



Healthcare Fraud and Abuse Review
2013

BASS BERRY SIMS  **SIMS** PLC

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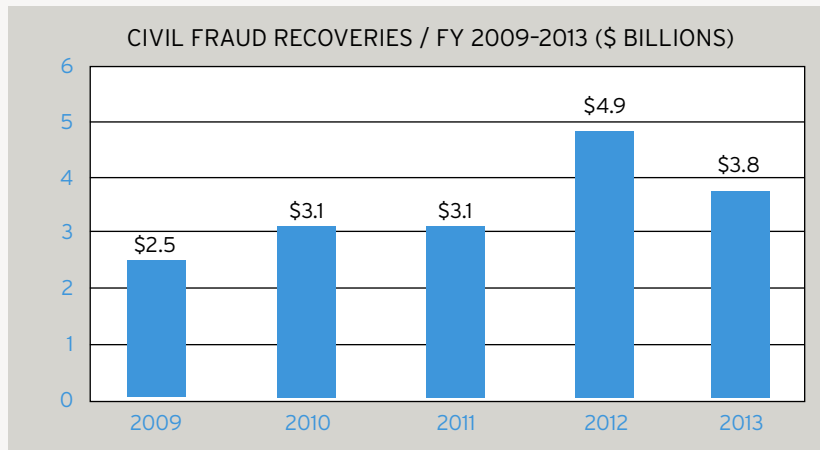
A LOOK BACK...A LOOK AHEAD

The previous year saw federal and state regulators continue the trend of increased enforcement concerning healthcare fraud and abuse.

During the fiscal year ending September 30, 2013, the federal government recovered nearly \$3.8 billion in settlements and judgments from civil cases involving fraud against the government; \$2.9 billion of this recovery stemmed from lawsuits filed under the *qui tam* provisions of the federal False Claims Act (“FCA”), and nearly \$2.6 billion of this recovery stemmed from matters involving healthcare fraud.¹ Among the largest of its FCA recoveries, the United States secured a \$237 million judgment against Tuomey Health Care based on alleged violations of the Stark Law.

Recoveries in *qui tam* cases during fiscal year 2013 totaled \$2.9 billion, with whistleblowers recovering \$388 million.

The number of *qui tam* lawsuits filed by whistleblowers likewise continues to grow at an extraordinary rate.² During the previous five years, the number of



In FY 2013, the United States recovered \$3.8 billion in fraud-related civil settlements and judgments.

new FCA lawsuits filed by whistleblowers has nearly doubled, with more than 750 new suits filed in FY 2013. For their part, whistleblowers recovered \$388 million last year as part of their share of *qui tam* settlements and judgments under the FCA.³

Equally impressive results have been secured by federal and state governments in pursuit of criminal enforcement concerning healthcare fraud and abuse laws. DOJ again secured a number of high-profile convictions and pleas in healthcare fraud matters against providers. The Medicare Fraud Strike Force filed charges against 274 individuals or entities, initiated 251 criminal actions, and secured \$333 million in investigative receivables.⁴ In May 2013, the Strike Force initiated a nationwide takedown in eight cities, which resulted in charges against 89 individuals, including doctors, nurses, and other licensed medical professionals, for their alleged participation in Medicare fraud schemes involving \$223 million in false billings.⁵ The Strike Force also scored significant results concerning home health providers, durable medical equipment, and individual physicians, among others.

For its part, the Office of the Inspector General for the U.S. Department of Health and Human Services (“HHS-OIG”) reported the exclusion of

1. See <http://www.justice.gov/opa/pr/2013/December/13-civ-1352.html>.

2. *Id.*

3. United States Department of Justice, Fraud Statistics Overview, Dec. 23, 2013, available at www.justice.gov/civil/docs_forms/C-FRAUDS_FCA_Statistics.pdf.

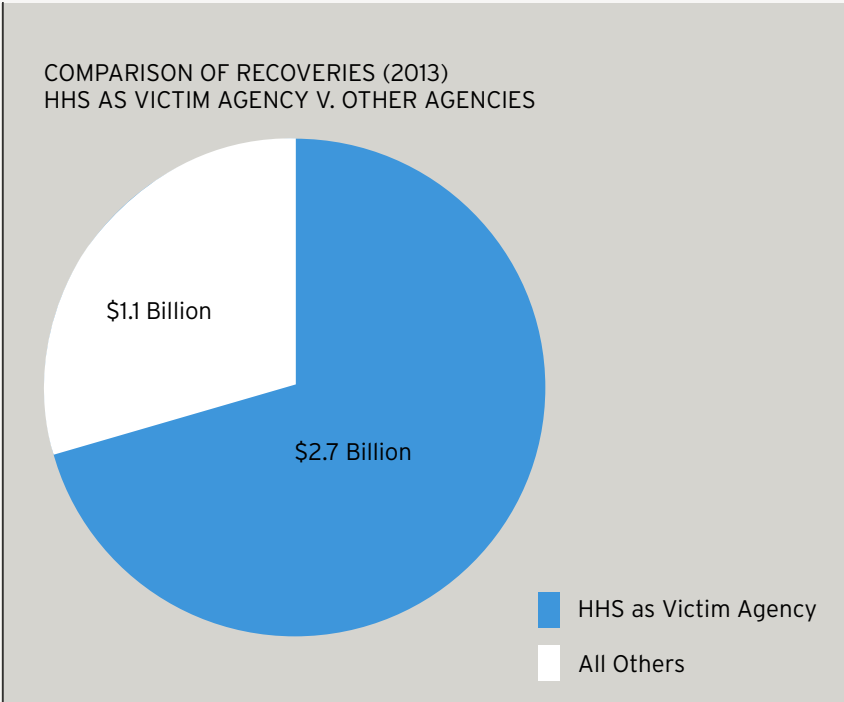
4. See <https://oig.hhs.gov/reports-and-publications/archives/semiannual/2013/SAR-F13-OS.pdf>.

5. See <http://www.justice.gov/opa/pr/2013/May/13-crm-553.html>.

3,214 individuals and entities from participation in the federal healthcare programs, 960 criminal actions against individuals and entities that engaged in crimes against HHS programs, and 472 civil actions, which included claims and unjust enrichment lawsuits filed in federal court, civil monetary penalty settlements, and administrative recoveries stemming from provider self-disclosures.⁶

In addition to the civil, criminal, and administrative enforcement results, courts grappled with a number of considerable issues arising under the FCA. Courts continue to examine public disclosure bar issues, pleading requirements, and damages under the FCA, among many other issues. There also has been a sharp increase in the number of cases seeking to expand FCA liability to Medicaid claims allegedly tainted by Stark Law violations - a possible expansion of FCA liability that providers should watch very closely in the coming year.

We hope this Healthcare Fraud and Abuse Review of 2013 will assist healthcare providers in staying abreast of legal developments relevant to their business and will offer insight as to what providers might see during the coming year. Without question, the government will continue its emphasis on enforcement and courts will consider an increasing number of complex issues arising under the FCA in the coming year.



6. See <https://oig.hhs.gov/reports-and-publications/archives/semiannual/2013/SAR-F13-OS.pdf>.

NOTEWORTHY SETTLEMENTS

Continuing the trend of the last several years, the overwhelming majority of recoveries in civil actions alleging fraud against the government involve allegations of healthcare fraud against the federal healthcare programs.

Nearly 70% of the government's recovery in civil fraud matters last year stemmed from matters involving healthcare fraud.

Despite the federal budget sequester and government shutdown in 2013, the previous year continued the trend in large healthcare fraud-related FCA settlements arising from *qui tam* litigation, federal and state investigations, and self-disclosures. Appendix A to our Healthcare Fraud and Abuse Review contains a detailed breakdown of the noteworthy settlements referenced in the trends discussed below.

The critical point in the life of a federal healthcare fraud investigation stemming from the filing of a *qui tam* lawsuit typically centers on the government's decision to intervene in a particular case. As anticipated, settlements and recoveries in intervened cases were vastly greater when the government intervened than in cases in which the government declined intervention. In settlements and judgments arising from intervened cases, the government collected more than \$2.87 billion in FY 2013 compared with only \$109 million in cases in which the government declined intervention.⁷

Because the vast majority of FCA settlements and recoveries result from lawsuits in which the U.S. has intervened, Appendix B contains a detailed breakdown of noteworthy FCA actions from the past year in which the federal government has intervened. Providers' increased willingness to litigate FCA lawsuits in which the government has intervened suggests these cases should be closely watched as they move forward.

HOSPITALS AND HEALTH SYSTEMS

As in years past, settlements involving FCA claims against hospitals and hospital systems again focused on resolution of claims for improper billing for one-day stays and short stays related to characterization of patient status as inpatient, outpatient, or observation.⁸ In addition to such cases, hospitals and hospital systems resolved several actions involving allegations of medical necessity, particularly in the cardiovascular context, and several settlements resolved claims based on allegations of unnecessary cardiac stenting.⁹ Hospitals and hospital systems also continued to resolve cases stemming from the government's investigation into kyphoplasty treatment.¹⁰

There also was a significant increase in FCA settlements resolving Stark Law and Anti-Kickback Statute allegations. These settlements typically involved allegations of improper payments to physicians for consulting services, lease arrangements, bonus compensation, and teaching agreements.¹¹

COMPARISON OF TOTAL RECOVERIES:
INTERVENED V. DECLINED CASES SETTLEMENTS AND JUDGMENTS

Year	Intervened Cases	Declined Cases
2009	\$1.96 billion	\$33.78 million
2010	\$2.28 billion	\$106.5 million
2011	\$2.65 billion	\$173.1 million
2012	\$3.20 billion	\$127.8 million
2013	\$2.87 billion	\$109.2 million

7. United States Department of Justice, Fraud Statistics Overview, Dec. 23, 2013, available at www.justice.gov/civil/docs_forms/C-FRAUDS_FCA_Statistics.pdf.

8. See Appendix A; see, e.g., <http://www.justice.gov/opa/pr/2013/February/13-civ-169.html>; <http://www.justice.gov/opa/pr/2013/August/13-civ-936.html>.

9. See Appendix A; see, e.g., <http://www.justice.gov/opa/pr/2013/January/13-civ-023.html>.

10. See Appendix A; see, e.g., http://www.justice.gov/usao/mie/news/2013/2013_7_10_jpatel_HCF.html.

11. See Appendix A; see, e.g., <http://www.justice.gov/opa/pr/2013/April/13-civ-378.html>.

The government also showed an increased focus on matters involving inadequate supervision of residents, nurses, and physician assistants.¹² We expect this topic to continue to be of interest to the government and relators.

PHYSICIAN SETTLEMENTS

Physician groups and individual physicians witnessed increased enforcement on an unprecedented level in 2013. Enforcement in the physician context often centered on physician billing, particularly allegations related to upcoding.¹³ In keeping with this recent trend, in December 2013, the U.S. announced that it intervened in an action against the largest hospitalist group in the country related to allegations the group engaged in upcoding by seeking payment for higher and more expensive levels of medical service than were actually performed.¹⁴

In addition to physician groups, there was also increased focus on individual physicians. In 2013, DOJ settled with an individual physician for \$26.1 million to resolve allegations regarding Anti-Kickback Statute violations related to a physician's relationship with a pathology laboratory.¹⁵ The settlement represents one of the largest settlements in history between DOJ and an individual.

HEALTH PLANS

We continue to see limited FCA activity concerning health plans. Last year, only one notable settlement with a health plan was reached, which concerned allegations that the plan artificially inflated patient risk adjustment scores to retain higher payments.¹⁶

LONG-TERM CARE

Hospice and home health companies remained a frequent target of federal investigations and *qui tam* litigation in 2013. As in previous years, hospice settlements primarily stemmed from allegations that hospice providers billed federal healthcare programs for medically unnecessary care with respect to ineligible patients.¹⁷ In most instances, patients allegedly lacked the requisite prognosis of six months or fewer to live.

Several FCA settlements involving long-term care providers resolved allegations of inadequate care or worthless services and unnecessary therapy services.¹⁸

PHARMACEUTICALS AND MEDICAL DEVICE COMPANIES

There were several trends in pharmaceutical-related settlements last year. Although not as many settlements reached the level of the multi-billion dollar settlements witnessed in previous years, the pharmaceutical off-label marketing settlement trend continued with several large settlements.

Settlements included off-label marketing allegations¹⁹ and Anti-Kickback Statute violations through the inducement of providers to switch government beneficiaries to a competitor drug, free continuing medical education courses and consultant meetings, and rebates and free equipment in exchange for purchasing medical devices.²⁰ Trends in 2013 also included settlements related to adulterated drugs, lack of medical necessity for devices, and encouraging physicians to submit claims with incorrect diagnosis and procedure codes.²¹

12. See Appendix A; see, e.g., <http://www.releasewire.com/Associated-Press/99911.pdf>; <http://www.justice.gov/usao/hi/news/1308wgh.html>.

13. See <http://www.justice.gov/opa/pr/2013/July/13-civ-758.html>. Other recent results include *U.S. v. Malik*, No. 1:12-cv-01234 (D.D.C.) (July 30, 2013), in which a FCA judgment was entered against a Washington, D.C.-based physician for submitting false nuclear cardiology claims by double billing for multi-day nuclear stress test studies.

14. See <http://www.justice.gov/opa/pr/2013/December/13-civ-1294.html>.

15. See <http://www.justice.gov/opa/pr/2013/February/13-civ-183.html>.

16. See Appendix A; <http://www.justice.gov/usao/cac/Pressroom/2012/112.html>.

17. See Appendix A; see, e.g., <http://www.justice.gov/opa/pr/2013/March/13-civ-326.html>.

18. See Appendix A; see, e.g., <http://www.justice.gov/usao/gan/press/2013/01-02-13.html>. <http://www.justice.gov/usao/tne/news/2013/March/030813%20Grace%20Healthcare%20Settlement.html>.

19. <http://www.justice.gov/opa/pr/2013/November/13-ag-1170.html>.

20. See Appendix A; see, e.g., <http://www.justice.gov/opa/pr/2013/May/13-civ-547.html>.

21. See Appendix A; see, e.g., <http://www.justice.gov/opa/pr/2013/July/13-civ-755.html>.

FALSE CLAIMS ACT UPDATE

Federal district and appellate courts continued to consider a wide range of legal issues arising under the FCA.

These issues involved the public disclosure bar, the pleading standards required by Rule 9(b), the pleading of falsity and materiality, and statute of limitations. Courts also considered the scope of discovery and issues related to the settlement of FCA actions. Perhaps most importantly, courts issued decisions in which relators and the government sought to significantly extend the limits of FCA liability.

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 discouraging parasitic lawsuits based on such information. Although case law, including recent decisions by the Supreme Court, generally counsels in favor of a broad interpretation of the public disclosure bar, Congress narrowed its scope as a result of amendments to the FCA set forth in the Patient Protection and Affordable Care Act ("PPACA"). Since PPACA, courts have considered the appropriate parameters of the public disclosure bar, including whether to apply the FCA's public disclosure bar as amended by PPACA depending on when the conduct and disclosures at issue occurred.

Whether to Apply the Public Disclosure Bar as Amended by PPACA

On March 23, 2010, President Obama signed PPACA into law, which, in part, amended the FCA's public disclosure bar. PPACA does not include an explicit retroactivity provision, and courts have relied upon varying approaches to determine whether to apply PPACA's amendments to the public disclosure

bar in any given case. Some courts have held that the version of the public disclosure bar that existed when the FCA action was filed should apply.²² Other courts have applied the version of the statute that was in effect when the alleged misconduct occurred.²³ At least one court has recognized the rationale of both approaches and yet noted that the version of the statute that is applied may not be outcome determinative of the public disclosure analysis.²⁴

The version of the statute applied by a court can directly affect the outcome of a public disclosure bar argument, as well as when a court takes up that argument, as PPACA removed the jurisdictional language from the public disclosure bar.²⁵ Not surprisingly, courts are split as to whether the public disclosure bar remains jurisdictional in nature after PPACA's amendments.²⁶ If a court finds that the public disclosure bar no longer is jurisdictional after the PPACA, it may refuse to consider evidence outside the pleadings when ruling on a public disclosure argument and such a decision may impact whether the relator bears the burden of proof as to whether the public disclosure bar applies.²⁷

When Are Disclosures Sufficient to Bar FCA Allegations?

In a number of recent decisions favorable to providers, courts have been hesitant to apply an unduly restrictive interpretation of the public disclosure bar and have refused to require complete identity between the public disclosures and the FCA allegations. Rather, courts have focused on the

22. See, e.g., *U.S. ex rel. Newell v. City of St. Paul, Minn.*, 728 F.3d 791, 794-95 (8th Cir. 2013); *U.S. ex rel. Chen v. EMSL Analytical, Inc.*, 2013 U.S. Dist. LEXIS 117030, *22 (S.D.N.Y. Aug. 16, 2013); *U.S. ex rel. Osheroff v. Healthspring, Inc.*, 938 F.Supp. 2d 724, 732 (M.D. Tenn. 2013); *U.S. ex rel. Oliver v. Philip Morris USA Inc.*, 2013 U.S. Dist. LEXIS 83087, at *10-11 (D.D.C. June 13, 2013).

23. See, e.g., *Leveski v. ITT Educ. Servs., Inc.*, 719 F.3d 818, 828 (7th Cir. 2013); *U.S. ex rel. Radcliffe v. Purdue Pharma L.P.*, 2013 U.S. App. LEXIS 24708, *13-24 (4th Cir. Dec. 12, 2013); *U.S. ex rel. Carter v. Halliburton Co.*, 2013 U.S. Dist. LEXIS 135087, *13-14 (E.D. Va. Sept. 19, 2013); *U.S. ex rel. Stratienko v. Chattanooga-Hamilton Cnty. Hosp. Auth.*, 2013 U.S. Dist. LEXIS 105584, *21-22 (E.D. Tenn. July 29, 2013); *U.S. ex rel. Lockey v. City of Dallas, Tex.*, 2013 U.S. Dist. LEXIS 9358, *15 (N.D. Tex. Jan. 23, 2013).

24. See, e.g., *U.S. ex rel. Whipple v. Chattanooga-Hamilton Cnty. Hosp. Auth.*, 2013 U.S. Dist. LEXIS 120615, *4-6 (E.D. Tenn. Aug. 26, 2013).

25. Compare 31 U.S.C. § 3730(e)(4) (2009) with 31 U.S.C. § 3730(e)(4) (2010).

26. Compare *U.S. ex rel. Paulos v. Stryker Corp.*, 2013 U.S. Dist. LEXIS 82294, *11 (W.D. Mo. June 12, 2013), *U.S. ex rel. Fox Rx, Inc. v. Omnicare, Inc.*, 2013 U.S. Dist. LEXIS 75696, *30 n.15 (N.D. Ga. May 17, 2013), *Stratienko*, 2013 U.S. Dist. LEXIS, *22-23 n. 6, with *U.S. ex rel. Beauchamp v. Academi Training Ctr., Inc.*, 933 F. Supp. 2d 825, 838-39 (E.D. Va. 2013).

27. See, e.g., *Chen*, 2013 U.S. Dist. LEXIS 117030, *25-26.

central question of whether the public disclosures were sufficient to put the government on notice of the potential for fraud.

