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2015 FCA Litigation Review: An Old Act With New Tricks

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By Mary Damitio, J.D.
Health Law Writer Analyst

Executive Summary

During the first half of 2015, Health Law Daily reported on 77 cases involving the False Claims Act (FCA) (31 U.S.C. § 3729 et seq.). The first half of 2015 has shown that such basic questions as who may bring a lawsuit as a relator in a qui tam action and what facts must be alleged are major issues that counsel on both sides of litigation will likely continue to face in handling FCA cases for the remainder of the year and possibly for years to come. The cases reported by Health Law Daily most often came from the trial court level and were commonly dismissed based upon pleading insufficiencies.

Notably, the U.S. Supreme Court weighed in on the FCA this year finding that times of war did not toll the statute of limitations and also interpreted the "first to file" rule (31 U.S.C. § 3730(b)(5)). Additionally, the Eleventh Circuit applied the Patient Protection and Affordable Care Act's (ACA) (P.L. 111-148) amendments to the public disclosure bar (31 U.S.C. § 3730(e)(4)) prospectively while the Sixth Circuit ruled on the scope of the pre-amendment public disclosure bar. The Ninth Circuit departed from 23 years of precedent and lowered the bar for relators bringing qui tam actions, and the hospital felt the bite of the FCA and the Stark Law (42 U.S.C. § 1395nn), when the Fourth Circuit in U.S. ex rel Drakeford v. Tuomey affirmed a $237 million verdict against it for prohibited physician compensation agreements. There were also a number of notable settlements involving hospitals and skilled nursing facilities (SNFs) resolving alleged violations of the Anti-Kickback Statute (AKS) (42 U.S.C. § 1320a-7(b)(b)) being a popular theme.

The Major Themes in FCA Litigation

According to Attorney Michael E. Clark, Special Counsel of Duane Morris LLP, the number of FCA case filings has continued to increase each year, with the statute being the Department of Justice's (DOJ's) "primary enforcement tool against the health care sector." Clark cautions, however, that long-term effect of the increasing popularity of FCA claims must be "seriously considered in light of the complexity of health care financing and the willingness of whistleblowers and the DOJ to pursue novel theories against putative healthcare defendants." As a result, Clark further warns that the FCA is moving closer to becoming the 'all purpose' antifraud law" that the U.S. Supreme Court warned against.

Pleading insufficiencies generally. The majority of the FCA case dismissals were based upon insufficiency of the pleadings. As noted in the 2014, the circuits are split as to what constitutes sufficient pleading under the FCA and, as a result, cases have varied as to what allegations are specific enough to state claims that can meet Federal Rule of Civil Procedure's Rule 9(b) fraud

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pleading requirement and withstand motions to dismiss. In the first half of the year, reported cases were dismissed more frequently due to a lack of pleading the submission of false claims to the government; however, some realtors who brought actions were allowed to maintain their claims for retaliatory discharge even though their FCA claims were dismissed.

Rule 9(b) pleading requirements. In an interview with Wolters Kluwer, Attorney Michael E. Paulhus of King & Spalding LLP noted that the issue of 9(b) pleading requirements will continue to be major focus of FCA litigation until the Supreme Court decides to provide clarity on the issue. According to Paulhus, "litigators need to be thoughtful in how they posture motion to dismiss arguments based on inadequate pleading." Attorneys must consider the circuit's position on Rule 9(b) while preparing a defense and may consider making a joint Rule 9(b) and Rule 8 [of the Federal Rules of Procedure] argument or relying solely on Rule 8's general pleading requirements depending on the court's view of FCA cases.

Attorney Michael Clark also noted that the varying pleading requirements affect strategy on both sides of FCA litigation. Clark stated that in actions filed in jurisdictions with a permissive approach under Rule 9(b), plaintiffs' counsel will commonly seek "leeway from the heightened pleading standards so that they may conduct discovery and thereby demonstrate the scope of the fraud." He added that defense counsel will instead "focus on plaintiffs' failure to show their entitlement to relief under . . . Rule 8(a)(2), which requires that a complaint include 'enough facts to state a claim to relief that is plausible on its face.'" Clark agreed with Paulhus that the Supreme Court needs to weigh in on the pleading requirements soon so as to provide clarity on the issue.

