffany | Two eye surgery product suppliers and their former CEO agreed to pay \$12 million to resolve FCA allegations that, to induce the use of their ophthalmological products and services, they provided physicians with luxury trips and payments under sham consulting agreements for services that were never performed or were not properly tracked, resulting in payments in excess of FMV. The government alleged that the former CEO directly participated in setting up the trips and establishing the agreements. As part of the settlement, Sightpath Medical entered into a five-year CIA with HHS-OIG. ⁹² | \$12 million |

88. <https://www.justice.gov/usao-wdok/pr/norman-orthopedic-practice-pays-1537796-resolve-allegations-false-claims-submitted>.

89. <https://www.justice.gov/usao-sdny/pr/acting-manhattan-us-attorney-settles-civil-fraud-lawsuit-against-narco-freedom-joining>.

90. <https://www.justice.gov/usao-mdtn/pr/pain-management-group-agrees-pay-312000-resolve-false-claims-act-and-overpayment>.

91. <https://www.justice.gov/usao-ndga/pr/atlanta-pain-clinic-and-its-owner-agree-pay-250000-resolve-allegations-they-violated>.

92. <https://www.justice.gov/usao-mn/pr/united-states-recovers-more-12-million-false-claims-act-settlements-alleged-kickback>.

| DATE | ENTITY | FCA ALLEGATIONS | SETTLEMENT AMOUNT |
|--------------------|--|--|-------------------|
| September 5, 2017 | Dental Dreams, LLC | A dental chain agreed to pay \$1.3 million to resolve FCA allegations that it improperly billed Medicaid for unnecessary and unjustifiable dental procedures, including surgical tooth extractions and a specific kind of oral examination. ⁹³ | \$1.3 million |
| September 7, 2017 | The Hartford Dispensary; The Hartford Dispensary Endowment Corp.; Paul McLaughlin | A substance abuse treatment provider and its former CEO agreed to pay \$627,000 to resolve FCA allegations that they made repeated false representations and false certifications that The Hartford Dispensary had a medical director, as defined by relevant regulations, who was performing the duties and responsibilities required by federal and state law. ⁹⁴ | \$627,000 |
| September 14, 2017 | Scott Quinn | The former CFO and COO of Southeast Orthopedic Specialists agreed to pay \$100,000 to resolve FCA allegations that Quinn, in his role overseeing billing and operations, routinely sought, or caused to be submitted for reimbursement, claims for ultrasound-guided injections that were medically unnecessary. In 2016, Southeast paid \$4.48 million to resolve related FCA allegations. ⁹⁵ | \$100,000 |
| September 27, 2017 | Edison Adult Medical Daycare; Dinesh Patel; Daxa Patel; Satish Mehtani | An adult daycare, its former owner, and its current owners agreed to pay \$2.72 million to resolve FCA allegations that the daycare improperly billed Medicaid despite its former owner, Dinesh Patel, having been excluded from participating in Medicaid following his 2012 conviction for accepting kickbacks. Dinesh Patel continued his involvement with the daycare despite his exclusion, and the current owners submitted claims to and received payment from Medicaid with full knowledge of Dinesh Patel's exclusion. ⁹⁶ | \$2.72 million |
| October 3, 2017 | New York Anesthesiology Medical Specialties, P.C. d/b/a New York Spine and Wellness Center | A spine and wellness center agreed to pay \$1.94 million to resolve FCA allegations that it billed for moderate sedation services when a physician had not spent at least 16 minutes face-to-face with the patient. The government alleged that the 16-minute rule was detailed in American Medical Association guidance released in 2011 and in a Medicare Administrative Contractor article in 2012, and that in 2015 a private insurance company had rejected certain of the center's claims for moderate sedation services because the "Medicare 16 minute span rule" was not satisfied, including during an audit. Even though the center utilized an independent billing company, the government contended that the center retained a contractual obligation to code its services accurately, and claimed that the billing company advised the center to review the audit findings, yet the improper billing did not stop until the center was notified of a government investigation. ⁹⁷ | \$1.94 million |

93. <https://www.justice.gov/usao-ma/pr/national-dental-clinic-chain-pay-13-million-resolve-allegations-overbilling-medicaid>.

