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2015 False Claims Act Year in Review: 5 Major Developments Affecting the Health Care Industry



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In fiscal year 2015, the U.S. Department of Justice (DOJ) recovered $3.5 billion in settlements and judgments under the federal False Claims Act (FCA) against providers and suppliers in the health care sector.[1] While less than the recoveries in 2014, this decrease is *not* a harbinger that the government's focus on health care fraud is waning or that the FCA will no longer be the major statute used in health care cases. As expected after DOJ's announcement last year that all new FCA *qui tam* complaints would be automatically reviewed by both its criminal and civil divisions, 2015 saw vigorous criminal enforcement relating to health care providers' billing practices and financial relationships.[2] Moreover, with Deputy Attorney General Sally Quillian Yates's issuance of the so-called "Yates Memorandum," the DOJ has set forth its intention to increase its focus on individuals' responsibility in allegations of criminal and civil corporate wrongdoing.[3]

Heightened enforcement efforts are also evident on the legislative front. Congress more than doubled fiscal year 2015 funding for the Health Care Fraud and Abuse Control program at the Centers for Medicare & Medicaid Services (CMS) to $672 million, the principal source of funding for the Department of Health and Human Services Office of Inspector General.[4] President Obama also recently signed into law the Bipartisan Budget Act

[1] Press Release, "Justice Department Recovers Over $3.5 Billion From False Claims Act Cases in Fiscal Year 2015," U.S. Dep't of Justice (Dec. 3, 2015).

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[2] *See* Justice News, "Remarks by Assistant Attorney General for the Criminal Division Leslie R. Caldwell at the Taxpayers Against Fraud Education Fund Conference," U.S. Dep't of Justice (Sept. 17, 2014); *see, e.g.*, "June 2015 Takedown," U.S. Dep't of Justice (July 14, 2015) (announcing charges against 243 individuals for alleged participation in Medicare fraud schemes involving approximately $712 million in false billings—the largest criminal health care fraud takedown in DOJ history).

[3] Sally Quillian Yates, "Individual Accountability for Corporate Wrongdoing," U.S. Dep't of Justice (Sept. 9, 2015). Pursuant to the Yates Memorandum's directive that the U.S. Attorneys' Manual be revised to reflect the focus on individuals, a revision of the manual was published on Nov. 16, 2015.

[4] *See* Consolidated and Further Continuing Appropriations Act of 2015, Pub. L. No. 113-235, 128 Stat. 2478 (Dec. 16, 2014).

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of 2015, which requires federal agencies to increase civil monetary penalties (including the statutory penalties mandated by the FCA) no later than Aug. 1, 2016, to account for inflation.[5]

With this background of the current ''enforcement climate,'' set forth below are five of the most significant FCA developments affecting the health care landscape from 2015.

1) While CMS Finalizes 60-Day Rule, New Overpayment Case Law Emerges

The Affordable Care Act (ACA) created a requirement that government overpayments must be reported and returned within 60 days after the date on which they were ''identified.'' Known as the ''60-Day Rule,'' failure to timely return an overpayment may constitute a ''reverse false claim.''[6]

CMS has been finalizing its proposed overpayments rule for Medicare Part A and Part B (originally issued in February 2012), and that process appears to be nearly complete. On Oct. 21, 2015, the Office of Management and Budget received the final rule from CMS, typically the last phase before publication in the *Federal Register*.[7]

The past year was significant for the reverse false claims theory because a federal court issued the first published guidance on when an overpayment is deemed ''identified.''[8] In *United States ex rel. Kane v. HealthFirst, Inc.*, the relator alleged that, due to a software glitch, three New York City hospitals erroneously billed the New York Medicaid program as a secondary payor after already being paid in full by the patients' Medicaid managed care plans. After the state comptroller inquired, management tasked the eventual relator with investigating. The employee later emailed management a spreadsheet of over 900 claims believed to be subject to the glitch. While the hospitals refunded the overpayments in full over the next two years, the government and relator alleged that the hospitals had fraudulently delayed repayment by taking two years, rather than the allotted 60 days. The U.S. District Court for the Southern District of New York denied the defendants' motion to dismiss, holding that the FCA's statutory 60-day clock for repaying identified overpayments begins ticking ''when a provider is *put on notice of a potential overpayment*, rather than the moment when an overpayment is conclusively ascertained.''[9]

2) Supreme Court Expected to Harmonize Circuit Split on Implied False Certification

Courts have recognized two types of actionable false claims under the FCA—''factually false claims'' and ''legally false claims.'' Factually false claims include billing for goods or services that were never performed or misrepresenting what was performed. Legally false claims occur when goods or services are provided in violation of a particular statute, regulation, or contractual term. Furthermore, there are two subcategories of legally false claims—those made by *express* false certification and those made by *implied* false certification. An express false certification occurs when a person falsely certifies compliance with a particular statute, regulation, or material contractual term that is a prerequisite to government payment. An implied false certification claim, however, is broader and premised on the theory that the act of submitting a claim for reimbursement itself implies compliance with all overarching federal rules that are prerequisites to payment—including compliance with certain statutes or regulations not identified in the claim itself.

Not all federal circuits recognize implied false certification, and the elements of such claims vary among circuits, and even within circuits.

On Dec. 4, 2015, the U.S. Supreme Court granted a petition for a writ of certiorari in *Universal Health Services, Inc. v. Escobar* to decide whether the implied false certification theory is viable, and if so, resolve the circuit split on whether it requires the alleged noncompliance to be an express condition of payment. The Supreme Court will be reviewing the U.S. Court of Appeals for the First Circuit's ruling that ''[p]reconditions of payment, which may be found in sources such as statutes, regulations, and contracts, need not be 'expressly designated.' ''[10] The opinion is expected by the end of June 2016.