In *U.S. ex rel. Stratienco v. Chattanooga-Hamilton County Hospital Authority**, the defendant argued that the relator's allegations were barred by public disclosures previously made in the news media, in other litigation, and in an FCA complaint that the government drafted against the defendant, but never filed or served. The relator argued that such disclosures should not bar her allegations because the disclosures occurred during a different time period, involved different transactions, and involved some different parties than were alleged in the *qui tam* complaint. The district court, however, rejected that argument, noting that "[n]ot a single circuit has held that a complete identity of allegations" is required and that the relator's allegations "substantially resemble[d] the allegations and transactions discussed in the public disclosures."²⁸ The district court noted that "while some of the parties to the arrangements may be different and the exact arrangements and transactions at issue may not be the same, the allegations appear to derive their very essence from matters that have already been raised" in previous public disclosures.²⁹ As such, the district court concluded that the government was already on notice that the defendant had engaged in similar activity, and the relator's allegations were sufficiently "based upon" those previous disclosures for the public disclosure bar to apply.

In *U.S. ex rel. Osheroff v. HealthSpring, Inc.**, the relator alleged that the defendants offered Medicare beneficiaries free food and transportation to induce them to enroll in their health plan. The defendants argued that such allegations had been previously publicly disclosed both through the news media and through the defendants' own websites. The district court agreed, concluding that the public disclosures tracked the "[r]elator's underlying premise" and "essential theory of liability," and, therefore, were sufficient to place the government on notice about the possibility of the alleged fraud.³⁰

*U.S. ex rel. Whipple v. Chattanooga-Hamilton County Hospital Authority** involved public disclosures derived from a government investigation and

audit. The district court rejected the relator's argument that disclosures to the government through the investigative and audit process were not sufficiently "public" to bar the allegations. The district court held that the prior audit and investigation included disclosure of both the true set of facts (*i.e.* what the defendant should have billed the government) and a false set of facts (*i.e.* what was actually billed to the government) for specific claims.³¹ Such disclosure was sufficient to put the government on notice of alleged fraud and to trigger the application of the public disclosure bar.³²

When Is a Relator an Original Source?

PPACA also amended the definition of an original source under the FCA. The amendments to the FCA, however, did not change the fact that the FCA requires relators to possess knowledge and information that is somehow separate and distinct from the publicly disclosed information to avoid the reach of the public disclosure bar.

In addition to considering the public disclosure bar issues discussed above, the district court in *Whipple** also analyzed the question of whether the relator was an original source under the FCA. With respect to the pre-PPACA original source requirements, the district court concluded that the relator did not possess the requisite "direct and independent knowledge" because his knowledge was not firsthand, derived from the source without interruption.³³ The district court noted that the alleged misconduct occurred before the relator worked for the defendant and that the relator had no firsthand knowledge concerning the circumstances surrounding the alleged submission of false claims or decisions made at the time of submitting the claims. Because the relator's knowledge was second hand and gained from other sources, it was not "direct and independent" for purposes of the pre-PPACA public disclosure bar.

With respect to the post-PPACA original source requirements, the relator argued that he offered knowledge about the defendant's culpable state of mind that was independent of and materially added to the previously disclosed facts. The district court rejected that argument, however, holding

28. 2013 U.S. Dist. LEXIS 105584, at *40-41.

29. *Id.* at *44.

30. 938 F. Supp. 2d at 733-34.

31. 2013 U.S. Dist. LEXIS 120615, at *15-16.

32. *Id.*

33. *Id.* at *22-24.

*Denotes matter handled by Bass, Berry & Sims attorneys

that “the scope of the prior [government] investigations offered ample opportunities for others to determine whether scienter existed.”³⁴

In *Osheroff**, the district court likewise took up the relator’s original source argument and held that the relator did not meet the post-PPACA original source requirements. The relator argued that the previous public disclosures did not reveal the true extent of the misconduct and that his *qui tam* complaint revealed much more serious and widespread violations than had been previously disclosed. Rejecting that argument, the district court stated that the relator’s supposedly additional information was “a matter of degree, and of little moment given that the Anti-Kickback Statute prohibits knowingly offering remuneration” that is likely to influence an individual.³⁵ The relevance of the relator’s additional information – that the defendant was offering more remuneration than previously known – was “necessarily dependent upon the fact that the [] services offered to Medicare enrollees,” information that was previously disclosed.³⁶ As such, the relator’s information was “not necessary to alert the Government to fraud that otherwise would have gone unnoticed,” and the relator was not an original source.³⁷

DEVELOPMENTS IN FCA PLEADING STANDARDS

Pleading with Particularity under Rule 9(b)

In numerous cases, federal courts examined the particularity of pleading required by Rule 9(b) of the Federal Rules of Civil Procedure in the context of FCA claims. Although courts generally agree that a relator must plead the who, what, when, where, and how of the alleged fraud, the manner in which courts applied this standard and the types of allegations considered sufficient to satisfy Rule 9(b) varied greatly.

In *U.S. ex rel. Ge v. Takeda Pharmaceutical Co. Ltd.*, the First Circuit rejected a relator’s “attempts to satisfy the Rule 9(b) requirements with a per se rule that if sufficient allegations of misconduct are made, it necessarily follows that false claims and/or material false information were filed.”³⁸ The First

Circuit explained that an FCA “complaint . . . must ‘sufficiently establish that false claims were submitted for government payment’ as a result of the defendant’s alleged misconduct.”³⁹ Even if the complaint were to have contained factual allegations sufficient to demonstrate fraudulent activity, the First Circuit concluded that it failed to allege specific details of any actual false claims resulting from that activity and, therefore, failed to satisfy Rule 9(b)’s pleading requirement.

The Fifth Circuit also interpreted Rule 9(b)’s pleading requirements strictly in *U.S. ex rel. Nunnally v. West Calcasieu Cameron Hospital*, holding that the relator had failed to plead fraud with particularity in numerous ways. Although the relator’s FCA claims were based on alleged violations of the Anti-Kickback Statute, the relator failed to plead with particularity the contents of the alleged referral agreements, the identity of the physicians involved in the alleged fraudulent scheme, any specific inducements provided to such physicians, any specific improper referrals made by such physicians, or any claims submitted by the defendant for services rendered pursuant to an illegal referral.⁴⁰ The Fifth Circuit also held that, to the extent the relator brought claims under the FCA premised on presenting false claims or making false records that were separate from the kickback allegations, those claims also failed to pass muster under Rule 9(b). Clarifying a previous ruling in which the Fifth Circuit had stated that “the contents of a false claim need not always be presented” under certain circumstances, “[t]his does not absolve [the relator] of the burden of otherwise sufficiently pleading the time, place, or identity details of the traditional standard, in order to effectuate Rule 9(b)’s function of fair notice and protection from frivolous suits.”⁴¹ Because the relator’s allegations were “entirely conclusory” and offered no “factual information with sufficient indicia of reliability,” the allegations failed to satisfy Rule 9(b).⁴²

Allegations in other actions satisfied Rule 9(b). In *U.S. ex rel. Osheroff v. Tenet HealthCare Corp.*, the district court held that the relator’s amended complaint sufficiently pleaded fraud with particularity after it had dismissed a

34. *Id.* at *25.

35. 938 F. Supp. 2d at 735.

36. *Id.*

37. *Id.*

38. 2013 U.S. App. LEXIS 24364, *19 (1st Cir. Dec. 6, 2013).

39. *Id.* at *17.

40. 519 Fed. App’x 890, 894-95 (5th Cir. 2013).

41. *Id.* at 895.

42. *Id.*

*Denotes matter handled by Bass, Berry & Sims attorneys

previous iteration of the complaint for failure to satisfy Rule 9(b). The district court held that the relator properly alleged violations of the Anti-Kickback Statute and Stark Law by providing specific examples of how the defendant underrepresented the size of the office space it leased to physicians, leased office space to physicians at rates below fair market value, and offered non-standard benefits to physician tenants as terms in the leases.⁴³ With respect to pleading inducement under the Anti-Kickback Statute, the district court held that the relator provided “a host of particular facts from which one may reasonably infer that [the defendant] offered below-market-rate leases to induce [patient] referrals,” such as requiring non-referring physicians to pay a higher rate than referring physicians and overstating the size of the leased office space to non-referring physician tenants.⁴⁴ Unlike with the relator’s previous complaint, the district court held that these new, particularized facts were sufficient to satisfy Rule 9(b)’s heightened pleading requirement.

Developments Concerning Falsity and Knowledge

In the wake of an active 2012, courts likewise have continued to address important FCA questions of falsity and knowledge. Perhaps chief among these is the reach of the implied certification theory of liability. While FCA allegations based on explicit false representations are comparably straightforward, courts often struggle in evaluating legal issues concerning FCA claims based on an implied certification. Jurisdictions remain split as to whether the FCA is a focused, fraud-based statute, or a comprehensive statute intended to remediate everything from alleged minor contractual breaches to slight regulatory infractions.

In *U.S. ex rel. Steury v. Cardinal Health, Inc.*, the Fifth Circuit considered how far the FCA reaches beyond claims that directly contain false statements.⁴⁵ In *Steury*, the relator alleged that by contracting with the U.S. Department of Veterans Affairs for the sale of medical devices, Cardinal Health had implicitly certified its compliance with the products’ warranty of merchantability. Choosing to avoid ruling broadly and definitively on the “cognizability of implied false certification claims,” the Fifth Circuit rejected the relator’s

novel merchantability theory and held that the “implied certification of an implied contract provision that is an implied prerequisite to payment” is not enough to satisfy Rule 9(b)’s heightened pleading requirements.⁴⁶ Further, the Fifth Circuit concluded that the relator failed to demonstrate that certification of compliance with those specific contractual provisions regarding merchantability, whether express or implied, was a condition without which the government would not have paid Cardinal Health: “[A]ny such claim, (whether express or implied) must assert that a certification was a ‘prerequisite’ to the payment sought.”⁴⁷ A contrary conclusion was reached by the Eighth Circuit in *U.S. ex rel. Simpson v. Bayer Healthcare (In re Baycol Prods. Litig.)*. There, the Eighth Circuit breathed new life into a previously dismissed FCA claim where the relator alleged that Bayer had submitted a claim to the U.S. Department of Defense for payment under a contract that was induced through false or fraudulent statements.⁴⁸

In *U.S. ex rel. Armfield v. Gills*, the district court considered whether a party’s reliance on the advice of a consultant in altering its billing practices can sufficiently shield it from FCA liability.⁴⁹ While the district court acknowledged that good faith reliance on advice of a healthcare consultant may refute a claim that the defendants acted with knowledge, the court found that the defendants must show that they had disclosed all material facts and that they had changed their behavior in accordance with the consultant’s advice.⁵⁰ The record was not entirely clear on these points, and the district court held that there was a sufficient dispute as to the defendants’ knowledge to justify denial of summary judgment.

Although not involving a healthcare provider, the district court’s opinion in *United States v. Science Applications International Corporation (SAIC)* provides useful guidance regarding whether a court might impute knowledge to a corporation if its employees were aware or should have been aware of the alleged fraud.⁵¹ The district court affirmed the requirement that a single employee must be aware of the behavior *and* its fraudulent nature to satisfy the knowledge requirement. That holding specifically rejected the “collective

43. 2013 U.S. Dist. LEXIS 44235, at *21-24.

44. *Id.* at *29-30.

45. 735 F.3d 202 (5th Cir. 2013) (*per curiam*).

46. *Id.*

47. *Id.*

48. 732 F.3d 869 (8th Cir. 2013).

49. 2013 US Dist. LEXIS 12475 (M.D. Fla. Jan. 30, 2013).

50. *Id.* at *38-39.

51. 2013 US Dist. LEXIS 102185 (D.D.C. Jul. 22, 2013).

[T]he FCA does not impose liability for providers' failure to anticipate needs of the [Medicare] program that have not been promulgated in regulations conditioning payment on compliance, in addition to providers' obligations to navigate the already-complicated scheme of regulations.

-*U.S. ex rel. Hobbs v. Medquest Assocs.*

knowledge requirement," which allows for a claim to succeed when one employee is aware of the behavior and another is aware that the behavior is fraudulent.⁵² The district court refused to piece together "innocent" knowledge to create the necessary intent.⁵³

In *United States v. King-Vassel*, the Seventh Circuit considered the question of whether an expert witness was necessary to prove knowledge when the claims submission process would be difficult for a lay person to understand.⁵⁴ Reversing the district court's decision, the Seventh Circuit held that the failure to identify an expert witness did not mean that a party's evidence was insufficient to establish knowledge.⁵⁵ Although the Seventh Circuit acknowledged the complicated nature of Medicaid claims processing, it nonetheless held that a plaintiff could establish that the defendant had sufficient awareness of submission of fraudulent claims absent expert proof.⁵⁶

When Are False Statements Material?

In order for a claim to be "false," - and to trigger FCA liability - it must be material to the government's decision to pay. In what is a positive development for providers, an increasing number of courts strictly construe this requirement.

In doing so, courts have held that violations of conditions of participation (as opposed to conditions of payment) typically are not material to the government's decision to pay claims for reimbursement, and therefore, cannot provide a basis for pleading an FCA violation. Nonetheless, other courts have been less eager to categorically apply this bright-line requirement, and instead have focused on the facts of a given case to determine whether the materiality requirement has been satisfied. In the previous year, courts continued to consider questions of materiality and, in several important decisions very favorable to healthcare providers, uniformly have held that violations of regulatory requirements not tied to a condition of payment are insufficient to state a claim under the FCA.

In *U.S. ex rel. Hobbs v. Medquest Assocs.*,^{*} the Sixth Circuit imposed a strict "condition of payment" requirement as a prerequisite to FCA liability.⁵⁷ In *Hobbs*, the relator and, later, the government alleged that an operator of diagnostic testing facilities violated the FCA by: (1) allowing unapproved physicians to supervise contrast procedures, and (2) submitting a claim using a former physician-owner's billing number rather than enrolling as an Independent Diagnostic Testing Facility ("IDTF").⁵⁸ Finding neither allegation to involve a violation of a condition of payment, the Sixth Circuit reversed the district court's \$11.1 million judgment in favor of the government. and reaffirmed that violations of conditions of participation are immaterial to the government's decision to pay claims for reimbursement.⁵⁹ Significantly, the Sixth Circuit was clear that the FCA is not a tool to "police technical compliance with complex federal regulations"⁶⁰ and that the appropriate remedy for mere regulatory noncompliance is administrative sanctions, not the "extraordinary remedies"⁶¹ of the FCA.

In another case considering IDTF enrollment issues, *U.S. ex rel. Ortloano v. Amin Radiology*, the district court considered whether enrollment of an imaging center as a physician practice, rather than as an IDTF, rendered all claims submitted to Medicare false.⁶² Adopting the Sixth Circuit's approach most recently articulated in *Hobbs*, the district court reasoned that because

52. *Id.* at *26.

53. *Id.* at *27.

54. 2013 US App. LEXIS 17989 (7th Cir. Aug. 28, 2013).

55. *Id.* at *11.

56. *Id.* at *14-15.

57. 711 F.3d 707 (6th Cir. 2013).

58. *Id.* at 709.

59. *Id.* at 716.

60. *Id.* at 717 (quotations omitted).

61. *Id.* at 713.

62. 2013 U.S. Dist. LEXIS 143206 (M.D. Fla. Oct. 3, 2013).

*Denotes matter handled by Bass, Berry & Sims attorneys

the relator could not point to any Medicare regulation that conditioned payment on proper classification of the imaging center – or any regulation that was at all violated – improper enrollment did not give rise to material falsity, as is required as a condition precedent for FCA liability.⁶³

The Eighth Circuit also reaffirmed its view that allegations of regulatory noncompliance are insufficient to state a claim under the FCA.⁶⁴ In *U.S. ex rel. Ketroser v. Mayo Foundation*, the relators argued that Mayo fraudulently billed Medicare by preparing and creating initial tissue sample slides but not preparing corresponding written reports.⁶⁵ Reasoning that “the FCA does not encompass those instances of regulatory noncompliance that are irrelevant to the government’s disbursement decisions,” the Eighth Circuit held that relators had failed to plead materiality.⁶⁶ In requiring that the alleged violations be tied to payment decisions, the Eighth Circuit held that “[t]he False Claims Act may not properly be used to impose an onerous and costly burden on the healthcare system without plausible evidence that Medicare would consider such redundant reports to be a material condition of payment.”⁶⁷

FCA STATUTE OF LIMITATIONS

After lying dormant for more than 40 years, a little-known and little-used World War II-era criminal code provision is threatening to upend the FCA’s six-year statute of limitations and expose providers to open-ended and extensive liability for otherwise stale claims.

The Wartime Suspension of Limitations Act (“WSLA”), 18 U.S.C. § 3287, provides that “[w]hen the United States is at war or Congress has enacted a specific authorization for the use of the Armed Forces . . . the running of the statute of limitations applicable to any offense (1) involving fraud or attempted fraud against the United States . . . shall be suspended until 5 years after the termination of hostilities as proclaimed by Presidential proclamation, with notice to Congress, or by a concurrent resolution of Congress.”

In October 2008, Congress amended the WSLA, significantly extending its scope to include specific authorizations by Congress for the use of the Armed Forces.⁶⁸ With relators and the government recently arguing for the WSLA’s applicability in FCA cases, a jurisdictional split has arisen in the case law. The diverging interpretations on the reach of the law continued in 2013, and the U.S. Supreme Court ultimately may weigh in on this issue.

Of particular note is the Fourth Circuit’s opinion in *U.S. ex rel. Carter v. Halliburton Co.*⁶⁹ In *Carter*, the Fourth Circuit overturned a district court opinion finding the pre-amendment WSLA inapplicable in a relator-initiated, non-intervened FCA case. The Fourth Circuit held that the WSLA applies to: (1) both criminal and civil actions; (2) actions where the U.S. is not a party; and (3) relator-initiated claims. Because the Fourth Circuit determined that the U.S. has been “at war” with Iraq since October 11, 2002, the Fourth Circuit concluded that the WSLA tolled the limitations period for the relator’s FCA claims regarding fraudulent billing for services provided to military forces in Iraq – claims which otherwise would have been barred by the FCA’s six-year statute of limitations.

Unfortunately for healthcare providers facing *qui tam* litigation, certain district courts have expanded the WSLA’s reach beyond military contracting and into the healthcare and financial services industries. In *U.S. ex rel. Paulos v. Stryker Corp.*, the district court held that the WSLA as amended does not apply strictly to “war frauds.” As a result, the FCA claims in the non-intervened *qui tam*, which were premised on allegations of medical device marketing fraud, were tolled due to the congressional authorization of the use of force for Afghanistan in September 2011.⁷⁰

In *United States v. Wells Fargo Bank, N.A.*, an FCA action brought directly by the U.S. involving allegations of misconduct in originating and underwriting government-insured home mortgage loans, the district court explained that, in applying the WSLA, “it makes no difference that the fraud in this case was . . . unrelated to the Iraqi or Afghani conflicts” as “[t]he WSLA

63. *Id.* at 20-21.

64. 729 F.3d 825 (8th Cir. 2013).

65. *Id.* at 826.

66. *Id.* at 829.

67. *Id.* at 832.

68. The WSLA was amended by the Wartime Enforcement of Fraud Act of 2008.

69. 710 F.3d 171 (4th Cir. 2013).

70. 2013 U.S. Dist. LEXIS 82294 (W.D. Mo. June 12, 2013).