A review of recent cases indicates that courts throughout the country took different views on the requirements for pleading under FCA. Other than the First Circuit, however, the courts of appeals have not yet provided additional rulings this year on the particularity requirement in FCA pleading.

Particularity. The First Circuit, taking its broad view of what constitutes a fraudulent claim under the FCA, found that a trial court improperly dismissed a qui tam action brought under the statute due to lack of particularity in the pleading (*United States ex rel. Escobar v. Universal Health Services, Inc.*, 1st Cir., March 17, 2015). In reversing the trial court's dismissal of the case, the First Circuit reiterated that it did not distinguish between factually false and legally false claims, but instead simply considered whether the defendant, when submitting a reimbursement claim, "knowingly misrepresented compliance with a material precondition of payment."

Retaliatory discharge after engaging in protected conduct. One area in particular in which litigants frequently encountered problems in getting out of the motion to dismiss starting gates of FCA litigation was the failure of relators to allege that they were engaged in protected conduct to state claims for retaliatory discharge. The FCA allows whistleblowers to bring claims against employers for retaliatory discharge (31 U.S.C. § 3730(h)(1), provided that a relator can allege that he or she was engaged in protected conduct, the employer was aware of the conduct, and the employer took adverse employment action against the employee because of the protected activity.

In certain cases, when the relators' qui tam suits were dismissed for failure to allege specifics as to the claims submissions, the court determined that the relators could instead state claims for retaliatory discharge (*McFeeters v. Northwest Hospital*, M.D. Tenn., January 23, 2015; *U.S. ex rel. Hagerty v. Cyberonics, Inc.*, D. Mass., March 31, 2015; *U.S. ex rel. Ibanez v. Bristol-Myers Squibb Co.*, S.D. Ohio, March 27, 2015).

***U.S. ex rel Campie v. Gilead Sciences, Inc*.** One case of note on this issue was *U.S. ex rel Campie v. Gilead Sciences, Inc.*, N.D. Cal. (June 12, 2015), in which a trial court dismissed a relator's complaint because it found that the relator's allegations did not amount to protected conduct to state a claim for retaliation under the FCA.

Campie involved a former employee of a drug manufacturing company who was fired after bringing his concerns about the company's Chief Compliance Officer and threatening to report the company's falsified data and test results to the FDA. Although the employer requested that Campie sign a severance agreement promising not to bring suit against the employer under the FCA, he refused. The court found that Campie's job required him to investigate and internally report FDA regulatory issues and, therefore, his actions were merely an investigation of fraud on the FDA, and he did not allege that he was concerned about the government fraudulently paying money to Gilead. The court concluded that Campie did not sufficiently allege that Gilead had knowledge of his FCA activities and, therefore, his complaint was insufficient to establish that the employer had knowledge of the impending FCA claim.

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Arthurs v. Global TPA, LLC. In an interesting departure from other retaliation cases, a district court in Florida allowed an FCA claim to proceed even though the employee did not allege any particulars about claims being submitted to the government. The court reasoned that the amendments to § 3730 expanded the scope of employee conduct that is protected against retaliation to include any conduct that furthers the interests of the Act rather than conduct that apprises the employer of the possibility of litigation (*Arthurs v. Global TPA, LLC*, M.D. Fla., March 25, 2015).