94. <https://www.justice.gov/usao-ct/pr/connecticut-substance-abuse-treatment-provider-pays-627k-settle-false-claims-act>.

95. <https://www.justice.gov/usao-mdfl/pr/former-jacksonville-chief-financial-officer-resolves-healthcare-fraud-allegations>.

96. <https://www.justice.gov/usao-nj/pr/adult-daycare-facility-agrees-272-million-settlement-resolve-allegations-violating-false>.

97. <https://www.justice.gov/usao-ndny/pr/syracuse-area-medical-practice-pay-nearly-2-million-resolve-false-claims-act-exposure>.

| DATE | ENTITY | FCA ALLEGATIONS | SETTLEMENT AMOUNT |
|-------------------|--|---|-------------------|
| October 11, 2017 | Dr. Gurunath Thota Reddy; Memorial Herman Endoscopy and Surgery Center North Houston; United Surgical Partners International; Digestive & Liver Disease Consultants P.A. | A surgery center, a surgeon who operated in the center, and other affiliated entities agreed to pay \$1.575 million to resolve FCA worthless services allegations. The government alleged Dr. Reddy and other physicians who performed colonoscopies failed to follow established medical standards of care and sanitation, sometimes spending less than two minutes per colonoscopy or not putting on a clean gown between each procedure. ⁹⁸ | \$1.575 million |
| October 13, 2017 | First Coast Cardiovascular Institute, P.A. | A cardiovascular practice agreed to pay \$448,821 to resolve FCA allegations that, despite repeated warnings, it delayed repayment of more than \$175,000 in credit balances or overpayments owed to federal healthcare programs until being notified that the DOJ had opened an investigation into its failure to repay the government. ⁹⁹ | \$448,821 |
| November 7, 2017 | Plaza Medical Centers, Corp. (Plaza) | An operator of medical clinics agreed to pay \$1.625 million to resolve FCA allegations in a qui tam action styled <i>U.S. ex rel. Graves v. Plaza Medical Centers, Corp., et al.</i> (S.D. Fla.), in which the government declined to intervene, that Plaza, related individuals, and Humana (1) submitted false claims for payment to Medicare resulting from purportedly unsupported diagnosis codes that the defendants submitted or caused to be submitted to Medicare for Medicare Advantage members; and (2) failed to timely return overpayments to Medicare. Humana agreed to pay \$1.375 million to resolve the allegations (see Managed Care section above). Humana and Plaza remain in litigation with the relator regarding her request for nearly \$6.3 million in attorneys' fees and expenses. ¹⁰⁰ | \$1,625,000 |
| November 28, 2017 | Cardiovascular Consultants Heart Center; Dr. Kevin Boran; Dr. Michael Gen; Dr. Rohit Sundrani; Dr. Donald Gregory; Dr. William Hanks | A cardiology clinic and its shareholder physicians agreed to pay \$1.2 million to resolve FCA allegations that they billed government healthcare programs for medically unnecessary diagnostic procedures. The government alleged the clinic automatically scheduled patients for nuclear stress tests without seeing them beforehand to confirm the necessity of the procedures. ¹⁰¹ | \$1.2 million |
| December 1, 2017 | Skin Care Doctors, P.A.; Michael J. Ebertz | A dermatologist practice and its CEO and founder agreed to pay \$850,000 to resolve FCA allegations that they improperly billed Medicare by billing for free samples of a phototherapy drug and upcoding office visits, lesion removal procedures, and phototherapy services. ¹⁰² | \$850,000 |

98. <https://www.justice.gov/usao-sdtx/pr/former-president-harris-county-medical-society-and-affiliated-facilities-settle>.

99. <https://www.justice.gov/usao-mdfl/pr/jacksonville-cardiovascular-practice-agrees-pay-more-440000-resolve-false-claims-act>.

100. *U.S. ex rel. Graves v. Plaza Medical Centers, Corp., et al.*, No. 1:10-cv-23382 (S.D. Fla.), Dkt. Nos. 909, 915, 916.