[T]he legislative history and Congressional intent behind both the WSLA and the FCA caution against application of the WSLA's tolling provisions to private FCA claims.

–*U.S. ex rel. Emanuele v. Medicor Assocs.*

serves not only to allow the government to combat fraud related to wartime procurement programs, but also to give the government sufficient time to investigate and prosecute pecuniary frauds of any kind committed while the nation is distracted by the demands of war.”⁷¹ The district court also rejected the defendant’s argument that the amendments to the WSLA were not retroactive, holding that any FCA “claims that were live as of October 24, 2008, when the WSLA was amended to apply to congressional authorizations for the use of military force, are timely.”

Not all courts, however, have interpreted the WSLA so broadly. In *U.S. ex rel. Emanuele v. Medicor Associates*, the district court provided a detailed analysis of both the majority and dissenting opinions in the Fourth Circuit’s opinion in *Carter*, ultimately rejecting the Fourth Circuit’s reasoning and concluding that the WSLA is inapplicable to a private FCA action (involving physician kickback allegations) in which the government declines to intervene.⁷² Specifically, the district court explained that “the legislative history and Congressional intent behind both the WSLA and the FCA caution against application of the WSLA’s tolling provisions to private FCA claims.”⁷³ To hold otherwise, the district court observed, would directly thwart the FCA’s purpose by “allowing private relators to take advantage of the WSLA’s tolling provisions”⁷⁴ by giving relators a “strong financial incentive”⁷⁵ to allow claims to build up over time in order to maximize the potential recovery.

In August 2013, Appellants-Petitioners in *Carter* filed a petition for writ of certiorari with the U.S. Supreme Court seeking review of the Fourth Circuit’s WSLA decision.⁷⁶ The Supreme Court has since invited the U.S. Solicitor General to file a brief expressing the views of the U.S. in this case. Should the Supreme Court grant certiorari, its opinion could have significant ramifications for defendants currently facing the prospect of ever-increasing costs and unpredictable liabilities arising from the WSLA’s tolling provision.

REVERSE FALSE CLAIMS CASES

Known as involving “reverse false claims,”⁷⁷ § 3729(a)(1)(G) provides for FCA liability where a defendant either: (1) knowingly makes, uses, or causes to be made or used a false record or statement material to an obligation to pay money to the government, or (2) knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay money to the government.⁷⁸ Like claims asserted under § 3729(a)(1)(A) and § 3729(a)(1)(B), reverse false claims allegations are subject to the heightened pleading standards of Rule 9(b).

The possibility of facing such claims has taken on increased significance for healthcare providers, as the Fraud Enforcement Recovery Act (“FERA”) amended the FCA such that knowing retention of overpayments is now explicitly actionable under the FCA. A healthcare provider’s affirmative obligation to investigate potential Medicare and Medicaid overpayments and, accordingly, to follow up on any evidence of such overpayments was emphasized by the district court in *U.S. ex rel. Keltner v. Lakeshore Med. Clinic, Ltd.*⁷⁹ The district court held that relator had satisfied Rule 9(b)’s heightened pleading requirements based on allegations that the defendant, a multi-specialty medical group, was overbilling Medicare by upcoding and intentionally refusing to investigate instances of improper coding. The district court held that relator “plausibly suggest[ed] that [defendant] acted with reckless disregard for the truth and submitted some false claims” and highlighted that if the “government

71. 2013 U.S. Dist. LEXIS 136539 (S.D.N.Y. Sept. 24, 2013).

72. 2013 U.S. Dist. LEXIS 104650 (W.D. Pa. July 26, 2013).

73. *Id.* at 20.

74. *Id.* at 19.

75. *Id.* at 14.

76. See *Kellogg Brown & Root Servs. v. U.S. ex rel. Carter*, No. 12-1497 (U.S. 2013), petition for writ of certiorari filed June 24, 2013.

77. 2013 U.S. Dist. LEXIS 97991, *58 (E.D. Mich. July 15, 2013).

78. 31 U.S.C. § 3729(a)(1)(G).

79. 2013 U.S. Dist. LEXIS 44640 (E.D. Wis. March 28, 2013).

overpaid defendant for . . . services and defendant intentionally refused to investigate the possibility that it was overpaid, it may have unlawfully avoided an obligation to pay money to the government.”⁸⁰

Although principally a public disclosure bar case as discussed above, the district court in *Osheroff* also considered whether the relator properly pleaded a reverse false claim.⁸¹ The relator alleged that defendant charged physicians below-market lease rates in order to induce referrals. Finding that the relator failed to allege that defendant committed fraud “for the purpose to conceal, avoid, or decrease an obligation to pay money to the government,” the district court dismissed the reverse false claim count.⁸² Specifically, the district court found that the relator failed to plead particular facts from which one could infer that Tenet owed an obligation to the government or made a fraudulent statement to avoid or decrease it.⁸³

Whether the relator pleaded a reverse false claims FCA claim in accordance with Rule 9(b) was at issue in *U.S. ex rel. Saldivar v. Fresenius Med. Care Holdings, Inc.* The relator alleged that the defendant, a dialysis services provider, was fraudulently billing Medicare and Medicaid for injectable drugs that it received free of charge as “overfill” in each vial.⁸⁴ In partially denying relator leave to file a third amended complaint, the district court reasoned that the relator’s reverse false claim allegations were not appropriately pleaded.⁸⁵ Absent allegations that the relator actually submitted a claim for payment to the federal government for “ghost overfills,” the court found the reverse false claim was not pled with the particularity demanded by Rule 9(b).⁸⁶

DEVELOPMENTS REGARDING DAMAGES

There have been a number of significant decisions concerning the manner in which damages should be calculated under the FCA. In *United States v. Anchor Mortgage Corp.*, the Seventh Circuit explained that when calculating the government’s actual damages that may be trebled under the FCA,

Basing damages on net loss is the norm in civil litigation....The district judge must recalculate the award using the net trebling approach.

-United States v. Anchor Mortgage Corp.

courts must look to the “net loss” sustained by the government rather than the gross amount paid on any false claims.⁸⁷ In endorsing what has been referred to as the “net trebling approach,” the Seventh Circuit rejected the government’s argument for “gross trebling,” which would apply any reduction to actual damages after trebling. While not in the healthcare context, the decision in *Anchor Mortgage* nonetheless offers providers an argument in favor of reducing damages in cases in which the government seeks an FCA recovery without suffering actual damages. Such a scenario might include an FCA claim based on a violation of the Anti-Kickback Statute in which the government seeks to recover reimbursement for medically necessary claims tainted by the alleged kickbacks. It remains to be seen whether courts will apply *Anchor Mortgage* in such a context.

In *SAIC*, the government sought the total amount paid to SAIC under its agreement with a federal agency as a result of what the government characterized as false claims and statements relating the SAIC’s failure to disclose certain conflicts. The district court explained that to recover the full amount that the government paid, the government must show by a preponderance of the evidence that the value of SAIC’s performance under the contract was completely compromised by the false claims and false statements.⁸⁸ The district court rejected SAIC’s claim that there was not sufficient evidence to allow this question to proceed to the jury and denied SAIC’s motion for summary judgment.

80. *Id.* at 10.

81. 2013 U.S. Dist. LEXIS 44235 (S.D. Fla. Mar. 27, 2013).

82. *Id.* at 30-31.

83. *Id.* at 31.

84. 2013 U.S. Dist. LEXIS 136970 (N.D. Ga. Sept. 17, 2013).

85. *Id.* at 29-30.

86. *Id.*

87. 711 F.3d 745 (7th Cir. 2013). See also *U.S. ex rel. Humane Society v. Hallmark Meat Packing Co.*, 2013 U.S. Dist. LEXIS 126946 (C.D. Cal. Apr. 30, 2013) (considering various damages arguments and discussing the Ninth Circuit’s approach to the calculation of damages).

88. 2013 U.S. Dist. LEXIS 102185, *63-68.

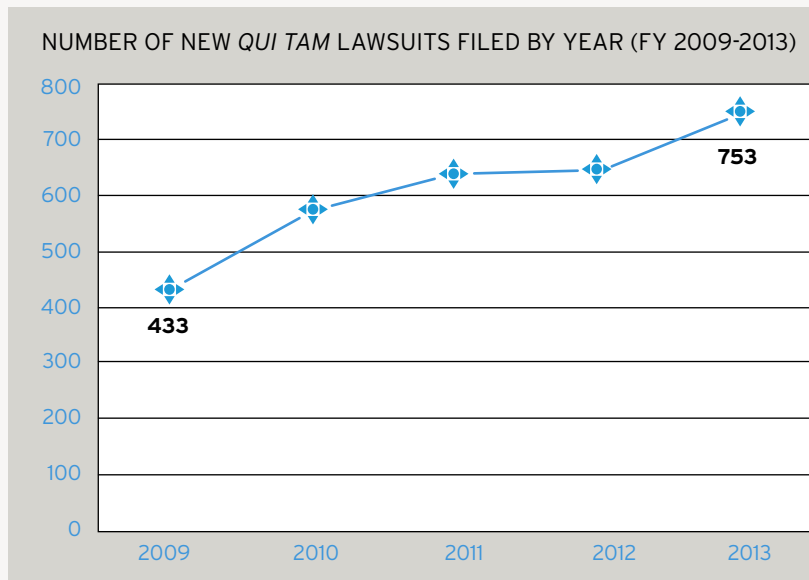
DEVELOPMENTS REGARDING RELATORS

Considering the First-to-File Rule

The first-to-file rule provides that a relator cannot maintain a *qui tam* action if a different relator already has filed a *qui tam* complaint regarding the same allegations. In *U.S. ex rel. Heineman-Guta v. Guidant Corp.*, the First Circuit considered whether the first-to-file rule requires that the first-filed complaint meet the heightened pleading requirements of Rule 9(b) to bar a later-filed complaint.⁸⁹ In affirming the decision of the district court, the First Circuit concluded that a previously-filed complaint bars a later-filed complaint if the later-filed complaint states all the essential facts of a previously-filed complaint or the same elements of fraud as described in the earlier suit. According to the First Circuit, the first-filed complaint did not have to meet the requirements of Rule 9(b) in order to bar the later-filed complaint.

FCA Retaliation Claims

The FCA protects whistleblowers who engage in protected activity under the FCA by prohibiting employers from taking adverse action against whistleblowers as a result of their protected activity. In general terms, a



Relators filed 753 new *qui tam* lawsuits under the FCA in FY2013.

successful claim for retaliation under the FCA requires that a whistleblower establish three elements: (1) that the whistleblower engaged in “protected activity” by acting in furtherance of a *qui tam* suit; (2) that the whistleblower’s employer knew of these acts; and (3) that the employer took adverse action against the whistleblower as a result of these acts.

In *Glynn v. Edo Corp.*, the Fourth Circuit considered the first of these requirements. The Fourth Circuit explained that to engage in “protected activity” the whistleblower must be engaged in the reporting of an act that could lead to a viable FCA lawsuit.⁹⁰ In other words, while a whistleblower need not file an actual *qui tam* lawsuit to be protected from retaliation under the FCA, the whistleblower must engage in activities (*i.e.*, investigation activities) that raise a distinct possibility of a viable FCA action, which the relator had not in *Glynn*. The Fourth Circuit reached this conclusion notwithstanding the fact that the activities of the whistleblower successfully triggered a federal criminal investigation.

The district court considered the third requirement to state a retaliation claim under the FCA in *U.S. ex rel. Schweizer v. Océ N. Amer.*⁹¹ Although courts have interpreted the third element of stating an FCA retaliation claim to require a showing that the adverse employment action was motivated *at least in part* by the employee’s engagement in protected activity, the district court in *Schweizer* explained that a recent decision by the Supreme Court in *Univ. Tex. Sw. Med. Ctr. v. Nassar*,⁹² demands that more stringent “but-for” requirement concerning pleading that an employer discharged the employee “because of” the protected activity should be applied. In doing so, the district court held that “where Congress has given plaintiffs the right to sue employers for adverse actions taken against them by their employer ‘because of’ X, plaintiffs may succeed only by showing that X was a ‘but-for’ cause of the adverse action, not merely one of several ‘motivating factors’

89. 718 F.3d 28, 34-35 (1st Cir. 2013).

90. 710 F.3d 209, 214-18 (4th Cir. 2013).

91. 2013 U.S. Dist. LEXIS 101419 (Jul. 19, 2013).

92. 133 S. Ct. 2517, 2520 (2013).

To succeed on her claim, a plaintiff must show that retaliation for protected activity was a 'but for' cause of the adverse action."⁹³

LIMITING DISCOVERY IN FCA CASES

Relators often allege nationwide practices which could entitle them to wide-ranging discovery. Last year, however, several courts demonstrated well-founded sensitivity to the expense and burden of nationwide discovery and curbed relators' broad discovery requests.

In perhaps the leading case on this issue, *U.S. ex rel. Duxbury v. Ortho Biotech Prods., L.P.*,⁹⁴ the First Circuit issued a rare appellate-level opinion on the scope of discovery into an alleged nationwide kickback scheme by the relator's former employer. In *Duxbury*, the district court imposed geographic and temporal limitations on the relator's discovery requests because the relator was an original source only with respect to claims arising during his employment with the defendant, and because he only possessed "direct and independent knowledge" of the defendant's activities in the locations for which he had responsibility.⁹⁵ After the relator was unable to identify any admissible evidence supporting his claim, the district court granted the defendant's motion to dismiss.⁹⁶

On appeal, the relator argued that the district court had inappropriately limited discovery. The First Circuit, however, affirmed the district court's restrictions on discovery, stating that it "was not required to expand the scope of discovery based upon the amended complaint's bold assertions that the purported kickback scheme continued after [relator's] termination or that it was 'nationwide' in scope."⁹⁷

In *U.S. ex rel. Spay v. CVS Caremark Corp.*,⁹⁸ the relator alleged that pharmacy benefit managers violated the FCA by engaging in an on-going, nationwide practice of fraudulently adjudicating claims and submitting inaccurate prescription drug event reports to CMS. Following the denial of the defendants' motion to dismiss, the relator sought extensive, nationwide

To succeed on her claim [under the FCA], a plaintiff must show that retaliation for protected activities was a "but-for" cause of the adverse action.

-*U.S. ex rel. Schweizer v. Océ N. Am., Inc.*

discovery from 2006 to the present. The defendants objected to both the temporal and geographic scope of the relator's requests.

The district court agreed with the defendants and dramatically limited the scope of the initial discovery. The district court observed that, although the relator had survived a motion to dismiss the nationwide claims, "[t]he cost of discovery in this case could be so prohibitive as to force Defendants into a settlement based not on any assessment of the merits of the case against it, but simply to avoid the undue burden associated with what could potentially be a mere fishing expedition."⁹⁹ Accordingly, the district court limited discovery to 2006 to 2008, the period for which the relator made specific factual allegations regarding the defendants' alleged fraud.¹⁰⁰ Furthermore, the district court limited the geographic scope of the relator's initial discovery to only the six jurisdictions (five states and Puerto Rico) in which the relator set forth specific examples of false claims based on its personal knowledge.¹⁰¹

Conversely, in *United States v. Education Management LLC*,¹⁰² the court approved an expansive plan of discovery with only relatively minor limitations. The plaintiffs alleged that a for-profit education company and its affiliates, engaged in a nationwide fraud by adjusting admissions officers' compensation based on the number of students they enrolled in violation of federal regulations. The district court allowed the relator an almost unfettered right to conduct substantial, nationwide discovery over the objection of

93. 2013 U.S. Dist. LEXIS 101419, at *32.

94. 719 F.3d 31 (1st Cir. 2013).

95. *Id.* at 36.

96. *Id.* at 32-33.

97. *Id.* at 39.

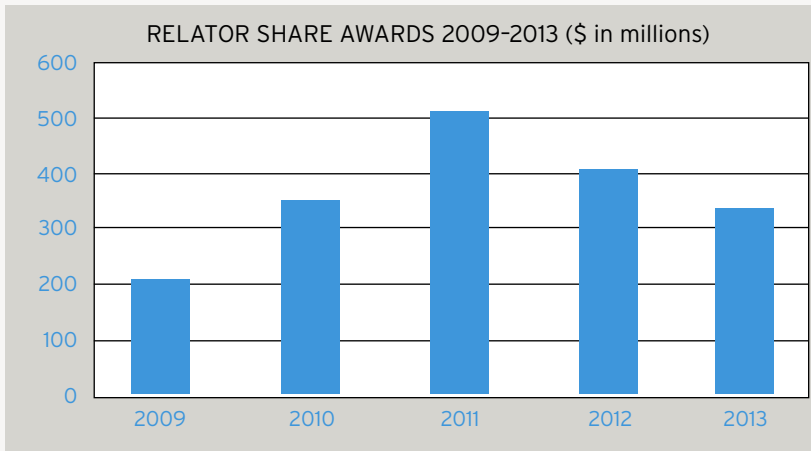
98. 2013 U.S. Dist. LEXIS 121554 (E.D. Pa. Aug. 27, 2013).

99. *Id.* at *27.

100. *Id.* at 12-13.

101. *Id.* at 29.

102. 2013 U.S. Dist. LEXIS 102549 (W.D. Pa. July 23, 2013).



defendants.¹⁰³ In evaluating the propriety of the requested discovery, the district court observed: “Discovery in this case will undoubtedly present a Herculean task. But in evaluating the burden and expense of discovery, the Court must consider it in the context of an amount in controversy of billions of dollars; that the government and [defendants] both possess significant resources; and that the issues are of surpassing importance, particularly to [defendants].”¹⁰⁴

In addition to disputes regarding the scope of discovery, courts have ruled on disputes over parties’ preservation obligations. In *United States ex rel. King v. Solvay, S.A.*, the relators sought discovery related to alleged “ongoing” fraud committed by a pharmaceutical company.¹⁰⁵ The defendant moved for a protective order, arguing that the relators’ requests were causing it undue burden and expense. The defendant’s protective order was remarkably detailed, identifying the number and storage volume of email back-up tapes, network share back-up tapes, and active network share drives, and providing an estimate of the costs of preservation and review.¹⁰⁶ The district court agreed that the discovery demanded by the relators was unduly burdensome, particularly given the relatively sparse allegations in the complaint regarding ongoing conduct (despite the court’s denial of the defendant’s motion to dismiss).¹⁰⁷ Accordingly, the district court limited discovery to the time period suggested by the defendant.

103. *Id.* at 16-17.

104. *Id.* at 16.

105. 2013 U.S. Dist. LEXIS 30752 (S.D. Tex. Mar. 5, 2013).

106. *Id.* at *7.

107. *Id.* at 13-14.

108. 2013 U.S. Dist. LEXIS 66234 (D. Mass. May 9, 2013).

109. 2013 U.S. Dist. LEXIS 108741 (S.D. Fla. Aug. 2, 2013).

JUDICIAL REVIEW OF SETTLEMENTS

As a consequence of the continued number of large FCA settlements, an increasing number of district courts have confronted settlement issues arising from such cases. Courts now have addressed the treatment of settlements for tax purposes and issues involving relators’ settlement share.