Submission of false claims. Other whistleblower suits were dismissed for failure to sufficiently plead any details about specific false claims that were actually submitted to the government (*Bonewitz v. NewQuest, LLC*, M.D. Tenn., April 22, 2015; *Phipps v. Agape Counseling and Therapeutic Services, Inc.*, E.D. Va., May 21, 2015; *U.S. ex rel. Lawson v. Aegis Therapies, Inc.*, S.D. Ga., March 31, 2015; *U.S. ex rel. Ibanez v. Bristol-Myers Squibb Co.*, S.D. Ohio, March 27, 2015). Additionally, in some instances when relator complaints were dismissed for failure to allege that false claims were submitted to the government, courts granted leave to the relators to amend their complaints, perhaps to provide them an opportunity to gather the information (*U.S. ex rel. Prather v. Brookdale Senior Living Communities, Inc.*, M.D. Tenn., March 31, 2015).

Public disclosure bar. Three of the circuits dealt with the FCA public disclosure bar in the first half of 2015, and the decisions thus far seem to show a relaxation of the bar.

According to Attorney George Breen of Epstein Becker Green, "FCA litigation in 2015 has reflected a further weakening of the Public Disclosure Bar."

U.S. ex rel. Whipple v. Chattanooga-Hamilton County Hospital Authority. The Court of Appeals for the Sixth Circuit in *U.S. ex rel. Whipple v. Chattanooga-Hamilton County Hospital Authority* (February 25, 2015) examined the pre-2010 public disclosure bar set forth in 31 U.S.C. § 3730(e)(4), which deprives courts of jurisdiction over qui tam cases that are based on public disclosure of allegations or transactions (1) in a criminal, civil, or administrative hearing; (2) in a congressional, administrative, or Government Accountability Office (GAO) report, hearing, audit, or investigation; or (3) from the new media. The bar does not apply to actions brought by the Attorney General or the person who was the original source of the information.

In *Whipple*, a relator brought a qui tam action under the FCA against his former employer based upon his personal observations of fraudulent claims. Unbeknownst to the relator, however, the government previously had conducted an internal investigation of the employer that was not disclosed to the public. Thereafter, the relator filed suit and had his claim dismissed under the public disclosure bar. The Sixth Circuit joined various other circuits in finding that the FCA public disclosure required an affirmative act of disclosure to the public outside of the government. Notably, the court rejected the Seventh Circuit's holding in *United States ex rel. Mathews v. Bank of Farmington*, January 20, 1999, that found such disclosures would serve as a bar. Instead, the court joined the majority of other circuits finding that the bar required actual disclosure to the public.

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U.S. ex rel. Osheroff v. Humana, Inc. The Eleventh Circuit decided a case involving the public disclosure bar and found that the amendments enacted by the Patient Protection and Affordable Care Act (ACA) (P.L. 111-148) did not apply retroactively; however, the court's decision as to retroactivity was based on the party's waiver of the issue (*U.S. ex rel. Osheroff v. Humana, Inc.*, 11th Cir., January 16, 2015).

The relator in the case, who operated medical office buildings in Miami, considered opening a health clinic. During his research of the health clinic market, he learned that many area clinics provided various free services to patients. He filed a qui tam action that alleged that three clinics and several health insurers that had contracts with the clinics were in violation of the FCA and the AKS. The health insurers moved to dismiss, arguing that the relator's action was barred by the FCA's public disclosure provision (42 U.S.C. § 3730(e)(4)). Specifically, the insurers argued that the allegations had been publicly disclosed in a prior state court lawsuit and through the news media.

Although the pre-2010 § 3730 deprived courts of jurisdiction over qui tam FCA cases that were based on

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allegations that were previously publicly disclosed, the amended section states that a "court shall dismiss an action or claim under this section, unless opposed by the Government, if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed" by certain sources is reviewed under a motion to dismiss for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6). The court also determined that it could examine extrinsic evidence when ruling on the motion to dismiss because the evidence was central to the claim and its authenticity was not contested. In the case, the court found that under either standard, the lawsuit was barred based upon prior public disclosure.