101. <https://www.justice.gov/usao-edca/pr/cvc-heart-center-pay-12-m-settle-allegations-billing-health-care-programs-medically>.

102. <https://www.justice.gov/usao-mn/pr/local-dermatologist-pays-850000-settle-false-claims-act-allegations>.

| DATE | ENTITY | FCA ALLEGATIONS | SETTLEMENT AMOUNT |
|-------------------|---|--|---|
| December 8, 2017 | 21st Century Oncology Inc. (21 st Century); various subsidiaries and affiliated entities | A cancer center and certain of its affiliated entities agreed to pay \$26 million to settle FCA allegations that, in connection with the Medicare EHR Incentive Program, they submitted or caused to be submitted false attestations concerning employed physicians' use of EHR software by falsifying data regarding the company's use of EHR software, fabricating software utilization reports, and superimposing EHR vendor logos onto the reports to legitimize them. 21st Century self-disclosed these allegations to the government. The settlement also resolves allegations from a <i>qui tam</i> action that 21st Century billed for services performed pursuant to referrals from physicians whose compensation did not satisfy any exception to the Stark Law. As part of the settlement, 21st Century agreed to enter into a five-year CIA with HHS-OIG. ¹⁰³ | \$26 million |
| December 8, 2017 | APT Foundation; Lynn Madden | A behavioral health and substance abuse healthcare organization and its CEO agreed to pay \$883,859 to settle FCA allegations that, despite clear guidance from the Medicaid program and a government audit finding indicating that on-site drug testing was part of a bundled rate, they routinely referred urine drug tests for patients of the organization's clinics to an outside, independent lab, leading Massachusetts Medicaid to pay for the claims twice. ¹⁰⁴ | \$883,859 |
| December 14, 2017 | Region 8 Mental Health Services (Region 8) | Region 8, a regional community health center operating a pre-school day treatment program for children with mental health issues, agreed to pay \$6.93 million to resolve FCA allegations it was paid for services that were either not provided or were not provided by qualified individuals. As part of the settlement, the clinic entered into a five-year CIA with HHS-OIG. ¹⁰⁵ | \$6.93 million |
| December 19, 2017 | EmCare Inc. | EmCare, which provides physicians to hospitals to staff their emergency departments, agreed to pay \$29.6 million to resolve FCA allegations that it received remuneration from now-defunct Health Management Associates (HMA) to recommend patients be admitted to HMA hospitals on an inpatient basis when the patients should have been treated on an outpatient basis. The government alleged that HMA tied EmCare's retention of existing contracts and receipt of new contracts to increased inpatient admissions and that HMA made certain bonus payments to EmCare physicians. As part of the settlement, EmCare's parent company, Envision Healthcare, agreed to enter into a five-year CIA with HHS-OIG. ¹⁰⁶ | \$29.6 million |
| December 19, 2017 | Physician's Alliance Ltd. (PAL); Lee Meyers; Michael Warren, M.D.; Wallace Longton, M.D. | A physician practice group and three of its executives agreed to pay \$4 million, plus a percentage of proceeds from the sale of PAL's interest in a joint venture with HMA, to resolve FCA allegations that PAL accepted illegal remuneration from HMA to refer patients to two HMA hospitals. ¹⁰⁷ | \$4 million (and percentage of joint venture sale) |

103. <https://www.justice.gov/opa/pr/21st-century-oncology-pay-26-million-settle-false-claims-act-allegations>.

104. <https://www.justice.gov/usao-ct/pr/substance-abuse-treatment-provider-and-ceo-pay-more-800000-settle-improper-billing>.

105. <https://www.justice.gov/usao-sdms/pr/mental-health-facility-pay-almost-7-million-resolve-fraud-allegations>.

106. <https://www.justice.gov/opa/pr/two-physician-groups-pay-over-33-million-resolve-claims-involving-hma-hospitals>.

107. <https://www.justice.gov/opa/pr/two-physician-groups-pay-over-33-million-resolve-claims-involving-hma-hospitals>.