Tax Treatment of FCA Settlements

In *Fresenius Medical Care Holdings, Inc. v. United States*, the district court issued a significant opinion for providers evaluating the likely tax treatment of an FCA settlement.¹⁰⁸ The district court did not disturb a jury’s verdict finding that \$95 million of \$126.7 million in disputed FCA settlement payments were compensatory damages, and therefore, tax deductible as an ordinary and necessary business expense. In so ruling, the district court held that “a manifest agreement is not necessary for Fresenius to establish that all or some portion” of the settlement payments were compensatory, and that “both the language of the settlement agreements and non-contractual evidence regarding the purpose and applications of the payments” must be considered by a fact finder to determine the categorization of the payments. This holding is significant because it means that despite the government’s customary inclusion of a tax neutrality provision in a settlement agreement resolving FCA claims, a provider still can present non-contractual evidence to demonstrate that the purpose served by a settlement payment was compensatory and therefore deductible.

Control Over FCA Settlement Agreements

In reviewing FCA settlements, district courts have continued to rein in the government’s discretion in the settlement process. In *U.S. ex rel. Osheroff v. MCCI Group Holdings, LLC*, the district court confronted the question of whether a settlement between a relator and a defendant is enforceable without the government’s consent when the government declined to intervene.¹⁰⁹ The relator in *Osheroff* reached an agreement with MCCI during mediation, the terms of which were set forth in a “Memo of Understanding” executed by both parties and their counsel. In subsequent negotiations to finalize a formal settlement agreement, MCCI removed certain provisions

regarding the potential tax treatment of the settlement and barring MCCI from charging back to the government any unallowable costs stemming from the settlement. In later communications, the government emphasized that it would not consent to the settlement without the inclusion of these two provisions. After MCCI attempted to back out of the settlement agreement, the relator moved to enforce the agreement.

In granting the relator's motion, the district court rejected a magistrate judge's recommendation that MCCI be permitted to withdraw from its agreement because the parties failed "to meet the condition precedent that the agreement be approved by the attorney general." The district court found that the parties reached an agreement on all the essential terms and memorialized the agreement in the Memo of Understanding. Because the government was not a party to the action, its input could not affect whether the parties reached an enforceable agreement.

Although the FCA states that the government must consent to dismissal, the district court noted that the FCA does not require the government's "consent to the parties' settlement in order for a binding agreement to result." Furthermore, the provisions sought by the government "amount to little more than boilerplate" and are "not germane to the dispute being resolved." The district court declined to address the question of whether the government's consent to dismissal is required in a non-intervened case, but noted in dicta that it had "its doubts."¹¹⁰

Last year, the D.C. Circuit ruled that the federal government could not settle a *qui tam* action over the objection of a relator absent a finding by the district court that the proposed settlement was fair, adequate, and reasonable under the circumstances, as required by 31 U.S.C. § 3730(c)(2) (B). On remand, in *U.S. ex rel. Schweizer v. Océ N. Am., Inc.*, the district court considered the following five factors in deciding whether the settlement was fair, adequate, and reasonable: (1) whether the settlement was the result of arm's length negotiations; (2) the terms of the settlement in relation to the strengths of plaintiffs' case; (3) the status of the litigation proceedings at the time of settlement; (4) the reaction of the relator; and (5) the opinion of

experienced counsel.¹¹¹ As a threshold issue, the district court held that that a relator is not entitled to "full-blown discovery" as a matter of right in order to demonstrate the inadequacy of a settlement (though the court noted there may be circumstances where limited discovery is appropriate).

In approving the settlement, the district court focused on the first three factors, concluding that each factor supported the approval of the settlement because: (1) the relator did not allege any collusion between the government and the defendant in reaching the settlement agreement; (2) "the government's assessments of the strength of plaintiff's claims and the attendant litigation risks are based on a significant investigative effort on their part [and] are sufficiently detailed and comprehensive;" and (3) the government's significant investigative efforts provided it with "adequate information to make an informed judgment regarding the settlement."

In *U.S. ex rel. Roberts v. Accenture, LLP*, the Eighth Circuit affirmed a lower court's award to the relators of a settlement share that was \$7 million more than the government anticipated.¹¹² In reaching a \$55 million settlement with one of the defendants to resolve kickback and defective pricing allegations in government contracting, the government expected to limit the relators' share to the settlement of the kickback scheme (\$9 million). The government contended that the relators were not entitled to any part of the defective pricing settlement (\$46 million) because their allegations as to that scheme were insufficient under Rule 9(b) and were unrelated to the defendant's voluntary disclosure or the government's own investigation of the matter. The Eighth Circuit disagreed, holding that, at least in a case where the government intervenes, Rule 9(b) plays no role in determining whether a relator is entitled to a share of any settlement proceeds. In addition, the Eighth Circuit noted that the relators' complaint and assistance in prosecuting the action spurred the defendant's internal investigation and the government's decision to intervene; thus, "the relators should be rewarded accordingly." Beyond strengthening the position of relators in settlement negotiations, this case also is significant for providers to consider because any change in a relator's settlement share for additional claims could alter the amount of attorneys' fees and costs for which a defendant is liable.

110. Specifically, the district court recognized the split of authority on this issue and noted an initial preference for the approach taken in *U.S. ex rel. Killingsworth v. Northrop Corp.*, 25 F.3d 715 (9th Cir. 1994) and *U.S. ex rel. Fender v. Tenet Healthcare Corp.*, 105 F. Supp. 2d 1228 (N.D. Ala. 2000), which hold that the government's "consent to dismissal is only required during the initial sixty-day (or extended) period in which the government may decide whether to intervene."

111. 2013 U.S. Dist. LEXIS 101419 (D.D.C. July 19, 2013).

112. 707 F.3d 1011 (8th Cir. 2013).

CASES TO WATCH

While there are undoubtedly a number of healthcare-related cases that will garner attention during the coming year, we believe that there are at least two cases that will be of particular interest to healthcare providers and practitioners.

Applying Stark to Medicaid Claims

It comes as no surprise when relator's counsel and the government seek to expand the reach of the FCA. This is certainly the case in recent efforts to premise FCA liability on Medicaid claims allegedly rendered false by violations of the Stark Law.

In *U.S. ex rel. Baklid-Kunz v. Halifax Medical Center*, the relator alleged that Halifax Medical Center's payment of productivity bonuses to employed medical oncologists, neurologists, and psychiatrists constituted an improper financial relationship with referring physicians in violation of the Stark Law and that Halifax's submission of claims to Medicare *and Medicaid* as a result of such tainted referrals violated the FCA.¹¹³ The United States intervened in the case with respect to the FCA claims premised on a violation of the Stark Law and specifically alleged that "[t]he Stark Statute also applies to claims for payment under Medicaid, and federal funds may not be used to pay for designated health services through a state Medicaid program."

Responding to the government's argument, Halifax pointed out that under Medicaid, providers are reimbursed by the state and not the federal government, and neither the Stark Law, nor the Medicaid statute prohibited states from paying claims based upon referral arrangements that may violate the Stark Law. Even assuming that the Medicaid claims Halifax submitted to the state implicated improper referral arrangements concerning Medicare, Halifax contended that the Stark Law should not be interpreted as to prohibit the former, "so there could be no FCA violation."

Halifax's interpretation was supported by the very language of the Stark Law and its implementing regulations - each of which refers to Medicare, not Medicaid - and the past two decades of regulatory activity, in which CMS considered, but never finalized rules that would have implemented § 1903(s) of the Social Security Act, which purported to expand the Stark Law to Medicaid. Consistent with Halifax's argument, it has been widely understood by practitioners and providers alike, and tacitly by CMS itself, that the Stark Law applied to claims submitted to Medicare, but not Medicaid.

Nonetheless, the district court adopted the government's argument, refusing to dismiss the FCA claims related to reimbursement under Medicaid from the lawsuit. "The Medicaid statute prohibits payments to a state for medical services resulting from improper referrals, as defined under the Stark Amendment," the district court wrote, and for its part, the FCA imposes liability on a defendant who causes another to submit a false claim. The district court found, therefore, that an FCA claim based on the allegation that Halifax caused the state of Florida to submit false claims to the federal government tainted by a violation of the Stark Law was sufficient to survive a Rule 12(b)(6) challenge.

On its face, *Halifax* signals that the government likely will continue to interpret the Stark Law to prohibit certain referral practices under Medicaid, not just Medicare. The government's assertion in *Halifax* that the Stark Law's prohibitions apply to Medicaid claims constituted a dramatic - and for Halifax, potentially costly - shift in interpretation. It remains to be seen whether other jurisdictions adopt this broad interpretation of the Stark Law as it applies to the FCA.

113. 2012 U.S. Dist. LEXIS 36304 (M.D. Fla. March 19, 2012).

Pleading the Presentment of a False Claim under Rule 9(b)

In *U.S. ex rel. Nathan v. Takeda Pharms. N. Am., Inc.*, the Fourth Circuit affirmed the district court's decision dismissing the relator's FCA claims based on an alleged off-label marketing scheme, in part, because the complaint failed to allege the "presentment" of an actual false or fraudulent claim to the government.¹¹⁴ In reaching this conclusion, the Fourth Circuit rejected the relator's argument for a more lenient application of Rule 9(b), which would excuse a lack of plausible allegations of presentment, if the relator pleaded allegations of a fraudulent scheme.

"Applying the principles" enunciated by several other circuits, the Fourth Circuit held that "when a defendant's actions, as alleged and as reasonably inferred from the allegations *could* have lead, but *need not necessarily* have led, to the submission of false claims, a relator must allege with particularity that specific false claims actually were presented to the government for payment." The Fourth Circuit recognized that in many instances, a relator may have difficulty accessing billing documentation, as a result of physical and legal barriers. Such circumstances, the Fourth Circuit explained, did not excuse a relator from "pleading facts that support all elements of a [FCA] claim," including presentment of an actual claim.

On May 10, 2013, the relator in *Takeda* filed a petition for a writ of certiorari with the U.S. Supreme Court, seeking review on the question of whether Rule

9(b) requires that a complaint under the FCA "allege with particularity that specific false claims actually were presented to the government for payment, as required by the Fourth, Sixth, Eighth, and Eleventh Circuits, or whether it is instead sufficient to allege the particular details of the scheme to submit false claims together with sufficient indicia that false claims were submitted, as held by the First, Fifth, and Seventh, and Ninth Circuits." On October 7, 2013, after the parties completed their briefing, the U.S. Supreme Court invited the U.S. Solicitor General to file a brief expressing the views of the United States on the matter. Such an invitation would seem to suggest at least some members of the Court are interested in reviewing the *Takeda* decision.

Rule 9(b)'s mandate, as set forth by several circuits, that a FCA complaint allege "presentment" of an actual claim with particularity is a critical hurdle upon which providers typically rely in seeking dismissal in FCA claims pursued by relators. Should the U.S. Supreme Court decide to grant certiorari and consider the pleading standard at issue in *Takeda*, it will be an incredibly important development, as the Court's opinion on this question could have a significant impact on a relator's ability to meet the requirements of Rule 9(b) and successfully plead a cause of action under the FCA.

114. 707 F.3d 451 (4th Cir. 2013).

STARK LAW/ANTI-KICKBACK STATUTE

It has been an active year for decisions interpreting the two most well-known fraud and abuse laws, the federal Stark Law (42 U.S.C. § 1395nn) and the federal Anti-Kickback Statute (42 U.S.C. § 1320a-7b).

Rule Making Challenges

CMS scored a victory in *Council for Urological Interests v. Sebelius*, that involved a dispute over CMS's 2008 expansion of the Stark Law's regulatory definition of "entity" and CMS's prohibition of "per-click" equipment lease payments for services referred to by the physician-landlord.¹¹⁵ Counsel for Urological Interests ("CUI") had alleged that CMS's 2008 regulatory interpretations failed to comply with the Administrative Procedures Act and the Regulatory Flexibility Act. The district court, however, concluded that CMS's interpretations of the statute did not violate congressional intent and were reasonable. As a result, the 2008 changes, already well-ingrained at this point, remain: (1) physician-owned joint ventures may not "furnish" inpatient or outpatient hospital services under arrangements, and (2) direct or indirect physician-landlords may not receive a per-click fee under a space or equipment lease to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.

Employment Relationships

No case captured the attention of healthcare providers concerning physician employment arrangements more than *U.S. ex rel. Drakeford v. Tuomey Health Care*.¹¹⁶ The *qui tam* complaint in *Tuomey* was filed by a physician whistleblower in 2005 accusing Tuomey of paying physicians more than their actual professional collections under employment contracts with the hospital. The relator accused the hospital of implementing this compensation scheme based on the rationale that it would make up for any shortfalls through referrals from the doctors for other services. After intervention by the U.S. and nearly eight years after the case was filed, including two jury trials and numerous appeals, the district court ordered Tuomey to pay \$237 million in damages and penalties.

According to the government, Tuomey and a competing surgery center were both granted certificates of need for surgery centers. The government alleged that Tuomey had determined that it would lose approximately \$9.6 million in revenue over a 13 year period if gastroenterologists redirected their endoscopies away from Tuomey and to the competing surgery center. To head off this decline in revenue, Tuomey recruited specialist physicians into lucrative part-time employment contracts, including compensation that amounted to 31% in excess of the total net collections those physicians would have earned as independent contractors, and, thus above fair market value for their services.

Tuomey ultimately offered 19 physicians on its medical staff part-time employment. Each contract specified that the physician was required to perform outpatient procedures at Tuomey (or facilities owned by Tuomey). Under each contract, Tuomey was solely responsible for billing and collections and agreed to pay each physician: (1) an annual base salary that fluctuated based on Tuomey's net cash collections for the outpatient procedures; (2) a productivity bonus equal to 80% of net collections; and (3) potentially, an incentive bonus that could total up to 7% of the productivity bonus.¹¹⁷ Each contract had a 10 year term and provided that the physicians would not compete with Tuomey during the term of the contract and for two years thereafter.

The jury heard testimony that Tuomey and the physician relator jointly retained a highly regarded healthcare attorney, who expressed concerns that the physician contracts were problematic. The jointly-retained attorney cautioned Tuomey that the terms of the contracts would raise a "red flag" and expose Tuomey to liability because, in his opinion, the physicians were being

115. 2013 US Dist. LEXIS 73610 (D.D.C. May 24, 2013).

116. 2013 US Dist. LEXIS 141316 (D.S.C. Sept. 30, 2013).

117. *Id.* at 7.

paid in excess of fair market value and the contracts contained “unusual” components.¹¹⁸ Toumey ultimately terminated the healthcare attorney and directed him not to prepare a written opinion.

At the conclusion of the trial, the jury concluded that the 19 physician arrangements violated the Stark Law and that Toumey had submitted 27,730 false claims. The district court then entered judgment in the amount of \$237 million after applying the FCA’s per claim penalty. The case is pending appeal before the Fourth Circuit.

Productivity Bonuses

The district court in *U.S. ex rel. Baklid-Kunz v. Halifax Hospital Medical Center and Halifax Staffing, Inc.*, issued several decisions providing interpretations relevant to the Stark Law and Anti-Kickback Statute in the context of physician employment. In *Halifax*, several medical oncologists employed by the hospital were paid an incentive bonus out of a pool comprised of 15% of the profits of the hospital’s oncology program, which included revenue for services not personally performed by the physicians.¹¹⁹ The bonus pool was divided among the physicians based on their individual production.

The district court ruled that, in order to meet the Stark Law’s employment exception, bonuses paid to employed physicians may only be based on personally performed services; accordingly, dividing a bonus pool that includes non-personally performed profits based on personally performed services is insufficient to comply with the Stark Law.

Regarding the same medical oncologist employment relationships, the district court subsequently denied the relator’s motion for summary judgment asserting that the incentive compensation induced referrals such that medical oncologists’ employment arrangements violated the Anti-Kickback Statute.¹²⁰ The district court explained that the bona fide employment safe harbor protects payments to legitimate employees from the normal prohibition on payments to induce referrals. As such, the district court rejected the relator’s assertion that the safe harbor did not apply

because incentive bonus induced referrals did not vitiate the protection of the safe harbor; such a result, the district court explained, would constitute “the rule swallowing the exception.”

The district court in *U.S. ex rel. Schubert v. All Children’s Health System, Inc.*, addressed a productivity bonus in granting the defendant’s motion to dismiss with respect to a claim regarding one physician.¹²¹ The court reiterated that productivity bonuses based on personally performed services are permissible.

Fair Market Value and Commercial Reasonableness

Several FCA *qui tam* cases during the previous year were based on allegations focused on the fair market value and commercial reasonableness of physician compensation relationships with hospitals in the context of the hospital losing money on the physician professional collections. In *Halifax*, the district court recently denied defendants’ motion for summary judgment on the issue of whether compensation paid to three neurosurgeons is fair market value and commercially reasonable.¹²² Beyond whether the total compensation was fair market value, whether inclusion of ancillary professionals (e.g., physician assistants) in the physicians’ productivity numbers inappropriately inflate those numbers for purposes of the Stark Law also remains at issue in *Halifax*.

Recruitment Agreements

In *U.S. ex rel. Dennis v. Health Management Associates, Inc.**, the district court dismissed all claims against the defendants in which the FCA claims were based on allegations that recruitment agreements violated the Stark Law and the Anti-Kickback Statute.¹²³ The relator alleged that the recruitment agreements were illegal because: (1) a provision in his recruitment agreement required that he maintain active staff privileges; and (2) hospital bylaws required active staff members to admit 24 patients a year. The district court dismissed these allegations as sufficient to form an FCA claim because a “contractual requirement that a physician maintain active staff status is not equivalent to a referral requirement” and held that a hospital bylaws provision requiring a minimum of 24 admissions per year did not cause the

118. *Id.* at 21-22.

119. 2013 U.S. Dist. LEXIS 161718 (M.D. Fla. Nov. 13, 2013).

120. 2013 U.S. Dist. LEXIS 167882 (M.D. Fla. Nov. 26, 2013).

121. 2013 U.S. Dist. LEXIS (M.D. Fla. Nov. 15, 2013).

122. 2013 U.S. Dist. LEXIS 163695 (M.D. Fla. Nov. 18, 2013).

123. 2013 US Dist. LEXIS 5212 (M.D. Tenn. Jan. 14, 2013).

*Denotes matter handled by Bass, Berry & Sims attorneys

arrangements to violate the Anti-Kickback Statute or the Stark Law.¹²⁴ The district court noted that “[i]t is a common and well known practice of hospitals to classify active staff based in part on the number of admissions per year,” and CMS “was aware of that fact” in allowing recruitment agreements to contain provisions requiring active staff membership.¹²⁵

Rental of Office Space

In *U.S. ex rel. Osheroff v. Tenet HealthCare Corp.*, the district court declined to dismiss FCA claims based on alleged violations of the Stark Law and Anti-Kickback Statute stemming from physician space leases at below-market rates.¹²⁶ The relator alleged that the space leases systematically underrepresented the size of the office space leased to physician tenants, which effectively resulted in a rate that was below fair market value. The relator also highlighted a number of allegedly non-standard benefits received by physicians, which further lowered the effective rental rate. These benefits included: (1) excessive tenant improvement allowances; (2) failure to charge referring physicians the full “cost of living” increase; (3) medical waste “red bag” collection service; (4) sharps collection service; (5) electrical and utilities; (6) parking; (7) janitorial service; and (8) paper goods that are more expensive than regular office paper goods.¹²⁷ The district court held that the relator’s detailed allegations were sufficient to allege a violation of both the Anti-Kickback Statute and Stark Law, and in turn, a claim under the FCA.