Original source. Two circuits weighed in on the original source exception, which provides that a relator may bring a qui tam action based on publicly disclosed information provided that he or she was the original source of the disclosure (31 U.S.C. § 3730(e)(4)(B)). In a surprising move, the Ninth Circuit reversed course on its original source stance and lowered the bar for a relators to bring qui tam actions.

U.S. ex rel Hartpence v. Kinetic Concepts, Inc. The Ninth Circuit departed from 23 years of precedent and held that under the FCA public disclosure bar, a relator may qualify as an original source (31 U.S.C. § 3730(e)(4)(B)) if, "he has direct and independent knowledge of the information on which the allegations in his court-filed complaint are based, and (2) he has voluntarily provided the information to the Government before filing his civil action" (*U.S. ex rel Hartpence v. Kinetic Concepts, Inc.*, July 7, 2015).

The case involved two relators who brought qui tam cases alleging that their former employer fraudulently filed for Medicare reimbursements. One relator alleged that the employer was misusing a billing code modifier and the other relator alleged that the company was billing for full months of therapy after it had stopped and restarted in the same month and did not comply with Medicare requirements relating to written orders. The trial court determined that the allegations had been publicly disclosed previously and, therefore, the relators were not the original sources of the information.

The appellate court reversed the trial court and found that the relators qualified as original sources. Prior to this decision, the Ninth Circuit required a relator to have "had a hand" in the public disclosure of lawsuit allegations. The Ninth Circuit determined that the original source provision of the FCA did not contain the third requirement and its prior decision holding otherwise was wrongly decided.

U.S. ex rel. Antoon v. Cleveland Clinic Foundation. The Sixth Circuit also considered whether a relator qualified as an original source under the FCA. In *U.S. ex rel. Antoon v. Cleveland Clinic Foundation* (June 11, 2015), the relator brought suit alleging that a surgeon submitted false claims to the government for surgery that he did not actually perform on the relator. The Sixth Circuit found the pre-2010 provisions of § 3730 applied and determined that the relator was not the original source because he did not have direct and independent knowledge of the allegations in his complaint. The court concluded that direct knowledge had to be gained from a relator's own efforts and could not be acquired from other persons. In this case, the relator merely suspected that the surgeon did not perform the surgery, but had no actual knowledge of that fact and, therefore, could not bring a qui tam action under the FCA.

First-to-file and statute of limitations. One of the major developments in FCA litigation thus far in 2015 was the U.S. Supreme Court's decision interpreting the FCA's first-to-file bar and whether times of war tolled its statute of limitations.

According to Attorney George Breen, "This holding will provide opportunity for relators to bring more troublesome cases after early filers' cases have been rejected by the government and abandoned by relators or dismissed by the Courts." He further stated that, "this decision allows for complex and sophisticated lawsuits that are not recognized at first blush but which can be brought at any time when there is nothing else relevant pending."

According to Attorney Michael Paulhus, the Supreme Court's decision in *Kellogg Brown & Root Services, Inc. v. U.S. ex rel Carter* (May 26, 2015) will likely lead to litigants focusing dismissal argument on the public disclosure bar, Rule 9(b), and FCA prima facie elements instead of first-to-file arguments. Paulhus also noted that the court did not address the issue of claim preclusion in such cases, and counsel should consider whether it is, "an alternative argument to advance instead of the first-to-file bar."

Kellogg Brown & Root Services, Inc. v. U.S. ex rel Carter. The U.S. Supreme Court interpreted the FCA the "first-to-file" rule and the statute of limitations in *Kellogg*. The "first-to -file" provision of the FCA (31 U.S.C. § 3730(b)(5)) prohibits parties from filing FCA claims when there is another action pending on a related claim. The Fourth Circuit held that the provision did not apply in instances when other litigation had been dismissed. The Supreme Court affirmed the Fourth Cir-

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cuit's decision, finding that cases are no longer "pending" within the terms of the statute after they are dismissed. The Court unanimously ruled that the FCA statute of limitations is not tolled by the Wartime Suspension of Limitations Act (WSLA) (18 U.S.C. § 3287). Although the qui tam case involved contractors in Iraq during times of war, the Supreme Court's decision affects FCA litigation in the health care arena.