INDIVIDUAL PROVIDERS

| DATE | PROVIDER | FCA ALLEGATIONS | SETTLEMENT AMOUNT |
|-------------------|--|--|--|
| February 1, 2017 | Robert E. Windsor, Jr., M.D. | A pain management physician agreed to the entry of a \$20 million consent judgment to resolve FCA allegations that he caused the submission of false claims for surgical monitoring services that he did not perform and for medically unnecessary diagnostic tests. ¹⁰⁸ | \$20 million (consent judgment) |
| February 1, 2017 | Meir Daller, M.D. | A urologist agreed to pay \$3.81 million to resolve FCA allegations that he caused the submission of claims for medically unnecessary tests related to the detection of bladder cancer. Dr. Daller also entered into a three-year Integrity Agreement with HHS-OIG. ¹⁰⁹ | \$3.81 million |
| February 7, 2017 | Gary Marder, D.O.; Robert Kendall, M.D. | Dr. Marder, the owner and operator of a dermatology and skin cancer clinic, agreed to entry of a \$18 million consent judgment to settle FCA allegations that he billed for (1) medically unnecessary biopsies and radiation therapy services; (2) radiation therapy services performed in contravention of standard practice regarding the amount of time between radiation treatments; and (3) radiation therapy services performed without direct supervision and by unlicensed and/or unqualified physician assistants. Dr. Kendall, another physician, agreed to pay \$250,000 to resolve allegations that he billed for laboratory services tainted by kickbacks to Dr. Marder. ¹¹⁰ | \$18 million (consent judgment) |
| February 10, 2017 | Dr. Paul B. Tartell; Paul B. Tartell, M.D., P.L. | A physician and his practice agreed to pay \$750,000 to resolve FCA allegations that they: (1) routinely performed diagnostic endoscopies on patients but billed these diagnostic procedures as more expensive and intrusive surgical debridements; and (2) billed for laryngeal video stroboscopies that were not performed or were not medically necessary. ¹¹¹ | \$750,000 |
| February 16, 2017 | The Oncology Practice of Dr. Kenneth D. Nahum; Dr. Kenneth D. Nahum; Ann Walsh | An oncologist, his practice, and his spouse (the practice manager) agreed to pay \$1.7 million to resolve FCA allegations that they illegally imported and billed Medicare for unapproved chemotherapy drugs from foreign distributors. ¹¹² | \$1.7 million |
| April 20, 2017 | Dr. Norman A. Brooks, M.D. | The owner of a dermatology practice agreed to pay \$2.7 million to resolve FCA allegations that he billed Medicare for Mohs micrographic surgeries for skin cancers that were medically unnecessary. Dr. Brooks also entered into a three-year Integrity Agreement with HHS-OIG. ¹¹³ | \$2.7 million |
| April 27, 2017 | Dr. Forrest S. Kuhn, Jr. | A physician agreed to pay \$751,681 to resolve allegations that he caused the submission of false claims for intracutaneous allergy tests that were never performed. ¹¹⁴ | \$751,681 |

108. <https://www.justice.gov/usao-edky/pr/pain-management-physician-resolves-false-claims-act-allegations>.

109. <https://www.justice.gov/usao-mdfl/pr/fort-myers-urologist-agrees-pay-more-38-million-ordering-unnecessary-medical-tests>.

110. <https://www.justice.gov/usao-sdfl/pr/dr-gary-marder-and-united-states-consent-final-judgement-over-18-million-settle-false>.

111. <https://www.justice.gov/usao-sdfl/pr/plantation-physician-and-physician-practice-pay-750000-resolve-false-claims-act>.

112. <https://www.justice.gov/usao-nj/pr/oncology-practice-doctor-and-practice-manager-pay-17-million-resolve-allegations-they>.

113. <https://www.justice.gov/usao-cdca/pr/encino-dermatologist-pays-nearly-27-million-resolve-allegations-he-billed-medicare>.