Application of the Stark Law to Medicaid Claims

As referenced above, relators are filing an increasing number of FCA cases based on the theory that Stark Law violations taint claims for reimbursement submitted to Medicaid. This is a potentially significant expansion of FCA liability. In *U.S. ex rel. Schubert v. All Children’s Health System, Inc.*, the

Certifying compliance with the Stark Amendment to ensure that CMS pays [Federal Financial Participation] for Medicaid claims that violate the Stark Amendment would be a violation of the False Claims Act in the same manner that certifying compliance for full reimbursement under Medicare would be.

-U.S. ex rel. Schubert v. All Children’s Health Sys., Inc.

district court concluded that the Stark Law clearly applies to Medicaid and a violation of the Stark Law could form the basis of an FCA claim if claims for reimbursement were submitted to Medicaid.¹²⁸

A similar result was reached in *U.S. ex rel. Osheroff v. Tenet HealthCare Corp.*, in which the relator alleged that Medicaid claims were false due to Stark Law violations. In its order denying the defendant’s motion to dismiss, the district court held that “because . . . cost reports submitted to Medicare can form the basis for liability under the False Claims Act, the court arrives at the same conclusion regarding the cost reports submitted to Medicaid and Tricare, in light of the fact that both Medicaid and Tricare rely on the representations made in the Medicare cost report.”¹²⁹

124. *Id.* at 30-31.

125. *Id.* at 34.

126. 2013 US Dist. LEXIS 44235 (S.D. Fla. Mar. 27, 2013).

127. *Id.*

128. 2013 U.S. Dist. LEXIS (M.D. Fla. Nov. 15, 2013).

129. 2013 US Dist. LEXIS 44235 (S.D. Fla. Mar. 27, 2013). As discussed above, the district court in *U.S. ex rel. Baklid-Kunz v. Halifax Hospital Medical Center and Halifax Staffing, Inc.*, 2013 U.S. Dist. LEXIS 161718 (M.D. Fla. Nov. 13, 2013), reached a similar conclusion regarding the possibility that the Stark Law could taint Medicaid claims.

MEDICARE CONTRACTORS AND RELATED LITIGATION

There were significant developments in litigation related to Medicare contractors during the previous year.

The American Hospital Association's ("AHA") challenge of CMS's refusal to reimburse hospitals for Part B services when Recovery Auditors (f/k/a as Recovery Auditor Contractors) denied hospitals' Part A inpatient claims for reasonable and necessary care continued during the previous year.¹³⁰ In *American Hosp. Ass'n v. Sebelius*, the AHA's Complaint argued that CMS had failed to pay hospitals for "hundreds of millions of dollars' worth of care" where it was undisputed that the care was reasonable and necessary. The AHA has sought an invalidation of CMS's current payment denial policy of only allowing payment for limited ancillary items. AHA also has sought an order that the plaintiff hospitals be paid full Part B reimbursement for the specific appeals at issue, and that *all* hospitals that received Part A denials based upon an incorrect setting of care be paid full Part B reimbursement.¹³¹ The AHA's Complaint contends that CMS's denial policy is against federal law and disturbs hospitals' financial planning and creates a dangerous uncertainty regarding Medicare coverage that may negatively affect patient care.¹³² Faced with mounting pressure from the AHA's lawsuit, as well as appellate decisions calling for Part B payments to offset Part A overpayments on inpatient hospital stays, CMS changed its policy stance with an interim ruling and final rule. The change revised CMS's policy to allow expanded Part B billing after Part A denials. On June 6, 2013, the HHS filed a motion to dismiss the AHA's suit for lack of subject matter jurisdiction and failure to state a claim, which remains pending.

In *Sebelius v. Auburn Reg'l Med. Ctr.*, the U.S. Supreme Court determined that the 180-day statute of limitations governing the filing of provider appeals to the Provider Reimbursement Review Board ("PRRB") was not "jurisdictional"

and may be extended in certain cases, but is not subject to equitable tolling to further extend the time limits.¹³³ Several hospitals received underpayments for care provided to low income patients between 1993 and 1996 due to CMS's miscalculation. In 2006, a group of these hospitals filed similar claims with the PRRB for full payment for years 1987 through 1994, more than 10 years after the expiration of the 180-day limitation. The hospitals argued that the 180-day statute of limitations should be equitably tolled because CMS knowingly failed to disclose its payment calculation error. The Supreme Court explained that the Secretary of HHS's regulation allowing for a three-year extension for good cause was permissible, as courts must defer to an agency's regulations unless they are "arbitrary, capricious or manifestly contrary to the statute."¹³⁴ Additionally, the Supreme Court reasoned that giving fiscal intermediaries more time to discover overpayments than providers have to discover underpayments may be justified by the "administrative realities" of the system, as intermediaries are responsible for multiple providers whereas a single provider need only concentrate on itself and is often a sophisticated party with legal representation.¹³⁵

In addition to those significant court cases, government agencies issued a number of reports during the previous year that scrutinized the role of government contractors in the reimbursement process. On August 22, 2013, the Government Accountability Office ("GAO") released its report to Congress entitled *Medicare Program Integrity: Increasing Consistency of Contractor Requirements May Improve Administrative Efficiency*.¹³⁶ GAO prepared its report in response to questions posed by Senate and House Committees

130. *American Hosp. Ass'n et al. v. Kathleen Sebelius*, No. 1:12-cv-1770 (D.D.C. Nov. 1, 2012).

131. *Id.* at 1, 27.

132. *Id.* at 4.

133. 133 S. Ct. 817 (U.S. 2013).

134. *See id.* at 826.

135. *See id.* at 820, 828.

136. *Medicare Program Integrity: Increasing Consistency of Contractor Requirements May Improve Administrative Efficiency*, GAO-13-522 (2013), available at <http://www.gao.gov/assets/660/656132.pdf>.

regarding CMS's use of multiple contractors to conduct post-payment Medicare claims reviews and the efficiency and efficacy of such reviews. The GAO report identified that CMS has varying post-payment review requirements across the different contractors conducting post-payment review in the areas of oversight of claims selection, timeframes for provision of documentation, communications to providers about the reviews, and quality assurance processes.¹³⁷ GAO also noted that contractors are subject to different requirements governing provider documentation submission formats, additional documentation requests and timelines, and staffing requirements for medical directors and other staff conducting reviews.¹³⁸

Providers have expressed concerns that the contingency fee payment structure created incentives for Recovery Audit Contractors ("RAC") to be too aggressive in determining improper claims, resulting in a significant provider burden. Providers also reported that CMS failed to penalize RACs for inaccurate claims determinations and noted that RACs were not required to have medical directors or coding experts during the demonstration period. The GAO found that these issues, in part, led to CMS more strictly limiting RACs through post-payment review of RAC activity.¹³⁹

The GAO concluded that differences across the Medicare contractor types may decrease efficiency and effectiveness of claims' reviews and complicate providers' compliance, which conflicts with executive-agency guidelines to streamline service delivery. The GAO recommended that CMS: (1) examine all post-payment review requirements and make them consistent where possible; (2) publicly communicate its findings and anticipated timeframe for improvements; and (3) decrease the number of different post-payment requirements across the contractors where it can be done without impeding its efforts to combat improper payments.¹⁴⁰

On September 2, 2013, HHS-OIG published a report entitled *Medicare Recovery Audit Contractors and CMS's Actions to Address Improper Payments, Referrals of Potential Fraud, and Performance*.¹⁴¹ The report identifies problems with CMS's oversight of RACs and predicts a continued high volume of improper payments. Based on data from FYs 2010 and 2011, RACs reviewed 2.6 million claims and found improper payments in half for a total of \$1.3 billion.¹⁴² The report identifies 46 of what CMS classifies as "vulnerabilities" or a specific issue with more than \$500,000 in improper payments.¹⁴³ CMS took corrective action to address these vulnerabilities, but did not evaluate the effectiveness of these actions, nor did it address six referrals of potential fraud it received from RACs.¹⁴⁴ CMS's RAC performance evaluations did not provide metrics to evaluate RACs' performance on all contract requirements.¹⁴⁵ The report recommends that CMS: (1) take appropriate action on vulnerabilities that are pending corrective action and evaluate the effectiveness of implemented corrective actions; (2) ensure that RACs review all appropriate cases of potential fraud; (3) review and take appropriate and timely action on RACs' referrals of potential fraud; and (4) develop additional performance evaluation metrics to improve RAC performance and make sure that RACs are evaluated on all contract requirements.¹⁴⁶

Finally, on October 2, 2013, HHS-OIG released a report entitled *The First Level of the Medicare Appeals Process, 2008-2012: Volume, Outcomes and Timelines*.¹⁴⁷ The study focuses on redetermination appeals for Medicare Part A and Part B claims at level one of the appellate process within HHS between 2008 and 2012. The OIG surveyed 18 contractors about the redetermination process and interviewed five to gather further information on how they process redeterminations.

137. *Id.* at 23-31.

138. *Id.*

139. *Id.* at 20.

140. *Id.* at 33.

141. *Medicare Recovery Audit Contractors and CMS's Action to Address Improper Payments, Referrals of Potential Fraud, and Performance*, OEI-04-11-00680 (2013), available at <http://oig.hhs.gov/oei/reports/oei-04-11-00680.pdf>.

142. *See id.* at 10-11.

143. *See id.* at 12-13.

144. *See id.* at 14-16.

145. *See id.* at 16.

146. *See id.* at 17-18.

147. *The First of Level of Medicare Appeals Process, 2008-2012*, OEI-01-12-00150 (2013), available at <http://oig.hhs.gov/oei/reports/oei-01-12-00150.pdf>.

The OIG reported that, in 2012, contractors processed 2.9 million redeterminations, involving 3.7 million claims, which represents a 33% increase since 2008.¹⁴⁸ Medicare Part A redeterminations have increased, although Part B claims account for 80% of all redeterminations.¹⁴⁹ As of 2012, RAC audits comprised 39% of appealed Part A claims.¹⁵⁰ Contractors decided in favor of Part B appellants more often than Part A appellants.¹⁵¹ Contractors generally met required timeframes for processing redeterminations, but fell short on deadlines for transferring case files for second-level appeals.¹⁵² The OIG's recommendations to CMS include: (1) using the Medicare-Appeals-System ("MAS") to monitor contractor performance; (2) continuing to encourage information sharing between the contractors; and (3) monitoring the quality of redeterminations data in MAS.¹⁵³

148. *See id.* at 8.

149. *See id.*

150. *See id.* at 10.

151. *See id.* at 11.

152. *See id.* at 14-16.

153. *See id.* at 21-22.

PHARMACEUTICAL AND MEDICAL DEVICE DEVELOPMENTS

In its landmark 2012 opinion in *United States v. Caronia*, the Second Circuit reversed a pharmaceutical sales representative's conviction under the Food, Drug, and Cosmetic Act, holding that the conviction violated his First Amendment right of free speech.¹⁵⁴

Courts since have grappled with how to apply the holding of *Caronia*, as demonstrated in *U.S. ex rel. Cestra v. Cephalon, Inc.*¹⁵⁵ In *Cephalon*, the relator predicated his *qui tam* on alleged off-label promotion of two cancer drugs. Relying on *Caronia*, the defendant has filed a motion to dismiss on First Amendment grounds which remains pending.

In response to the motion to dismiss, the U.S. filed a statement of interest attempting to distinguish the case from *Caronia*.¹⁵⁶ The U.S. argued that although the FCA does not forbid off-label promotion, it does forbid conduct that may "cause" false claims to be submitted to the government.¹⁵⁷ The U.S. also claimed that in off-label promotion FCA cases, "the central question is whether the defendant's marketing caused the submission of the false claims."¹⁵⁸ This statement of interest, in conjunction with the defendant's motion to dismiss on First Amendment grounds, demonstrates lingering questions about how courts will approach off-label claims following the decision *Caronia*.

In another off-label case, the Fourth Circuit affirmed the dismissal of a *qui tam* on Rule 9(b) grounds where the relator failed to sufficiently allege the "presentment" of a false or fraudulent claim.¹⁵⁹ In *U.S. ex rel. Nathan v.*

Takeda Pharms. N. Am., the relator argued that it need only "allege the existence of a fraudulent scheme that supports the inference that false claims were presented to the government for payment."¹⁶⁰ The Fourth Circuit disagreed: "when a defendant's actions, as alleged and as reasonably inferred from the allegations could have led, but need not necessarily have led, to the submission of false claims, a relator must allege with particularity that specific false claims actually were presented to the government for payment."¹⁶¹ Thus, the Fourth Circuit held that despite the relator's detailed description of the defendant's business practices and his identification of specific physicians who prescribed the defendant's drugs, his complaint could not survive a motion to dismiss.¹⁶²

In contrast, in *U.S. ex rel. Dickson v. Bristol Myers Squibb Co.*,¹⁶³ the district court applied a remarkably liberal pleading standard. In *Dickson*, the relator alleged that the defendants manipulated clinical trial data to make their drugs appear more efficacious than comparable cheaper alternatives.¹⁶⁴ In denying the defendants' motion to dismiss, the district court concluded that the relator's allegations regarding the defendants' alleged scheme were sufficiently detailed, although the decision made no reference to the specificity of the relator's allegations with respect to the presentation of false claims.

154. 703 F.3d 149 (2d Cir. 2012).

155. No. 10-cv-6457. (S.D.N.Y.).

156. *Statement of Interest of the United States of America, United States ex rel. Cestra v. Cephalon, Inc.*, No. 10-cv-6457 (S.D.N.Y. filed Nov. 7, 2013).

157. *Id.* at 2.

158. *Id.* at 4.

159. 707 F.3d 451 (4th Cir. 2013).

160. *Id.* at 456.

161. *Id.* at 457.

162. *Id.* at 460-461.

163. 289 F.R.D. 271 (S.D. Ill. 2013).

164. *Id.* at 274.

HOSPITALS AND HOSPITAL SYSTEMS

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
January 4, 2013	EMH Regional Medical Center, North Ohio Heart Center Inc.	EMH Regional Medical Center and North Ohio Heart Center Inc. agreed to pay \$4.4 million to resolve FCA allegations that they performed angioplasty and stent placement procedures on Medicare patients who had heart disease but whose blood vessels were not sufficiently occluded to require the particular procedures at issue. ¹	\$4.4 million
January 17, 2013	Cooper Health System d/b/a Cooper University Hospital	Cooper Health System d/b/a Cooper University Hospital agreed to pay \$12.6 million to resolve FCA allegations that it made improper payments to physicians under consulting and compensation agreements to induce the referral of patients to its cardiovascular program. ²	\$12.6 million
January 17, 2013	Wayne Medical Center	After a voluntary self-disclosure, Wayne Medical Center agreed to pay \$883,000 to resolve FCA allegations that it received payment for ambulance services that were not medically necessary or for which medical necessity was not documented, that were assigned an incorrect transport level, that were billed with incorrect mileage units, for which a Physician Certification Statement was not obtained, and for which the requisite signatures were not obtained. ³	\$883,000
February 6, 2013	St. Luke's Roosevelt Hospital Center; Continuum Health Partners, Inc.; SLR Psychiatric Associates	On February 6, 2013, St. Luke's Roosevelt Hospital agreed to pay \$2.325 million to resolve FCA allegations that it double-billed Medicare and Medicaid for outpatient psychiatric services by, <i>inter alia</i> , seeking and receiving payments for non-reimbursable costs relating to services provided by one of its outpatient clinics. ⁴	\$2.325 million
February 7, 2013	St. Joseph's Medical Center	St. Joseph's Medical Center agreed to pay \$4.9 million to resolve potential FCA liability after it disclosed that it engaged in a practice of admitting patients for short stays - typically one or two days - that were not warranted by the patient's medical condition, and thereby generated a larger reimbursement than was proper for each patient. ⁵	\$4.9 million
February 22, 2013	Temple University	Temple University agreed to pay \$100,000 to resolve FCA allegations that it submitted claims for neurology services that were improperly coded higher than the appropriate codes supported by the documentation for those services. ⁶	\$100,000
March 19, 2013	Easton Hospital	Easton Hospital agreed to pay \$454,866 to resolve FCA allegations that it improperly billed Medicare for evaluation and management services that were not permitted under Medicare regulations. ⁷	\$454,866
March 19, 2013	University of California-Irvine	The University of California-Irvine agreed to pay \$1.2 million to resolve FCA allegations that it submitted Medicare claims for anesthesia administered by Certified Registered Nurse Anesthetists or residents when there was no supervisory anesthesiologist present or immediately available, in violation of federal regulations. ⁸	\$1.2 million

1. <http://www.justice.gov/opa/pr/2013/January/13-civ-023.html>.

2. <http://www.justice.gov/usao/nj/Press/files/Cooper%20Settlement%20PR.html>.

3. <http://www.justice.gov/usao/tnm/pressReleases/2013/1-17-13.html>.

4. <http://www.justice.gov/usao/nys/pressreleases/February13/STLukesRooseveltSettlementPR.php>.

5. <http://www.justice.gov/opa/pr/2013/February/13-civ-169.html>.

6. http://www.justice.gov/usao/pae/News/2013/Mar/temple_release.htm.

7. <http://www.justice.gov/usao/pam/hcf.html>.

8. <http://www.releasewire.com/Associated-Press/99911.pdf>.

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
March 27, 2013	St. Luke's University Health Network, Inc.	St. Luke's University Health Network agreed to pay \$1.029 million to resolve FCA allegations that its hospitals improperly billed Medicare for evaluation and management services that were not permitted under Medicare regulations. ⁹	\$1.029 million
March 28, 2013	Intermountain Health Care, Inc.	Intermountain Health Care, Inc. agreed to pay \$25.5 million to resolve FCA allegations that it violated the Stark Law by entering into employment agreements under which the physicians received bonuses that improperly took into account the value of some of their patient referrals and entering into improper office leases and compensation arrangements with referring physicians. ¹⁰	\$25.5 million
April 30, 2013	St. Vincent Healthcare and Holy Rosary Healthcare	St. Vincent Healthcare and Holy Rosary Healthcare, agreed to pay \$3.95 million to resolve FCA allegations that they violated the Stark Law by paying several physicians incentive compensation that took into account the value or volume of their referrals by improperly including certain designated health services in the formula for calculating physician incentive compensation. ¹¹	\$3.95 million
May 1, 2013	Adventist Health System/ West d/b/a Adventist Health and White Memorial Medical Center	Adventist Health System/West d/b/a Adventist Health and White Memorial Medical Center agreed to pay \$14.1 million to resolve FCA allegations that they violated the Anti-Kickback Statute and the Stark Law by improperly compensating physicians who referred patients to the hospitals by transferring assets, including medical and non-medical supplies and inventory, in a transaction below fair market value and paying referring physicians compensation above fair market value to provide teaching services at a residency program. Under the terms of the agreement, White Memorial also entered a CIA with HHS-OIG. ¹²	\$14.1 million
July 1, 2013	University Medical Center d/b/a University of Louisville Hospital	University Medical Center d/b/a University of Louisville Hospital agreed to pay \$2.8 million to resolve FCA allegations that it submitted more than one Medicare claim for the work of certain physician assistants and nurse practitioners. University Medical Center claimed this work on cost reports filed with Medicare while the supervising physicians also billed and collected from Medicare for the physician assistants' and nurse practitioners' professional services. ¹³	\$2.8 million
July 2, 2013	Various Hospitals	55 hospitals agreed to pay \$34 million to settle FCA allegations related to kyphoplasty spinal fracture treatment. The government alleged that the hospitals submitted inflated and unnecessary bills to Medicare by treating the procedure as an inpatient rather than an outpatient procedure. ¹⁴ Currently, DOJ has settled FCA claims with more than 100 hospitals related to kyphoplasty treatment.	\$34 million
July 10, 2013	Allegiance Health and Jackson Cardiology Associates	Allegiance Health and Jackson Cardiology Associates agreed to pay \$4 million to resolve FCA claims that cardiologists employed by Jackson Cardiology Associates performed medically inappropriate cardiac procedures, including invasive catheterizations, at Allegiance Health. A portion of the settlement with Allegiance Health also covered medically unnecessary outpatient peripheral stents. Under the agreement, Allegiance Health and Jackson Cardiology Associates entered into a five-year CIA with HHS-OIG. ¹⁵	\$4 million

9. <http://www.justice.gov/usao/pam/hcf.html>.