FCA and Stark Law

While FCA litigation based on alleged Stark Law violations in the first half of 2015 was not as prevalent as FCA-only cases, a recent lawsuit involving physician compensation agreements demonstrated just how serious violations of the anti-referral law can be for health care providers when the Fourth Circuit recently affirmed an over $237 million verdict against Tuomey Healthcare System, Inc. for engaging in prohibited referrals (*U.S. ex rel. Drakeford v. Tuomey*, July 2, 2015)

Physician compensation agreements. Tuomey is a nonprofit hospital located in rural South Carolina. Prior to 2000, most of the physicians that practiced at Tuomey were not employees of the hospital. At some point, however, the physicians began performing surgeries at locations outside the hospital. The loss of the surgery revenue was a major concern to Tuomey, which then began negotiating part-time employment agreements with certain physicians in the attempt to mitigate its losses. Tuomey entered into agreements with 19 physicians. The agreements provided for a guaranteed annual base salary that was adjusted based upon the amount the physicians collected. Also, the physicians were entitled to a "productivity bonus," which was 80 percent of their collections for the year and an "incentive bonus" that was 7 percent of the physicians' earned productivity bonus. The hospital also paid for the physicians' malpractice insurance and their practice groups' share of employment taxes. It also allowed the physicians to participate in its health insurance plan and even paid for the physicians' billing and collection fees.

Advice of counsel. Tuomey sought advice from various sources when drafting the physician agreements and again sought advice from a consultant about the legality of the agreements after a physician raised objections.

The jury verdict. After an initial trial and retrial, a jury found that Tuomey had violated the Stark Law and the FCA and submitted 21,730 false claims to Medicare for payment totaling over $39 million, which the trial court trebled and added a civil money penalty as required by the FCA. The total judgment topped $237 million. Tuomey appealed the verdict claiming that the judgment was excessive and it had not violated the FCA.

The appellate court decision. The Fourth Circuit determined that it was reasonable for the jury to have determined that Tuomey violated the Stark law when it paid compensation to physicians based on patient referrals. The amount of procedures that the physicians performed at the hospital resulted in more facility fees for Tuomey, which resulted in more compensation to the physicians. Additionally, the court rejected Tuomey's claims that it reasonably relied on the advice of counsel because the record was "replete with evidence indicating that Tuomey shopped for legal opinions approving of the employment contracts, while ignoring negative assessments."

> *"It seems as if, even for well-intentioned health care providers, the Stark Law has become a booby trap rigged with strict liability and potentially ruinous exposure—especially when coupled with the False Claims Act."*

Concern over Stark. The concurring opinion noted that while the trial court did not abuse its discretion in granting a new trial and the jury did not act irrationally when it found that Tuomey violated the FCA, it nonetheless expressed concerns over the "bootstrapping" of Stark and the FCA. Judge James Wynn, Jr. stated in his concurring opinion, "It seems as if, even for well-intentioned health care providers, the Stark Law has become a booby trap rigged with strict liability and potentially ruinous exposure—especially when coupled with the False Claims Act."

Warning signs. According to Richard P. Kusserow, CEO of Strategic Management Services, LLC, who served as HHS Inspector General for 11 years, and who was called as a witness during the trial, the Tuomey case highlights several "yellow and red flags" that should raise