114. <https://www.justice.gov/usao-wdky/pr/louisville-based-physician-settles-federal-false-claims-act-and-state-civil-claims>.

| DATE | ENTITY | FCA ALLEGATIONS | SETTLEMENT AMOUNT |
|--------------------|---|--|-------------------|
| June 27, 2017 | Dr. Anindya Sen; Patricia Posey Sen | A physician and his spouse agreed to pay \$1.2 million to resolve FCA allegations that their medical practice illegally imported and billed federal healthcare programs for unapproved anticancer and infusion drugs from foreign distributors. ¹¹⁵ | \$1.2 million |
| July 13, 2017 | Perrin D. Edwards | A podiatrist agreed to pay \$410,000 and admit to civil FCA liability involving allegations that he billed Medicare and private insurance companies for services that he never provided or that he knew were not necessary based on the patient's conditions. Edwards also pleaded guilty to related criminal charges. ¹¹⁶ | \$410,000 |
| July 24, 2017 | Dr. James Norman | The owner and operator of a parathyroid practice agreed to pay \$4 million to resolve FCA allegations that he: (1) billed for pre-operative examinations performed on the day before or the day of surgery; and (2) charged and collected extra fees from federal healthcare beneficiaries for services for which he already had received payment from the government. Dr. Norman also agreed to enter into a three-year Integrity Agreement with HHS-OIG. ¹¹⁷ | \$4 million |
| September 11, 2017 | Family Medicine Centers of South Carolina LLC (FMC); Dr. Stephen F. Serbin; Victoria Serbin | A physician-owned chain of family medicine clinics agreed to pay \$1.56 million, and its principal owner and its former laboratory director agreed to pay \$443,000, to resolve FCA allegations that they billed Medicare (1) in violation of the Stark Law, as a result of an incentive compensation plan that paid FMC's physicians a percentage of the value of laboratory and other diagnostic tests that they personally ordered through FMC; and (2) for medically unnecessary laboratory services. As part of the settlement, FMC and the Serbins agreed to enter into a five-year CIA with HHS-OIG. ¹¹⁸ | \$2 million |
| December 1, 2017 | Arthur S. Portnow, M.D., P.A. d/b/a Apple Medical and Cardiovascular Group d/b/a Apple Medical Group; Arthur S. Portnow, M.D. | A cardiovascular physician and his practice agreed to pay \$1.95 million to resolve FCA allegations that they billed Medicare for medically unnecessary echocardiograms and ultrasounds of the carotid and other arteries. As part of the settlement, they agreed to enter into a three-year Integrity Agreement with HHS-OIS. DOJ initially declined to intervene in the underlying <i>qui tam</i> action, styled U.S. ex rel. Siwicki v. Arthur S. Portnow, M.D., et al. (M.D. Fla). ¹¹⁹ | \$1.95 million |

115. <https://www.justice.gov/opa/pr/physician-and-wife-pay-12-million-settle-false-claims-act-allegations-they-billed-medicare>.

116. <https://www.justice.gov/usao-ndny/pr/kinderhook-podiatrist-pleads-guilty-health-care-fraud-pays-410000-resolve-false-claims>.

117. <https://www.justice.gov/usao-mdfl/pr/owner-tampa-parathyroid-practice-agrees-pay-4-million-resolve-false-claims-act>.

118. <https://www.justice.gov/opa/pr/south-carolina-family-practice-chain-its-co-owner-and-its-laboratory-director-agree-pay>.

119. <https://www.justice.gov/usao-mdfl/pr/sarasota-physician-agrees-pay-195-million-resolve-false-claims-act-allegations>.

MISCELLANEOUS/NON-PROVIDERS

| DATE | ENTITY | FCA ALLEGATIONS | SETTLEMENT AMOUNT |
|----------------------------|---|---|-----------------------------|
| <p>May 31, 2017</p> | <p>eClinicalWorks (ECW); Girish Navani; Rajesh Dharampuriya, M.D.; Mahesh Navani; Jagan Vaithilingam; Bryan Sequeir</p> | <p>An EHR vendor agreed to pay \$155 million to resolve FCA allegations that it falsely obtained certification for its EHR software when it concealed from its certifying entity that its software did not comply with certification requirements (e.g., modifying its software by “hardcoding” only the drug codes required for testing), causing the submission of false claims for EHR Incentive Program payments. The settlement also resolved allegations that ECW paid kickbacks to certain customers in exchange for product promotion. Under the agreement, ECW’s Chief Medical Officer, CEO and COO are jointly and severally liable for \$154.92 million, and two project managers and a developer separately will pay \$15,000 and \$50,000, respectively. ECW also entered into a five-year CIA with HHS-OIG.¹²⁰</p> | <p>\$155 million</p> |