10. <http://www.justice.gov/opa/pr/2013/April/13-civ-378.html>.

11. <http://www.justice.gov/opa/pr/2013/May/13-civ-495.html>.

12. <http://www.justice.gov/usao/cae/news/docs/2013/05-2013/05-03-13Adventist.html>.

13. <http://www.justice.gov/usao/kyw/news/2013/20130701-01.html>.

14. <http://www.justice.gov/opa/pr/2013/July/13-civ-745.html>.

15. http://www.justice.gov/usao/mie/news/2013/2013_7_10_jpateI_HCF.html.

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
July 11, 2013	Maryland General Hospital	Maryland General Hospital agreed to pay \$750,000 to resolve FCA allegations that it improperly billed Medicare for cardiac perfusion studies by routinely utilizing three separate CPT codes to bill for a single study. Even after senior financial managers learned of the problem, the hospital allegedly failed to repay the overbilled amounts. ¹⁶	\$750,000
July 15, 2013	Dubuis Health System; Southern Crescent Hospital for Specialty Care, Inc.	Dubuis Health System and Southern Crescent Hospital agreed to pay \$8 million to resolve FCA allegations that it billed Medicare for long term acute care hospitalizations that were medically unnecessary. ¹⁷	\$8 million
July 25, 2013	Beth Israel Deaconess Medical Center	Beth Israel Deaconess Medical Center agreed to pay \$5.3 million to resolve FCA allegations that it admitted and billed federal healthcare programs for patients as inpatient when the patients should have been billed as outpatient or observation status. ¹⁸	\$5.3 million
July 29, 2013	Shands Teaching Hospital & Clinics Inc.; Shands Jacksonville Medical Center Inc.; and Shands Jacksonville Healthcare Inc.	Shands Jacksonville Healthcare agreed to pay \$26 million to resolve FCA allegations that six of its healthcare facilities billed federal healthcare programs for patients as inpatient when the patients should have been billed as outpatient services. ¹⁹	\$26 million
July 30, 2013	Northwestern University	Northwestern University agreed to pay \$2.93 million to resolve FCA allegations that it allowed a former researcher and physician at the university's cancer center to submit improper claims for reimbursement under federal research grants for goods and services that did not meet the applicable National Institutes of Health and government guidelines. ²⁰	\$2.93 million
July 31, 2013	University of Pittsburgh Medical Center and UPMC VNA Home Health	University of Pittsburgh Medical Center and UPMC VNA Home Health agreed to pay \$956,590 to resolve FCA allegations resulting from a self-disclosure regarding Medicare billings for home health services that were not supported by a documented face-to-face encounter with a physician or authorized non-physician practitioner. ²¹	\$956,590
August 28, 2013	Emory University	Emory University agreed to pay \$1.5 million to resolve FCA allegations that it billed Medicare and Medicaid for oncology clinical trial services that were already reimbursed by the sponsor of the clinical trial. ²²	\$1.5 million
August 29, 2013	Wahiawa General Hospital	Wahiawa General Hospital agreed to pay \$451,428 to resolve FCA allegations that it billed federal government healthcare programs for services provided by residents without proper documentation of the teaching faculty's supervision of the residents or of the coding of services performed. ²³	\$451,428
September 10, 2013	Hutchinson Regional Medical Center	Hutchinson Regional Medical Center agreed to pay \$853,651 to resolve FCA allegations that it billed Medicare for hyperbaric oxygen wound therapy services that were not medically necessary, lacked supporting documentation of medical necessity, or resulted from kickback arrangements between the hospital, at least one of its physicians, and the supplier of oxygen chambers. As part of the settlement, Hutchinson entered into a five-year CIA with HHS-OIG. ²⁴	\$853,651

16. <http://www.law360.com/articles/464573>.

17. <http://www.justice.gov/opa/pr/2013/July/13-civ-851.html>.

18. <http://www.justice.gov/usao/ma/news/2013/July/BethIsraelDeaconessMedicalCenterSettlementPR.html>.

19. <http://www.justice.gov/opa/pr/2013/August/13-civ-936.html>.

20. http://www.justice.gov/usao/iln/pr/chicago/2013/pr0730_01.html.

21. http://www.justice.gov/usao/paw/news/2013/2013_july/2013_07_31_01.html.

22. <http://www.justice.gov/usao/gan/press/2013/08-28-13b.html>.

23. <http://www.justice.gov/usao/hi/news/1308wgh.html>.

24. <http://www.justice.gov/usao/ks/PressReleases/2013/Sept2013/Sept%2017a.html>.

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
September 12, 2013	Forest Park Medical Center LLC	Forest Park Medical Center agreed to pay \$258,600 to resolve criminal and FCA allegations that it paid kickbacks to physicians in exchange for the referral of Tricare patients. The physician-owned hospital also entered into a non-prosecution agreement, which included a 24-month federal monitoring program. ²⁵	\$258,600
October 2, 2013	Tuomey Healthcare System, Inc.	Although not a settlement, a jury awarded the United States a significant FCA judgment resulting. On October 2, 2013, the U.S. District Court for the District of South Carolina corrected the sum of a damages award and civil monetary penalties - from \$276 million to \$237 million - resulting from a jury verdict in May 2013 against Tuomey Healthcare based on allegations that Tuomey entered into part-time employment agreements with several physicians that were in excess of the fair market value of their services in the hope that the physicians would refer outpatient procedures to Tuomey, in violation of the Stark Law. ²⁶	\$237 million (damages and civil penalties)
October 3, 2013	Medcath Corporation	Medcath announced that it agreed to pay \$6.1 million to resolve any civil or administrative claims, including FCA claims, in connection with an industry-wide investigation of allegations that certain hospitals, including several of Medcath's former hospitals, were billing Medicare for implantable cardioverter defibrillators that were utilized in violation of Medicare coverage guidelines. ²⁷	\$6.1 million
October 30, 2013	SSM Health Care of Oklahoma, Inc.	SSM Health Care, which owns and operates St. Anthony's Hospital in Oklahoma City, agreed to pay \$475,000 to resolve FCA allegations that it billed Medicare for inpatient services that should have been billed as outpatient services. ²⁸	\$475,000
December 16, 2013	Adventist Health System/Sunbelt Inc.	The parties in the <i>qui tam</i> styled <i>U.S. ex rel. Dittman v. Adventist Health System/Sunbelt Inc.</i> filed a notice of settlement in the Middle District of Florida resolving FCA allegations that Adventist unbundled payments for bundled medical services, improperly utilized a drug pricing code, and routinely billed for services not provided. The United States previously declined intervention in the action. ²⁹	Unknown
December 18, 2013	Tenet Healthcare Corporation	The parties in the <i>qui tam</i> styled <i>U.S. ex rel. Osheroff v. Tenet Healthcare Corporation</i> filed a joint stipulation of dismissal in the Southern District of Florida, indicating that the parties have reached a settlement in this action involving FCA allegations that Tenet charged below fair market value rates to physicians for the lease of space in Tenet's medical office buildings for the purpose of inducing or rewarding physicians referrals, in violation of the Stark Law. The United States previously declined intervention in the action.	Unknown
December 31, 2013	Sisters of Charity Leavenworth Health System; St. James Healthcare	On December 31, 2013, Montana-based hospital St. James Healthcare and its parent company, Sisters of Charity Leavenworth Health System, agreed to pay \$3.85 million to resolve allegations that they violated the Anti-Kickback Statute, Stark Law, and FCA by providing improper financial incentives to physicians and physician groups that were involved in a joint venture with St. James to own and operate a medical office building. The incentives included a payment to the joint venture that increased the physicians' and physicians groups' share values in the joint venture and lowered the lease rates for physicians renting space in the building below fair market value. Other incentives included below fair market value ground lease rates and arrangements related to shared facilities, use, and maintenance. St. James self-disclosed the allegedly improper physician incentives after they were discovered by an internal compliance audit and reviewed by an outside compliance firm. ³⁰	\$3.85 million

25. http://www.justice.gov/usao/txn/PressRelease/2013/SEP2013/sep12FPMC_sett.html.

26. <http://www.law360.com/articles/477736/hospital-to-pay-237m-for-fraud-after-clerical-error-fixed>.

27. <http://phx.corporate-ir.net/phoenix.zhtml?c=129804&p=irol-newsArticle&ID=1860046&highlight=>

28. http://www.justice.gov/usao/okw/news/2013/2013_10_30_2.html.

29. <http://www.law360.com/articles/496907/adventist-health-settles-whistleblowers-er-billing-claims>.

30. <http://www.justice.gov/opa/pr/2013/December/13-civ-1369.html>.

HEALTH PLANS

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
August 10, 2012	SCAN Health Plan	On August 10, 2012, SCAN Health Plan agreed to pay \$320 million to resolve FCA allegations that it artificially caused an inflation of some of its patients' risk adjustment scores and that it knowingly retained payments at rates for long-term-care-certified patients that were over the legal ceiling set by state statute and regulations. ³¹	\$320 million

31. <http://www.justice.gov/usao/cac/Pressroom/2012/112.html>.

LONG-TERM CARE PROVIDERS

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
December 21, 2012	GGNSC Holdings, LLC	GGNSC Holdings, LLC, agreed to pay \$613,300 to resolve FCA allegations that it provided nursing home residents with inadequate and worthless monitoring, documentation, and prevention and treatment of wounds. Under the terms of the agreement, GGNSC also entered a CIA with HHS-OIG. ³²	\$613,300
February 13, 2013	Fairfax Nursing Center	Fairfax Nursing Center, a Virginia-based skilled nursing facility, agreed to pay \$700,000 to resolve FCA allegations that it provided and charged for excessive, medically unnecessary, or otherwise non-reimbursable physical, occupational, and speech therapy services to 37 Medicare beneficiaries. Allegedly, the therapy services often were excessive, duplicative, performed without clear goals or direction, and, in some instances, performed primarily to capture higher reimbursement rates. ³³	\$700,000
February 28, 2013	Techota, LLC	Techota, LLC, a home healthcare provider, agreed to pay \$150,000 to resolve FCA allegations that it billed Medicare for home health services that were not eligible for reimbursement because the services were not medically reasonable and necessary or were not provided under a valid plan of care. Under the settlement, Techota entered a CIA with HHS-OIG. ³⁴	\$150,000
March 4, 2013	Grace Healthcare, LLC, and Grace Ancillary Services, LLC	Grace Healthcare, LLC, and Grace Ancillary Services, LLC, agreed to pay \$2.7 million to resolve FCA allegations that it knowingly submitted or caused the submission of false claims for medically unreasonable and unnecessary rehabilitation therapy. Under the terms of the agreement, Grace Healthcare and Grace Ancillary Services also entered a CIA with HHS-OIG. ³⁵	\$2.7 million
March 20, 2013	Hospice of Arizona L.C.; American Hospice Management LLC; American Hospice Management Holdings LLC	Hospice of Arizona L.C., American Hospice Management LLC, and American Hospice Management Holdings LLC agreed to pay \$12 million to resolve FCA allegations that they submitted claims to Medicare for ineligible hospice services provided to patients who did not need end of life care or for whom the hospice billed at a higher reimbursement rate than it was entitled. As a part of the settlement, American Hospice Management Holdings entered into a CIA with HHS-OIG which provides for procedures and reviews to be put in place to avoid and promptly detect similar conduct. ³⁶	\$12 million
May 21, 2013	U.S. Renal Care	U.S. Renal Care agreed to pay \$7.3 million to resolve FCA allegations that Dialysis Corporation of America, a company U.S. Renal Care previously acquired, billed Medicare for more of an anemia drug than it actually administered. The company allegedly billed for 10-11% overfill whenever it administered the drug, but it was not able to withdraw and administer 10-11% overfill in every administration because of the types of syringes the company used. ³⁷	\$7.3 million
June 18, 2013	Parkshore Home Health Care, LLC, d/b/a Renaissance Home Health Care, Inc.	Parkshore Home Health Care, LLC, d/b/a Renaissance Home Health Care, Inc., agreed to pay \$1 million to resolve FCA allegations that it provided unqualified home health aides to home health agencies, which in turn sent these unqualified aides into the homes of Medicaid recipients and billed Medicaid for their services. ³⁸	\$1 million

32. <http://www.justice.gov/usao/gan/press/2013/01-02-13.html>.

33. <http://www.justice.gov/opa/pr/2013/February/13-civ-193.html>.

34. http://www.justice.gov/usao/alm/press/2013/2013_03_13_techota.html.

35. <http://www.justice.gov/usao/tne/news/2013/March/O30813%20Grace%20Healthcare%20Settlement.html>.

36. <http://www.justice.gov/opa/pr/2013/March/13-civ-326.html>.

37. <http://www.justice.gov/opa/pr/2013/May/13-civ-588.html>.

38. <http://www.justice.gov/usao/nye/pr/2013/2013jun18.html>.

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
July 22, 2013	Hernando-Pasco Hospice, Inc. d/b/a HPH Hospice	HPH Hospice agreed to pay \$1 million to resolve FCA allegations that it submitted claims to Medicare for ineligible hospice services provided to patients who did not need end of life care or for whom the hospice billed at a higher reimbursement rate than it was entitled. HPH Hospice also purportedly provided kickbacks through free services to skilled nursing facilities in exchange for patient referrals. As part of the agreement, HPH Hospice entered into a five-year CIA with HHS-OIG. ³⁹	\$1 million
October 24, 2013	Hospice of the Comforter, Inc.	The Hospice of the Comforter (HOTC) agreed to pay \$3 million to resolve FCA allegations that billed Medicare for patients that were not terminally ill as a result of instructing its staff to admit patients without regard to their Medicare eligibility, falsifying medical records for ineligible patients, employing field nurses without hospice training, delaying discharge for patients when they became ineligible for the Medicare hospice benefit, and implementing procedures to limit physicians' roles in examining whether a patient is terminally ill. As part of the agreement, HOTC entered into a five-year CIA with HHS-OIG. ⁴⁰	\$3 million
November 19, 2013	The Ensign Group, Inc.	The Ensign Group agreed to pay \$48 million to resolve FCA allegations that six of its California skilled nursing facilities submitted claims to Medicare for medically unnecessary physical, occupational, and speech therapy services. Ensign purportedly created a corporate culture that improperly incentivized therapists to increase their therapy services to meet Medicare revenue targets that were set without regard to the therapy needs of individual patients. As part of the agreement, The Ensign Group entered into a five-year CIA with HHS-OIG. ⁴¹	\$48 million

39. http://www.justice.gov/usao/flm/press/2013/july/20130722_HPH.html.

40. <http://www.justice.gov/opa/pr/2013/November/13-civ-1179.html>.

41. <http://www.justice.gov/opa/pr/2013/November/12-civ-1235.html>.

PHARMACEUTICAL AND DEVICE

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
March 5, 2013	Par Pharmaceutical Companies Inc.	Par Pharmaceutical Companies Inc. agreed to pay \$45 million to resolve criminal and FCA allegations that it engaged in off-label marketing of a prescription drug approved by the FDA to treat anorexia, cachexia, or other significant weight loss suffered by patients with AIDS. Par Pharmaceutical did not include in its application to the FDA that it also intended the drug to treat non-AIDS-related geriatric wasting. The civil portion of the settlement totaled \$22.5 million. As a part of the agreement, Par Pharmaceutical entered into a CIA with HHS-OIG. ⁴²	\$45 million
March 8, 2013	Corning Incorporated	Corning Incorporated agreed to pay \$5.65 million to resolve FCA allegations that its life sciences division failed to meet its contractual obligations to provide the General Services Administration ("GSA") with current, accurate, and complete information about its commercial sales practices, including discounts offered to other customers, as required to participate in GSA's Multiple Award Schedule program. Corning allegedly knowingly made false statements to GSA about its sales practices and discounts for its commercial customers and failed to pass those discounts on to government customers, in violation of the price reduction clause of its GSA contract. ⁴³	\$5.65 million
April 16, 2013	Amgen Inc.	Amgen Inc., a biotechnology company, agreed to pay \$24.9 million to resolve FCA allegations that it paid kickbacks to long-term care pharmacy providers in return for their implementing programs designed to switch Medicare and Medicaid beneficiaries from a competitor drug to one manufactured by Amgen. The kickbacks took the form of performance-based rebates tied to market-share or volume thresholds. ⁴⁴	\$24.9 million
May 9, 2013	Ranbaxy USA Inc.	Ranbaxy USA Inc., a subsidiary of Indian generic pharmaceutical manufacturer Ranbaxy Laboratories Ltd., agreed to pay \$500 million to resolve criminal and FCA allegations that it introduced batches of adulterated drugs into interstate commerce; failed to maintain complete testing records; failed to implement an adequate stability program; failed to timely file field alerts for batches of drugs that had failed certain tests; and made false, fictitious, and fraudulent statements to the FDA in Annual Reports regarding the dates of stability tests conducted on certain batches of drugs. ⁴⁵	\$500 million
May 13, 2013	C.R. Bard Inc.	C.R. Bard Inc., a corporation that develops, manufactures, and markets medical products, agreed to pay \$48.26 million to resolve FCA allegations that it provided illegal remuneration to customers and physicians to induce them to purchase Bard's brachytherapy seeds, in violation of the Anti-Kickback Statute. The illegal remuneration took the form of grants, guaranteed minimum rebates, conference fees, marketing assistance and free medical equipment. As a part of the settlement, Bard has agreed to refine its written policies and procedures and to monitor medical education grants to ensure compliance with Federal requirements. ⁴⁶	\$48.26 million
May 16, 2013	International Rehabilitative Sciences d/b/a RS Medical	International Rehabilitative Sciences d/b/a RS Medical, a durable medical equipment company, agreed to pay \$1.2 million to resolve FCA allegations that it submitted claims to Medicare for various pieces of medical equipment that lacked physician orders, lacked the required supporting documentation, or lacked medical necessity. As a part of the agreement, International Rehabilitative Sciences entered into a CIA with HHS-OIG. ⁴⁷	\$1.2 million

42. <http://www.justice.gov/opa/pr/2013/March/13-civ-270.html>.

43. <http://www.justice.gov/opa/pr/2013/March/13-civ-289.html>.

44. <http://www.justice.gov/opa/pr/2013/April/13-civ-438.html>.