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Table 1: Notable cases in first half of 2015
Particularity
United States ex rel. Escobar v. Universal Health Services, Inc., 1st Cir., March 17, 2015
Retaliatory discharge after engaging in protected conduct
McFeeters v. Northwest Hospital, M.D. Tenn., January 23, 2015
U.S. ex rel. Hagerty v. Cyberonics, Inc., D. Mass., March 31, 2015
U.S. ex rel. Ibanez v. Bristol-Myers Squibb Co., S.D. Ohio, March 27, 2015
U.S. ex rel Campie v. Gilead Sciences, Inc., N.D. Cal., June 12, 2015
Arthurs v. Global TPA, LLC, M.D. Fla., March 25, 2015
Submission of false claims
Bonewitz v. NewQuest, LLC, M.D. Tenn., April 22, 2015
Phipps v. Agape Counseling and Therapeutic Services, Inc., E.D. Va., May 21, 2015
U.S. ex rel. Lawson v. Aegis Therapies, Inc., S.D. Ga., March 31, 2015
U.S. ex rel. Ibanez v. Bristol-Myers Squibb Co., S.D. Ohio, March 27, 2015
U.S. ex rel. Prather v. Brookdale Senior Living Communities, Inc., M.D. Tenn., March 31, 2015
Public disclosure bar
U.S. ex rel. Whipple v. Chattanooga-Hamilton County Hospital Authority, 6th Cir.,February 25, 2015
U.S. ex rel. Osheroff v. Humana, Inc., 11th Cir., January 16, 2015
Original source
U.S. ex rel Hartpence v. Kinetic Concepts, Inc., 9th Cir., July 7, 2015
U.S. ex rel. Antoon v. Cleveland Clinic Foundation, 6th Cir., June 11, 2015.
First-to-file and statute of limitations
Kellogg Brown & Root Services, Inc. v. U.S. ex rel Carter, U.S., May 26, 2015
Stark Law
U.S. ex rel. Drakeford v. Tuomey, 4th Cir., July 2, 2015

concerns for anyone dealing with physician compensation agreements.

Kusserow identified the red flags in the physician compensation agreements at issue in *Tuomey* as follows:

(1) the fair market value determination exceeded 90 Medical Group Management Association (MGMA) percentile;
(2) the record indicated that *Tuomey* feared competition and used agreements to block it;
(3) *Tuomey* shopped around when its advisors did not give it the answer it wanted;
(4) the physicians who took part in the agreements saw their incomes increase dramatically; and
(5) the compensation agreements took into account the volume of the physicians' referral to the hospital.

Kusserow also identified unusual elements in the agreements that raised "yellow flags," including the following provisions: the agreements were long term, some as long as 10 years; were part-time, partial service contracts; the physicians guaranteed that they would exclusively use the hospital for surgeries; the compensation formula arrangements were complicated; and full-time benefits were provided for part-time employees. Also, there were no identifiable work requirements for the salaries. Further, the agreements involved only out-patient services and the incentive compensation was provided prior to the beginning of work.

While Kusserow emphasized that the *Tuomey* case does not foreclose all agreements between hospitals

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and physicians; he advised providers to carefully scrutinize any agreements to ensure they do not violate Stark and the AKS.

Significant Settlements

A number of large FCA claims were settled at the beginning of 2015, including the ongoing DaVita Healthcare Partners, Inc., saga, which has seemed to involve a settlement of some sorts every few weeks. Also, the DOJ announced the largest settlement ever to involve a SNF and prohibited kickbacks. Other the settlements involved compensation agreements and other prohibited referrals, which appear to be areas that are being targeting for FCA enforcement.

DaVita Healthcare Partners, Inc. DaVita, the largest provider of dialysis services in the United States, faced several large settlements stemming from claims that it violated the FCA and the AKS. In 2014, DaVita agreed to pay over $475 million to settle various claims that it violated the AKS by entering into joint ventures with physicians with large renal patient practices (see *Another day, another DaVita settlement; $450M this time*, June 25, 2015). In 2015, DaVita again settled with shareholders (that involved no monetary payments) and entered into a $450 million settlement to resolve claims that it violated the FCA by creating and billing for avoidable waste when it administered Zemplar® and Venofer® to dialysis patients.

Hebrew Homes Health Network, Inc. A Florida SNF agreed to pay a record-breaking $17 million to settle claims that it violated the FCA by paying kickbacks to doctors in exchange for Medicare patient referrals. The settlement was the largest ever to involve SNFs and alleged kickbacks.