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

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 an experienced healthcare regulatory compliance and enforcement attorney. Drawing upon his experience as a senior healthcare attorney in Washington D.C. with both HHS-OIG and DOJ, Brian 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 focuses his practice on government compliance and investigations and related FCA litigation, focusing on issues of healthcare fraud and abuse. Taylor represents healthcare providers in government inquiries and investigations by the HHS-OIG, U.S. Attorneys' Offices and the DOJ.

Bob Cooper advises clients on matters related to compliance and enforcement issues and assists clients in responding to internal government investigations. Bob rejoined the firm in 2015 after 12 years of public service, serving as legal counsel to Tennessee Governor Phil Bredesen from 2003-2006 and Attorney General from 2006-2014. While Tennessee Attorney General, Bob formed a division within the Attorney General's Office devoted to pursuing provider Medicaid fraud and recovered more than \$150 million for the state.

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 School of Law, 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 the DOJ, FTC, various state regulators and other governmental agencies.

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

John Kelly is the Managing Partner of the firm's Washington, D.C. office and is an experienced trial lawyer who represents healthcare providers, life sciences companies and individuals in investigations and enforcement actions concerning the FCA, AKS, Stark Law and the FDCA. 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.

Eli Richardson helps businesses respond to government investigations involving alleged white-collar crime or quasi-criminal civil violations. He conducts internal investigations,

advises on compliance policies, provides compliance training and helps clients in self-disclosure to government authorities. Eli previously held positions with the DOJ, including serving as Criminal Chief at the U.S. Attorney's Office and with the FBI.

Lisa Rivera focuses her practice on advising healthcare providers on matters related to civil and criminal healthcare fraud and abuse, as well as government investigations and enforcement. Lisa previously served for 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 Civil and Criminal Healthcare Fraud Coordinator and responsible for coordination of all criminal and civil healthcare fraud investigations.

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 School of Law, 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, and operational matters, including self-disclosures, voluntary repayments, overpayments, compliance plans and audits, and internal investigations.

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 hospital billing practices, medical necessity issues, and other fraud and abuse matters.

Chris Climo helps clients in the healthcare industry navigate investigations and litigation matters brought by whistleblowers and the federal government, including those under the FCA, AKS and Stark Law.

Nick Deuschle represents healthcare companies in fraud and abuse investigations, enforcement 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 investigation matters 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.

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

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

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.

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

Jeff Gibson defends individuals and companies facing white collar criminal charges, quasi-criminal civil claims and compliance violations. He leads internal investigations, addresses compliance issues and provides crisis management services.

Kaitlin Harvie represents healthcare providers in connection with internal investigations and related proceedings, focusing on issues of healthcare fraud and abuse. She has significant experience with conducting anti-corruption investigations, compliance reviews and due diligence efforts.

Kate Hunter concentrates her practice on investigations and litigation related to inquiries involving alleged violations of the FCA, the Foreign Corrupt Practices Act (FCPA), various securities laws and other federal statutes.

Brian Irving counsels 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.

Katherine Linsey focuses her practice on corporate compliance matters, including those related to healthcare fraud and abuse, and adherence to federal anti-corruption laws such as the FCA and the FCPA.

Sara Morgan represents healthcare clients on 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.

Robert Platt defends individuals and companies facing white collar criminal charges and compliance violations. He regularly represents clients in government and internal investigations matters involving DOJ, HHS-OIG, the SEC and other federal enforcement and regulatory agencies.

Molly Ruberg represents clients in connection with government enforcement actions, investigations and related civil and criminal proceedings, particularly involving matters of fraud and abuse in the healthcare sector. She routinely counsels clients related to compliance and defense of FCA violations, self-disclosures and responding to governmental inquiries.

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

Julia Tamulis advises healthcare providers on Medicare appeals and hearings related to reimbursement denials, and provides guidance on governmental investigations of healthcare providers concerning potential fraud and abuse matters. Julia previously was as 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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