45. <http://www.justice.gov/opa/pr/2013/May/13-civ-542.html>.

46. <http://www.justice.gov/opa/pr/2013/May/13-civ-547.html>.

47. <http://www.justice.gov/usao/sc/news/5.16.13.rsmedical.html>.

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
May 24, 2013	ISTA Pharmaceuticals, Inc.	ISTA Pharmaceuticals, Inc., agreed to pay \$33.5 million to resolve criminal and FCA allegations that it introduced a misbranded drug into interstate commerce and violated the Anti-Kickback Statute. ISTA allegedly used continuing medical education programs and post-operative instruction sheets to promote the drug for uses unapproved by the FDA, and it paid physicians in order to induce them to prescribe the drug. ⁴⁸	\$33.5 million
June 28, 2013	TranS1 Inc.	TranS1 Inc., a medical device manufacturer now known as Baxano Surgical Inc., agreed to pay \$6 million to resolve FCA allegations that it caused healthcare providers to submit claims with incorrect diagnosis or procedure codes for minimally-invasive spine fusion surgeries using one of its systems and that it paid illegal remuneration to certain physicians for participating in speaker programs and consultant meetings intended to induce them to use TranS1 products, in violation of the Anti-Kickback Statute. ⁴⁹	\$6 million
July 3, 2013	Mallinckrodt LLC	Mallinckrodt LLC agreed to pay \$3.5 million to resolve FCA allegations that the pharmaceutical manufacturer paid physician consultants to participate in clinical trials, speaker programs, and meetings, or to complete specific forms, for the purpose of inducing them to prescribe the company's drugs. ⁵⁰	\$3.5 million
July 9, 2013	Omnicare Inc.	Omnicare Inc. agreed to pay an undisclosed amount to resolve FCA allegations that it improperly paid kickbacks as part of a \$25 million purchase of pharmaceutical benefits manager Total Pharmacy Services LLC in 2004. In November 2009, Omnicare agreed to pay \$98 million to settle other FCA claims arising out of the same transaction. ⁵¹	Undisclosed
July 30, 2013	Wyeth Pharmaceuticals Inc.	Wyeth Pharmaceuticals Inc. agreed to pay \$490.9 million to resolve criminal and FCA allegations that it unlawfully marketed its immunosuppressive drug Rapamune for uses not approved as safe and effective by the FDA. \$257.4 million of the settlement was allocated to resolving the civil FCA claims. Pfizer, Inc., who acquired Wyeth in 2009, is currently under a CIA with HHS-OIG covering former Wyeth employees who now perform sales and marketing functions at Pfizer. ⁵²	\$490.9 million
August 23, 2013	Pfizer, Inc.	Pfizer, Inc. agreed to pay an undisclosed amount to resolve a <i>qui tam</i> action, in which the government declined to intervene in 2005, involving allegations that Pharmacia Corp. (now part of Pfizer) marketed the human growth hormone Gentropin for uses not approved by the FDA and provided kickbacks to physicians that caused pharmacies to submit false claims to Medicaid programs. This matter settled while it was pending before the U.S. Court of Appeals for the First Circuit for the second time after a federal district judge granted Pfizer's motion to dismiss (for a second time). Pharmacia entered into a deferred prosecution agreement in 2007 requiring it to pay \$34.7 million to resolve criminal allegations that it violated the Anti-Kickback Statute through these allegedly illegal Gentropin payments. ⁵³	Undisclosed
October 17, 2013	Boston Scientific Corp.; Cardiac Pacemakers, Inc.; Guidant LLC; Guidant Sales LLC	Boston Scientific Corporation and its subsidiaries, including Guidant LLC, agreed to pay \$30 million to resolve FCA allegations that they sold defective implantable cardiac defibrillators to Medicare beneficiaries, even after becoming aware of the defects. Boston Scientific acquired Guidant in 2006, after the alleged misconduct occurred. In February 2010, Guidant pleaded guilty to criminal charges related to the defective devices for misleading the FDA and failing to provide a labeling change to the FDA. ⁵⁴	\$30 million

48. <http://www.justice.gov/opa/pr/2013/May/13-civ-606.html>.

49. <http://www.justice.gov/opa/pr/2013/July/13-civ-755.html>.

50. http://www.justice.gov/usao/can/news/2013/2013_07_18_mallinckrodt.settled.press.html.

51. http://www.law360.com/health/articles/456561?nl_pk=5ada6078-fca0-4976-b2f3-e4e46e7845c2&utm.

52. <http://www.justice.gov/opa/pr/2013/July/13-civ-860.html>.

53. <http://www.law360.com/articles/467464/pfizer-settles-former-exec-s-fca-suit-in-1st-circ>.

54. <http://www.justice.gov/opa/pr/2013/October/13-civ-1107.html>.

55. <http://www.justice.gov/usao/ks/PressReleases/2013/Oct2013/Oct22d.html>.

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
October 22, 2013	Global Medical Direct, LLC; Global Medical, Inc.; Robert Shea; Mark Franz	Global Medical Direct, Global Medical, and their owners, Robert Shea and Mark Franz, agreed to pay a combined \$12 million to resolve criminal and civil FCA allegations that Shea and Franz caused the mail-order diabetic supply companies to enter marketing contracts with insurance brokerage and other companies with customer pools likely to include a large number of diabetes patients and paid the companies based on the number of patient referrals for diabetic supplies. As part of the settlement, Shea and Franz received 20-year exclusions from participation in federal healthcare programs. ⁵⁵	\$12 million
October 23, 2013	Omnicare Inc.	Omnicare agreed to pay \$120 million to resolve FCA allegations that it engaged in a “swapping” kickback scheme whereby it provided discounts to nursing homes on Medicare Part A prescription drugs in exchange for the referral of Medicare Part D patients. The settlement agreement still must be approved by the DOJ, which initially declined to intervene in the matter. ⁵⁶	\$120 million
December 2, 2013	Caremark LLC	Caremark agreed to pay \$4.25 million to resolve FCA allegations that it failed to reimburse Medicaid programs in five states for the prescription drug costs of Medicaid beneficiaries, who also were eligible for drug benefits under private health plans. ⁵⁷	\$4.25 million

55. <http://www.justice.gov/usao/ks/PressReleases/2013/Oct2013/Oct22d.html>.

56. <http://www.complianceweek.com/omnicare-agrees-to-pay-120m-for-violations-of-false-claims-act/article/318503/>.

57. <http://www.justice.gov/opa/pr/2013/December/13-civ-1267.html>.

PHYSICIANS AND OTHER PROVIDERS

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
January 28, 2013	James P. Ralabate, M.D.; Primary Care Associates, P.C.	James P. Ralabate, M.D. and his professional corporation agreed to pay \$700,000 to resolve FCA allegations that he billed Medicare for high-level physician services that were medically unnecessary or lacked adequate supporting documentation. In addition, Dr. Ralabate allegedly billed Medicare for nursing home services for patients who were not actually in nursing homes at the time, but were transferred to local hospitals for treatment. As part of this agreement, Dr. Ralabate entered into a CIA with HHS-OIG. ⁵⁸	\$700,000
February 11, 2013	Steven J. Wasserman, M.D.	Steven J. Wasserman, M.D., a dermatologist practicing in Florida, agreed to pay \$26.1 million to resolve FCA allegations that he accepted illegal kickbacks from a pathology laboratory and billed the Medicare program for medically unnecessary services. Dr. Wasserman allegedly sent biopsy specimens for Medicare beneficiaries to a laboratory for testing, and the laboratory allegedly provided him a diagnosis on a pathology report that included a signature line to make it appear to Medicare that he had performed the diagnostic work. Further, Dr. Wasserman substantially increased the number of skin biopsies he performed on Medicare patients, thus increasing the referral business for the laboratory, and performed thousands of unnecessary adjacent tissue transfers on Medicare beneficiaries. The settlement is one of the largest ever with an individual under FCA. ⁵⁹	\$26.1 million
February 25, 2013	Williston Rescue Squad Inc.	Williston Rescue Squad Inc. agreed to pay \$800,000 to resolve FCA allegations that it billed Medicare for routine, non-emergency ambulance transports that were not medically necessary and created false documents to make the transports appear to meet the Medicare requirements. Under the terms of the agreement, Williston Rescue Squad also entered a CIA with HHS-OIG. ⁶⁰	\$800,000
April 2, 2013	Prevea Clinic, Inc.	Prevea Clinic, Inc., a group of clinics that employ physicians and other healthcare providers, agreed to pay \$94,000 to resolve FCA allegations that it submitted false claims to Medicare for the services of an assistant surgeon who lacked required credentials during neurosurgery procedures. ⁶¹	\$94,000
April 10, 2013	T. Hemanth Prabhakar Rao, M.D.; The Neurological Institute, P.A.	Dr. Rao and The Neurological Institute, of which Rao is the sole owner and operator, agreed to pay \$2 million to resolve FCA allegations that Dr. Rao billed Medicare for intravenous immunoglobulin therapy services that failed to meet Medicare's supervision regulations. As part of the agreement, Dr. Rao entered into a one-year CIA with HHS-OIG. ⁶²	\$2 million
April 25, 2013	Louis Francis Curte	Louis Francis Curte, the former owner of Wilkesboro Clinical Laboratory, agreed to pay \$300,000 to resolve FCA allegations that he and his company violated the Stark Law and that they billed Medicare for identification and susceptibility tests, when, in fact, no such tests were performed and even when the initial testing indicated that no pathogen was actually present in the specimen. ⁶³	\$300,000

58. <http://www.justice.gov/usao/ct/Press2013/20130131.html>.

59. <http://www.justice.gov/opa/pr/2013/February/13-civ-183.html>.

60. <http://www.justice.gov/opa/pr/2013/February/13-civ-232.html>.

61. http://www.justice.gov/usao/wie/news/2013/pr20130402_Prevea_Clinic_Settlement.html.

62. http://healthlawrc.bna.com/hlrc/4206/split_display.adp?fedfid=31220205&vname=hlreref1000&fn=32390401&jd=a0d9m7b4u8&split=0;

http://oig.hhs.gov/fraud/cia/agreements/T_Hemanth_Prabhakar_Rao_04092013.pdf.

63. <http://www.justice.gov/usao/ncw/pressreleases/2013/Charlotte-2013-04-25-curte.html>.

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
May 17, 2013	Las Vegas Urology, LLP	Las Vegas Urology, LLP, agreed to pay \$1 million to resolve FCA allegations that it improperly billed Medicare and other federal healthcare insurance programs for various urology services. As a part of the settlement, the government agreed not to seek to exclude Las Vegas Urology from federal healthcare programs, and Las Vegas Urology entered into a CIA with HHS-OIG. ⁶⁴	\$1 million
June 6, 2013	Dennis Schuller, D.D.S.	Dennis Schuller, D.D.S., agreed to pay \$100,000 to resolve FCA allegations that he improperly billed Medicare for certain x-rays and exams, medically unnecessary procedures, and other medically unnecessary items. ⁶⁵	\$100,000
June 20, 2013	Alfred Chan, M.D., Judy Chan	Alfred Chan, M.D., and his wife agreed to pay \$3.1 million to resolve FCA allegations that they routinely billed federal healthcare programs for at least twice the amount of cancer treatment drugs actually administered to Dr. Chan's patients. To conceal the fraud, they subsequently destroyed documents and falsified medical records. ⁶⁶	\$3.1 million
July 2, 2013	William R. Kincaid, M.D.; Millard R. Lamb, M.D.; and Charles O. Famoyin, M.D.	William R. Kincaid, M.D.; Millard R. Lamb, M.D.; and Charles O. Famoyin, M.D., former partners in East Tennessee Hematology-Oncology Associates, P.C., d/b/a McLeod Cancer and Blood Center, agreed to pay \$4.25 million to resolve FCA allegations that the McLeod Cancer and Blood Center administered and submitted Medicare claims for misbranded, unapproved chemotherapy drugs. These drugs were manufactured in foreign facilities not registered with the FDA, and some of their labels were in foreign languages or lacked dosage information. ⁶⁷	\$4.25 million
July 2, 2013	Sound Inpatient Physicians Inc.	Sound Inpatient Physicians Inc., a provider of hospitalists and other physicians to hospitals and other medical facilities, agreed to pay \$14.5 million to resolve FCA allegations that it submitted inflated Medicare claims on behalf of its hospitalist employees for higher and more expensive levels of service than were documented by hospitalists in patient medical records. ⁶⁸	\$14.5 million
July 18, 2013	Park Avenue Medical Associates, P.C.; Park Avenue Health Care Management, LLC; and Park Avenue Health Care Management, Inc.	Park Avenue Medical Associates, P.C. and its affiliated companies ("PAMA") agreed to pay \$1 million to resolve FCA allegations that they billed for psychiatric diagnostic examinations and psychotherapy services in violation of certain Medicare rules and policies. As part of the agreement, PAMA entered into a five-year CIA with HHS-OIG. ⁶⁹	\$1 million
July 25, 2013	Richard S. Obedian, M.D.	Richard S. Obedian, M.D., agreed to pay \$388,000 to resolve FCA allegations that he submitted claims to Medicare for kyphoplasty treatment using incorrect billing codes assigned to more invasive and complicated surgeries. ⁷⁰	\$388,000
July 30, 2013	Dr. Ishtiaq Malik; Ishtiaq Malik M.D., P.C.; and Advanced Nuclear Diagnostics	Although representing a judgment and not a settlement, on July 30, 2013, the U.S. District Court for the District of Columbia entered a sizable judgment against Dr. Ishtiaq Malik; Ishtiaq Malik M.D., P.C.; and Advanced Nuclear Diagnostics for more than \$17 million for submitting false nuclear cardiology claims to federal and state healthcare programs. The FCA allegations focused on Dr. Malik's inappropriate claims for myocardial perfusion studies, commonly referred to as nuclear stress tests, claiming that he and his companies double-billed for multi-day nuclear stress test studies. ⁷¹	\$17 million (judgment)

64. http://www.justice.gov/usao/nv/news/2013/20130521_lvu.html.

65. http://www.justice.gov/usao/ian/news/2013/jun_13/6_6_13_Schuller.html.

66. <http://www.justice.gov/usao/waw/press/2013/June/chan.html>.

67. <http://www.justice.gov/usao/tne/news/2013/July/070213%20Johnson%20City%20Doctors%20Settlement.html>.

68. <http://www.justice.gov/opa/pr/2013/July/13-civ-758.html>.

69. <http://www.justice.gov/usao/nys/pressreleases/July13/ParkAveMedicalAssociatesSettlementPR.php>.

70. <http://www.justice.gov/opa/pr/2013/August/13-civ-944.html>.

71. <http://www.justice.gov/opa/pr/2013/July/13-civ-864.html>.

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
August 2013	Babubhai Rathod	Babubhai Rathod agreed to pay \$1 million to resolve civil FCA allegations that he directed an “upcoding” scheme and a scheme to pay physicians for referring patients to medical clinics, physical therapy clinics, and a home healthcare agency. Rathod owned and operated this network of affiliated companies. Rathod agreed to a 20-year exclusion from federal healthcare programs as part of the settlement. In a parallel criminal proceeding, Rathod was sentenced to four years in prison. ⁷²	\$1 million
August 9, 2013	Bostwick Laboratories	Bostwick Laboratories agreed to pay \$503,668 to resolve FCA allegations that its sales representatives made illegal payments to physicians to induce them to enroll patients in a clinical study in order to utilize Bostwick’s laboratory testing services, some of which were not medically necessary. ⁷³	\$503,668
August 20, 2013	Planned Parenthood Gulf Coast	Planned Parenthood Gulf Coast agreed to pay \$4.3 million to resolve FCA allegations that it overbilled several government healthcare programs for additional testing and services that were not medically necessary, not medically indicated, or not actually provided. ⁷⁴	\$4.3 million
August 27, 2013	Imagimed LLC	Imagimed LLC and its former owners and former chief radiologist agreed to pay \$3.57 million to resolve FCA allegations that Imagimed billed federal healthcare programs for MRI services performed with a contrast dye without the direct supervision of a qualified physician, in violation of federal regulations, and for services referred to Imagimed by physicians with whom the company had improper financial relationships. ⁷⁵	\$3.57 million
September 13, 2013	Gulf Region Radiation Oncology Centers Inc.; Gulf Region Radiation Oncology MSO LLC; Sacred Heart Health Systems Inc.; West Florida Medical Center Clinic P.A.; Emerald Coast Radiation Oncology Center LLC	Radiation oncology providers in Pensacola, FL agreed to pay \$3.5 million to resolve FCA allegations that they improperly billed for services that were not rendered, already billed, upcoded, or performed by clinical staff not supervised by a physician as required by federal law. As part of the agreement, Gulf Region Radiation Oncology Centers entered into a three-year CIA with HHS-OIG. ⁷⁶	\$3.5 million
September 18, 2013	Hee Jung Mun; GreatCare Home Health Agency	A federal district judge issued a \$14.9 million default judgment against Hee Jung Mun, the former owner of GreatCare Home Health Agency, concluding a civil FCA case alleging that Mun and GreatCare operated a fraudulent scheme targeted at the elderly involving kickbacks to physicians for patient referrals, payments to patients to sign up for medically unnecessary home health services, billing Medicare for ineligible home health patients, creating false medical records, and upcoding. In January 2012, Mun pleaded guilty to defrauding Medicare in a parallel criminal proceeding. ⁷⁷	\$14.9 million (default judgment)
September 25, 2013	Jun Xu, M.D.; Rehabilitation Medicine and Acupuncture Center M.D., LLC	Jun Xu and Rehabilitation Medicine and Acupuncture Center agreed to pay \$300,000 to resolve FCA allegations that they billed Medicare for physical therapy services that were medically unnecessary or performed in violation of Medicare regulations - specifically, physical therapy services provided by message therapists and individual therapy services that were actually conducted in a group setting. ⁷⁸	\$300,000

72. http://www.justice.gov/usao/miw/news/2013/2013_0813_BRathod.html.

73. <http://www.justice.gov/usao/nye/pr/2013/2013aug20a.html>.

74. <http://www.justice.gov/usao/txe/News/2013/edtx-settlement-plan-081613.html>.

75. <http://www.justice.gov/opa/pr/2013/August/13-civ-958.html>.

76. <http://www.justice.gov/opa/pr/2013/September/13-civ-1027.html>.

77. <http://www.justice.gov/usao/cac/Pressroom/2013/116.html>.

78. <http://www.justice.gov/usao/ct/Press2013/20131018-1.html>.