Hebrew Homes provides skilled nursing services at seven rehabilitation and skilled nursing facilities in the Miami area. Hebrew Homes is alleged to have participated in an illegal kickback scheme from 2006 through 2013, during which time it contracted with and hired numerous physicians as "medical directors." The medical director contracts set forth the physicians' hours and job duties. Each facility had several medical directors who were receiving payments of several thousand dollars each month. These positions were actually "ghost positions," and most of the medical directors performed only very few of their contractual duties because the payments were made in exchange for Medicare patient referrals to Hebrew Homes facilities.

Table 2: Significant Settlements

NAME	SETTLED ALLEGATIONS
DaVita Healthcare Partners, Inc.	Fraudulent claims and illegal referrals—AKS
Hebrew Homes Health Network, Inc.	Illegal physician referrals and kickbacks—AKS
Recovery Home Care Inc., Recovery Home Care Services Inc., and National Home Care Holdings LLC	Illegal physician referrals and kickbacks—AKS/Stark
Health Diagnostics Laboratory Inc. and Singulex, Inc.	Illegal physician referrals and kickbacks—AKS
Citizens Medical Center	Illegal physician referrals and kickbacks—AKS/Stark
Daiichi Sankyo, Inc.	Illegal physician kickbacks—AKS
Medical Center of Central Georgia	Improper inpatient billing—FCA

According to Attorney Brian Dickerson, a corporate compliance attorney, the Hebrew Homes settlement is representative of the increase in the number of lawsuits brought against SNFs. Attorney Dickerson stated, "The Hebrew Homes Health Network settlement is similar to other current civil and criminal investigations of SNFs trying to create a compensation system for physicians for actual referrals, which the industry knows cannot be legally accomplished."

Fraud alert. The Office of Inspector General (OIG) issued a fraud alert related to physician compensation agreements just days before the Hebrew Homes settlement was announced. With the increasing frequency of such agreements, Attorney Dickerson sees the timing of the fraud alert and the settlement announcement as no coincidence. Dickerson stated, "I do not think it is by chance that OIG reissued its warning on medical director compensation within the same month as the announcement of this settlement. With the factual basis for the kickback violation, DOJ can argue that all patient billing was false, which would make the recovery a lot greater than just for services billed which were not rendered."

Recovery Home Care Inc., Recovery Home Care Services Inc., and National Home Care Holdings LLC, agreed to pay $1.1 million to settle claims of improper payments to doctors in exchange for referrals of home health care services provided to Medicare patients. The qui tam suit alleged that Recovery Home

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Care paid thousands of dollars each month to physicians to perform chart reviews. The physicians were overcompensated for their work, and the payments were prohibited referrals under the AKS and the Stark Law.

Health Diagnostics Laboratory Inc. and Singulex, Inc. Health Diagnostics Laboratory, Inc. agreed to pay $47 million to settle claims that it violated the FCA by paying kickbacks to physicians for referrals of cardiac patients and performing and billing for medically unnecessary testing. Singulex, Inc. of Alameda, California also agreed to pay $1.5 million to resolve similar claims.

Citizens Medical Center. A Texas hospital agreed to pay $21,750,000 to settle allegations that it violated the FCA and the Stark Law by entering into illegal referral arrangements with physicians. The qui tam lawsuit alleged that the hospital used a bonus scheme to increase referrals to the hospital's cardiology department. The suit also alleged that the hospital paid compensation to cardiologists in excess of the fair market values of the services. Additionally, the lawsuit alleged that the hospital paid bonuses to emergency room physicians that were based on the number of their cardiology referrals.

Daiichi Sankyo, Inc., a global pharmaceutical company, agreed to a $39 million settlement that included a five-year Corporate Integrity Agreement (CIA) with HHS OIG and several state Medicaid programs. Daiichi allegedly violated the FCA and AKS by paying kickbacks to physicians in exchange for them writing prescriptions using only Daiichi's drugs under the guise of "speaker fees" for speaking engagements.

Medical Center of Central Georgia agreed to $20 million settlement based on claims that it violated the FCA by knowingly billing Medicare for costly inpatient services that should have been billed on an outpatient basis.

FCA Areas to Watch

Attorneys in the health care industry have noted several areas to watch for future FCA litigation including statistical sampling, overpayment liability, and the effects of the impending Two-Midnight Rule.

Statistical sampling. According to Paulhus, qui tam relators in 2015 increasingly attempted to rely on statistical sampling and extrapolation to establish FCA liability and damages. He further pointed out that while district courts seemed to approve of sampling in cases involving a large volume of claims, the court in *U.S. ex rel. Michaels v. Agape Senior Community, Inc.*, June 25, 2015, found statistical sampling to be inappropriate in such cases because it required "highly fact-intensive" inquiries involving medical testimony and reviews of individual patient charts. The court certified the statistical sampling question for interlocutory review, so the Fourth Circuit may provide some guidance on the issue soon.

Attorney Breen also noted that, "the use of statistical sampling in FCA litigation to establish falsity – as compared to determining damages – has clearly been a focus in 2015." Breen further added, "While, previously, courts had allowed the use of statistical sampling for the purposes of demonstrating damages, this effort to use sampling to prove falsity is concerning and one that should be subjected to vigorous challenges by defendants."

In *U.S. ex rel. Ruckh v. Genoa Healthcare, LLC*, M.D. Fla., April 28, 2015, a court noted that there was no universal ban on statistical sampling in FCA cases and indicated that such evidence may be admissible in future proceedings.

Attorney Sara Kay Wheeler of King & Spalding LLP also pointed out that a provider's own compliance and risk-assessment efforts may result in being admissible evidence in FCA. Therefore, it is advisable for providers to consult with outside counsel prior to performing sampling work.

Attorney Clark also noted that federal courts have not recognized a "Self-Critical Analysis" privilege and adds, that "proactive audits and related risk assessments may pose real liability concerns for providers."

Overpayment liability. Another area highlighted by Clark for future FCA litigation is overpayment liability that was added to Soc. Sec. Act Section 1128J(d) by Section 6402(d) of the ACA. Although case law in this area is not developed as of yet, Clark noted a recent case to watch in which the DOJ has intervened involved a whistleblower alleging that a hospital system was liable for violating a duty to report "known overpayments" (*U.S. v. Continuum Health Partners, Inc. et al.*, S.D.N.Y).

Two-Midnight Rule. A highly controversial area is the Two-Midnight Rule as it relates to inpatient versus outpatient status and may prove to be an area of, "tremendous uncertainty," if the rule remains as it is currently drafted, according to Wheeler. Wheeler noted that since August 2013, CMS has issued guidance documents or updated guidance documents at least 33 times and recently proposed additional changes to the rule. Although there have not been any enforcement actions based on the rule, Wheeler cautioned providers to be prepared for whistleblowers challenges to claims. Wheeler also

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predicted that whistleblower focus may ultimately turn toward long observation stays.

Conclusion

The first half of 2015 has shown that absent the U.S. Supreme Court weighing in on the issue, litigants will continue to fight over pleadings requirement for a FCA case. Additionally, the circuits seem to be opening up FCA litigation to a whole class of relators who previously would have been barred from bringing suit based on the public disclosure bar. Moreover, the Stark Law has been revealed for the liability trap that it is, leading to one circuit judge to lament its "bootstrapping" with the FCA. Finally, an increasing amount of settlements involving SNFs and prohibited referral agreements or kickbacks indicate that the government is targeting those types of providers and activities in FCA investigations. Finally, according to attorneys in the health care compliance field, the hot areas to watch for the remainder of the year include statistical sampling, overpayment liability, and the Two-Midnight Rule.

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