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
September 25, 2013	Kan-Di-Ki LLC d/b/a Diagnostic Laboratories and Radiology	Diagnostic Laboratories and Radiology agreed to pay \$17.5 million to resolve FCA allegations that it paid kickbacks in the form of deep discounts for less profitable mobile diagnostic services to skilled nursing facilities in exchange for the referral of more lucrative outpatient services. ⁷⁹	\$17.5 million
September 27, 2013	Winter Park Urology Associates, P.A.	Winter Park Urology Associates reached an agreement with a <i>qui tam</i> relator for an undisclosed amount to resolve FCA allegations that it billed Medicare for radiation therapy treatments without proper supervision from radiation oncologists rendering the procedures medically unnecessary and in violation of Medicare regulations. ⁸⁰	Undisclosed
October 2, 2013	M. Scott Ellender, M.D.	M. Scott Ellender, M.D., an optometrist with Budget Optical, agreed to pay \$283,499 to resolve allegations that he submitted improper claims to federal programs for bifocal lenses, trifocal lenses and new patient visits, and for medically unnecessary exams. As part of the settlement agreement, Ellender and Budget Optical have entered into a CIA with HHS-OIG. ⁸¹	\$283,499
October 4, 2013	Hafeez Kahn, M.D.; U.S. Care Pain Clinic LLC; U.S. Care, Inc.	Hafeez Kahn, M.D. and two corporations he owned settled allegations that he improperly billed Medicare and Medicaid for services never performed and overbilled the government programs for other services to patients. ⁸²	\$1.2 million
October 18, 2013	Siouxland Community Health Center	Siouxland Community Health Center agreed to pay \$200,000 to resolve FCA allegations that it improperly billed Iowa Medicaid for dental outreach services performed on children that were not eligible for the service. ⁸³	\$200,000
November 6, 2013	Sabine Optical Laboratories, Inc. d/b/a The Vision Center; Carl Carnaggio, M.D.; Carl Carnaggio, Jr., M.D.; Lori Carnaggio; Cypress Optical Laboratory, LLC	Sabine Optical Laboratories agreed to pay \$1.2 million to resolve FCA allegations that it billed Medicaid for services provided by an unauthorized provider using the Medicaid provider number of a different provider, for worthless services based on the number of Medicaid patients being seen in a single day, for services never performed, and for lenses that were never made. Under the agreement, Sabine also entered into a three-year CIA with HHS-OIG. ⁸⁴	\$1.2 million
November 18, 2013	FILYN Corporation d/b/a Lynch Ambulance	Lynch Ambulance agreed to pay \$3.05 million to resolve FCA allegations that it billed federal healthcare programs for ambulance transport of patients who were not "bed-confined" or whose transports otherwise were medically unnecessary. As part of the agreement, Lynch Ambulance agreed to operate under a five-year CIA. ⁸⁵	\$3.05 million
November 21, 2013	Vantage Oncology LLC	Vantage Oncology agreed to pay \$2.08 million to resolve FCA allegations that it improperly billed Medicare for radiation oncology services by double billing, overbilling, billing for services without supporting documentation, and billing for services without the requisite physician supervision. ⁸⁶	\$2.08 million

79. <http://www.justice.gov/opa/pr/2013/September/13-civ-1068.html>.

80. <http://www.bizjournals.com/orlando/blog/2013/09/20-million-whistleblower-lawsuit.html?page=all>.

81. <http://legalnewsline.com/news/federal-government/244592-s-d-ag-announces-settlement-with-optometrist>.

82. <http://www.justice.gov/usao/ri/news/2013/oct2013/kahn.html>.

83. http://www.justice.gov/usao/ian/news/2013/oct_13/10_18_13_SCHC.html.

84. <http://www.justice.gov/usao/lam/news/2013/pr2013051.html>.

85. <http://www.fbi.gov/losangeles/press-releases/2013/orange-county-ambulance-company-pays-more-than-3-million-to-settle-allegations-that-it-overbilled-federal-health-care-programs>.

86. <http://www.justice.gov/opa/pr/2013/November/13-civ-1243.html>.

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
November 21, 2013	Edward Hamilton, M.D.; Centennial Pediatrics	Edward Hamilton, M.D. entered into a settlement and plea agreement to resolve civil and criminal FCA allegations that he billed - through Centennial Pediatrics - newborn hearing screenings and pediatric urinalysis as more comprehensive tests when in fact they lacked the equipment necessary to perform the higher-billed tests. Centennial Pediatrics joined the civil settlement. In total, to resolve the civil and criminal FCA allegations, Dr. Hamilton and Centennial Pediatrics paid \$1.6 million. Pursuant to the criminal plea and civil settlement, Hamilton was excluded from participation in all federal healthcare programs for 20 years and required to divest himself of ownership of Centennial Pediatrics. ⁸⁷	\$1.6 million
November 22, 2013	Lymphedema & Wound Care Institute of Texas Inc.	Lymphedema & Wound Care Institute and its affiliates agreed to pay \$4.3 million to resolve FCA allegations that it billed for physical therapy services provided by unqualified therapists and for pneumatic pumps that were not medically necessary or sold to patients but never actually provided to them. Pursuant to the agreement, the institute, which runs eight rehabilitation clinics in Texas, agreed to operate under a five-year CIA, and the institute's founder and CEO agreed to be barred from participating in federal healthcare programs for 10 years. ⁸⁸	\$4.3 million
December 13, 2013	Ravi Sharma, M.D.; Premier Vein Centers; Life's New Image	Ravi Sharma, M.D. and two Florida-based clinics owned and operated by Dr. Sharma agreed to pay \$400,000 to resolve FCA allegations that they knowingly billed Medicare for vein injections and physician office visits performed by unqualified personnel and for medically unnecessary procedures. As part of the settlement, Dr. Sharma entered into a three-year CIA with HHS-OIG. ⁸⁹	\$400,000
December 19, 2013	Elie H. Korban, M.D.	Elie H. Korban, M.D., agreed to pay \$1.15 million to resolve FCA allegations that he billed Medicare and Medicaid for medically unnecessary cardiac stent procedures and for services performed by substitute doctors when he was not able to perform the services himself. The <i>qui tam</i> lawsuit was originally brought against two West Tennessee hospitals, their respective CEOs and a radiologist, in addition to Korban. The government intervened only as to Korban. As a part of the agreement, Korban entered into a CIA with HHS-OIG. ⁹⁰	\$1.15 million
December 23, 2013	Rural/Metro Corporation	Rural/Metro Corporation agreed to pay more than \$2.8 million to resolve FCA allegations that various ambulance companies - owned and operated by Rural/Metro - billed Medicare for transporting patients from one hospital to another on an emergency basis when the calls were not actually emergencies. ⁹¹	\$2.802 million

87. <http://www.justice.gov/usao/tnm/pressReleases/2013/11-22-13.html>.

88. <http://www.justice.gov/usao/txs/INews/Releases/2013%20December/131202%20-%20Morgan%20et%20al.html>.

89. <http://www.justice.gov/opa/pr/2014/January/14-civ-009.html>.

90. <http://www.justice.gov/opa/pr/2013/December/13-civ-1333.html>.

91. http://www.justice.gov/usao/az/press_releases/2013/PR_12262013_Rural_Metro.html.

INTERVENED CASES (PRIOR TO SETTLEMENT)

DATE OF INTERVENTION	CASE STYLE	FCA ALLEGATIONS	STATUS
April 23, 2013	<i>United States v. Novartis Pharmaceuticals Corp.</i> , No. 11-8196 (S.D.N.Y.)	The lawsuit, initiated in November 2011, alleges that Novartis provided kickbacks, disguised as rebates or discounts, to approximately 20 pharmacies in return for the pharmacies switching kidney transplant patients to Novartis' drug from a competitor's drug and preventing patients from purchasing the cheaper generic equivalent. ¹	Amended Complaint and Intervenor Complaints filed
April 26, 2013	<i>U.S. ex rel. Bilotta v. Novartis Pharmaceuticals Corp.</i> , No. 11-71 (S.D.N.Y.)	The lawsuit, initiated in January 2011, alleges that Novartis provided kickbacks - including speaking engagements that were allegedly more like "social occasions" and lavish dinners - to induce physicians to prescribe the company's pharmaceutical products. ²	Pending MTD and motion to stay discovery
May 2, 2013	<i>U.S. ex rel. Gonzales v. Vitas Healthcare Corp.</i> , No. 13-344 (W.D. Mo.)	These lawsuits, initially filed in August 2007 (<i>Spottiswood</i>), August 2008 (<i>Urlick</i>) and January 2012 (<i>Gonzales</i>), were all transferred to the U.S. District Court for the Western District of Missouri and consolidated into one action after the government intervened in each case in May 2013. The government alleges that Chemed and 18 of its Vitas Healthcare Corp. subsidiaries engaged in a scheme to defraud Medicare by submitting claims for hospice services that were not necessary, not actually provided, or not performed in accordance with Medicare requirements. ³	Pending MTD
May 10, 2013	<i>U.S. ex rel. Spottiswood v. Chemed Corp. f/d/b/a Vitas Hospice Services, et al.</i> , No. 13-505 (W.D. Mo.)		
May 31, 2013	<i>U.S. ex rel. Urlick v. Vitas HME Solutions, et al.</i> , No. 13-563 (W.D. Mo.) [Consolidated Action] <i>United States v. Vitas Hospice Services LLC</i> , No. 13-449 (W.D. Mo.)		
June 10, 2013	<i>U.S. ex rel. Denk v. PharMerica Corp.</i> , No. 09-720 (E.D. Wisc.) <i>U.S. ex rel. Beeders, et al. v. PharMerica Corp.</i> , No. 11-706 (E.D. Wisc.)	The <i>Denk</i> lawsuit, initiated in July 2009, alleges that PharMerica routinely dispensed Schedule II controlled drugs in non-emergency situations before obtaining a written prescription from a treating physician. The <i>Denk</i> action subsequently has been consolidated with another FCA complaint filed against PharMerica by two relators (<i>Beeders</i>). ⁴	Pending MTD
July 8, 2013	<i>U.S. ex rel. Heesch v. Diagnostic Physicians Group, P.C., IMC-Diagnostic and Medical Clinic, P.C., Infirmary Medical Clinics, P.C., Infirmary Health System, Inc., and IMC-Northside Clinic</i> , No. 11-364 (S.D. Ala.)	The lawsuit, filed in July 2011, alleges that the IMC-Diagnostic and Medical Clinic improperly paid physicians from the Diagnostic Physicians Group compensation that included a percentage of the Medicare reimbursement for tests and procedures the doctors referred to the clinic, in violation of the Stark Law and Anti-Kickback Statute. ⁵	Pending MTD

1. <http://www.justice.gov/usao/nys/pressreleases/April13/NovartisLawsuitPR.php>; <http://www.justice.gov/opa/pr/2013/April/13-civ-481.html>.

2. <http://www.justice.gov/opa/pr/2013/April/13-civ-481.html>.

3. <http://www.justice.gov/opa/pr/2013/May/13-civ-500.html>; <http://www.law360.com/articles/475598/chemed-hospice-units-want-medicare-scam-suit-nixed>.

4. <http://www.justice.gov/opa/pr/2013/August/13-civ-903.html>.

5. <http://www.justice.gov/opa/pr/2013/July/13-civ-768.html>.

DATE OF INTERVENTION	CASE STYLE	FCA ALLEGATIONS	STATUS
July 18, 2013	<i>U.S. ex rel. Guthrie v. A Plus Home Health Care, Inc., et al.</i> , No. 12-60629 (S.D. Fla.)	The lawsuit, filed in April 2012, alleges that A Plus Home Health Care engaged in a scheme to increase Medicare referrals by employing several physicians' spouses and a physician's boyfriend for marketing purposes and generating sham personnel files for them, while requiring them to perform little to no actual work. ⁶	In discovery (MTDs denied; answer filed)
October 24, 2013	<i>U.S. ex rel. Renfree v. Brown Hand Center, et al.</i> No. 10-527 (S.D. Tex.)	The United States intervened in the relator's litigation, initiated in February 2010, as to allegations that Brown Hand Center billed Medicare for improperly unbundled medical services related to surgical procedures on the hand, and submitted duplicative claims or claims for a higher level of services than was actually provided, based on the improper use of CPT code modifiers. The United States declined to intervene in relator's claims against numerous co-defendants and claims that the defendants fraudulently billed Medicaid.	Stayed pending Brown Hand Center's Chapter 11 bankruptcy proceeding
November 20, 2013	<i>U.S. ex rel. Kurnik v. Omnicare, Inc.</i> , No. 11-1464 (D.S.C.)	The lawsuit, filed in June 2011, alleges that Omnicare and two other long-term care pharmaceutical services companies accepted kickbacks from Amgen, Inc., a biotechnology company, in return for their implementing programs designed to switch Medicare and Medicaid beneficiaries from a competitor drug to one manufactured by Amgen. The kickbacks consisted of performance-based rebates tied to market-share or volume thresholds. The government intervened only as to Omnicare. It previously settled with Amgen in April 2013. ⁷	Intervened for purpose of settlement; parties have until February 10, 2014 to finalize settlement agreement and obtain necessary approvals
December 3, 2013	<i>U.S. ex rel. Oughatiyan v. IPC Hospitalist Company Inc., et al.</i> , No. 09-5418 (N.D. Ill.)	The lawsuit, initiated in September 2009 against IPC and its subsidiaries in 24 states, alleges that IPC physicians sought payment for higher and more expensive levels of medical service than were actually performed. Specifically, the lawsuit alleges that IPC encouraged "upcoding" by training new physicians to utilize higher level codes, through its physician compensation structure, and by monitoring programs that identified physicians who needed to "catch up" to their peers. ⁸	Government has until March 2, 2014 to serve its complaint on the defendants
December 16, 2013	<i>U.S. ex rel. Nurkin v. Health Management Associates, Inc., et al.</i> , No. 11-14 (M.D. Fla.)	The lawsuit, initiated in January 2011, alleges that HMA and two HMA-owned hospitals engaged in a kickback scheme with a local physicians' group in exchange for patient referrals and hospital admissions. The alleged kickbacks came in the form of free office space, equipment, staff, and direct monthly expense payments. ⁹	Stayed pending MDL transfer ruling
December 16, 2013	<i>U.S. ex rel. Brummer v. Health Management Associates, Inc., et al.</i> , No. 09-135 (M.D. Ga.)	The United States intervened in the relator's litigation, initiated in November 2009, as to allegations that HMA and two HMA-owned hospitals billed for inpatient services that should have been billed as outpatient or observation services by pressuring hospitalists and emergency department contract groups into admitting a certain percentage of patients. The United States declined to intervene as to relator's allegations regarding unnecessary lab testing in the Emergency Department. ¹⁰	Stayed pending MDL transfer ruling

6. <http://www.justice.gov/opa/pr/2013/July/13-civ-717.html>.

7. Bloomberg BNA Health Law Resource Center, <http://healthlawrc.bna.com/hlrc>.

8. <http://www.justice.gov/opa/pr/2013/December/13-civ-1294.html>.

9. <http://www.justice.gov/opa/pr/2014/January/14-civ-037.html>; <http://www.law360.com/articles/497772>.

10. <http://www.justice.gov/opa/pr/2014/January/14-civ-037.html>.

DATE OF INTERVENTION	CASE STYLE	FCA ALLEGATIONS	STATUS
December 16, 2013	<i>U.S. ex rel. Williams v. Health Management Associates, Inc., et al.</i> , No. 12-151 (M.D. Ga.)	The lawsuit, initiated in December 2012, alleges that HMA and its subsidiaries billed Medicare and Medicaid for inpatient services that should have been billed as outpatient or observation services. ¹¹	Stayed pending MDL transfer ruling
December 16, 2013	<i>U.S. ex rel. Paul Meyer v. Health Management Associates, Inc., et al.</i> , No. 11-62445 (S.D. Fla.)	The lawsuit, initiated in November 2011, alleges that HMA implemented a nationwide strategy to increase Medicare payments by HMA-owned hospitals (1) maintaining improper financial relationships with, and making improper payments to, physicians, in violation of the Stark Law and Anti-Kickback Statute, and (2) billing for inpatient services that should have been billed as outpatient or observation services. Twenty-two HMA-owned hospitals across eight states are named as co-defendants. ¹²	Stayed pending MDL transfer ruling
December 16, 2013	<i>U.S. ex rel. Plantz v. Health Management Associates, et al.</i> , No. 13-1212 (N.D. Ill.)	The United States intervened in the relator's litigation, initiated in February 2013, as to allegations that HMA and 50 HMA-owned hospitals caused false claims to be submitted to federal healthcare programs for patients admitted through the Emergency Department that should have been placed in observation or outpatient status, or discharged, and as a result of providing kickbacks to Emergency Department physicians and physician groups in order to improve metrics and benchmarks related to inpatient admissions, in violation of the Anti-Kickback Statute. The United States declined to intervene as to relator's allegations regarding unnecessary testing on patients, and inflating the acuity of patients, in the Emergency Department. The United States declined to intervene against Defendant ProMed Clinical Systems, LLC. ¹³	Stayed pending MDL transfer ruling
December 16, 2013	<i>U.S. ex rel. Miller, et al. v. Health Management Associates, et al.</i> , No. 10-3007 (E.D. Pa.)	The United States intervened in relators' litigation, initiated in June 2010, against HMA and two HMA-owned hospitals. The complaint in this action remains under seal. The United States has been granted additional time to decide whether to intervene as to Defendant Physicians Alliance Ltd. ¹⁴	Stayed pending MDL transfer ruling; the United States has been granted additional time to decide whether to intervene as to Defendant Physicians Alliance Ltd.
December 16, 2013	<i>U.S. ex rel. Mason, et al. v. Health Management Associates, et al.</i> , No. 10-472 (W.D.N.C.)	The United States intervened in the relators' litigation, initiated in September 2010, as to allegations that HMA and two HMA-owned hospitals caused false claims to be submitted to federal healthcare programs for patients admitted through the Emergency Department that should have been placed in observation or outpatient status, or discharged, and as a result of providing kickbacks to Emergency Department physicians and physician groups in order to improve metrics and benchmarks related to inpatient admissions, in violation of the Anti-Kickback Statute. The United States declined to intervene as to relator's allegations regarding unnecessary testing on patients, and inflating the acuity of patients, in the Emergency Department. ¹⁵	Stayed pending MDL transfer ruling; the United States has been granted additional time to decide whether to intervene as to Defendants Emergency Medical Services Corp.; EmCare Inc.; EmCare Holdings, Inc.; and Emergency Medical Services, L.P.

11. <http://www.justice.gov/opa/pr/2014/January/14-civ-037.html>.

12. <http://www.justice.gov/opa/pr/2014/January/14-civ-037.html>.

13. <http://www.justice.gov/opa/pr/2014/January/14-civ-037.html>.

14. <http://www.justice.gov/opa/pr/2014/January/14-civ-037.html>.

15. <http://www.justice.gov/opa/pr/2014/January/14-civ-037.html>.

DATE OF INTERVENTION	CASE STYLE	FCA ALLEGATIONS	STATUS
December 16, 2013	<i>U.S. ex rel. Jacqueline Meyer, et al. v. Health Management Associates, Newsome, et al.</i> , No. 11-1713 (D.S.C.)	The United States intervened in the relators' litigation, initiated in July 2011, as to allegations that HMA and former HMA CEO Gary Newsome caused false claims to be submitted to federal healthcare programs for patients admitted through the Emergency Department that should have been placed in observation or outpatient status, or discharged, and as a result of providing kickbacks to Emergency Department physicians and physician groups in order to improve metrics and benchmarks related to inpatient admissions, in violation of the Anti-Kickback Statute. The United States declined to intervene as to relator's allegations regarding unnecessary testing on patients in the Emergency Department. ¹⁶	Stayed pending MDL transfer ruling; the United States has been granted additional time to decide whether to intervene as to Defendants Emergency Medical Services Corp. and EmCare, Inc.

16. <http://www.justice.gov/opa/pr/2014/January/14-civ-037.html>.

ABOUT BASS, BERRY & SIMS PLC

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 in 2013 alone. 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 <http://www.bassberry.com/healthcare-fraud>.



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