Other noteworthy court decisions in 2015 on implied false certifications include:

Fourth Circuit. In *United States ex rel. Badr v. Triple Canopy, Inc.*, the U.S. Court of Appeals for the Fourth Circuit, for the first time, recognized an implied false certification liability theory.[11] The Fourth Circuit held that ''the Government pleads a false claim when it alleges that the contractor, with the requisite scienter, made a request for payment under a contract and withheld information about its noncompliance with material contractual requirements.''[12] Triple Canopy's petition for a writ of certiorari is currently pending in the U.S. Supreme Court, requesting that the court determine the validity and proper application of the implied false certification doctrine.[13]

Seventh Circuit. In *United States v. Sanford-Brown*, the U.S. Court of Appeals for the Seventh Circuit expressly declined to recognize implied false certification liability.[14] The Seventh Circuit held that the FCA ''is

[5] *See* Bipartisan Budget Act of 2015, Pub. L. No. 114-74 § 701, 129 Stat. 584 (Nov. 2, 2015).

[6] *See* 42 U.S.C. § 1320a-7k(d)(1).

[7] Reporting and Returning of Overpayments (CMS-6037-F), *Office of Management and Budget*, http://www.reginfo.gov/public/do/eoDetails?rrid=125655.

[8] 2015 U.S. Dist. LEXIS 101778 (S.D.N.Y. Aug. 3, 2015).

[9] *Id.* at *38 (emphasis added). The parties were unable to reach a settlement at an Oct. 29, 2015, settlement conference; the litigation is currently ongoing.

[10] 780 F.3d 504, 512 (1st Cir. 2015).

[11] 775 F.3d 628, 636 (4th Cir. 2015) (petition for writ of certiorari filed June 5, 2015).

[12] *Id.* at 636–37.

[13] Petition for Writ of Certiorari, *United States ex rel. Badr v. Triple Canopy, Inc.*, No. 14-1440 (U.S. June 5, 2015).

[14] 788 F.3d 696, 711–12 (7th Cir. 2015). The Seventh Circuit stated the following:

[W]e conclude that it would be . . . unreasonable for us to hold that an institution's continued compliance with the thousands of pages of federal statutes and regulations incorporated by reference into the PPA are conditions of payment for purposes of liability under the FCA. Although a number of other circuits have adopted this so-called doctrine of implied false

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simply not the proper mechanism'' to enforce compliance with all regulations and held that the purportedly violated conditions of participation are ''for the [subsidizing] agency—not a court—to evaluate and adjudicate.''[15]

D.C. Circuit. In *United States ex rel. Davis v. District of Columbia,* the U.S. Court of Appeals for the District of Columbia Circuit clarified its position with respect to implied false certification and supported its viability.[16] While the D.C. Circuit reversed the district court's award of summary judgment for the relator on grounds that he failed to show a ''knowing'' violation of the regulations, the D.C. Circuit nevertheless took an opportunity in dicta to articulate its stance on implied false certification, noting that ''[t]o establish knowledge on the basis of an implied false certification, Davis had to prove that the District . . . knew both that it violated a legal obligation and that its compliance was a condition of payment.''[17]

3) FCA's "Knowledge" Requirement Provides Fertile Ground for Dispositive Motions

Knowledge (also known as ''scienter'') is a requirement for all types of FCA claims and means that a person, with respect to information: (1) has actual knowledge of the information, (2) acts in deliberate ignorance of the truth or falsity of the information, or (3) acts in reckless disregard of the truth or falsity of the information.[18] Over the past year, the knowledge requirement has proven to be fertile ground for defense dispositive motions.

In *United States ex rel. Saldivar v. Fresenius Medical Care Holdings, Inc.*, the U.S. District Court for the Northern District of Georgia held on summary judgment that the relator failed to prove the knowledge element of his FCA claims.[19] The relator alleged that the defendant provider was purportedly extracting not only the entire labeled amount of medicine in drug vials, but also the ''overfill'' (the amount of a drug in the vial in excess of the labeled amount), and then billing government payors for administered overfill.[20] The court, in determining whether the defendant knew that the overfill was not reimbursable under the Medicare rules and regulations, held that ''the overwhelming evidence shows that [the defendant] reasonably interpreted ambiguous Medicare rules, relied on the advice of its counsel, reasonably believed that at all times the Government knew it was billing for overfill and condoned such billing, and acted in conformity with others in the industry.''[21]

The U.S. District Court for the Eastern District of Pennsylvania also granted a motion for summary judgment on scienter grounds in *United States ex rel. Budike v. PECO Energy*.[22] The relator alleged that the defendant violated the FCA by overcharging the United States Navy for electricity—relying largely on a malfunctioning power meter that caused several bills to be calculated with estimated, rather than actual, usage data. The court noted how the defendant made multiple attempts to repair the malfunctioning meter and held that ''[m]istakes, problems, and negligence do not establish scienter in the context of the FCA. . . . [T]he record here is clear that PECO did repeatedly address the malfunctions and attempt to remedy them.''[23]

The D.C. Circuit in *United States ex rel. Purcell v. MWI Corp.* held that FCA liability cannot attach to a defendant's objectively reasonable interpretation of an ambiguous regulatory provision.[24] The government alleged that false claims had been submitted as a result of certifications made by defendant MWI Corporation to the Export-Import Bank (bank) in order to secure loans to finance MWI's sale of water pumps to Nigeria. As part of the loan process, the bank required MWI to certify that it had paid only ''regular commissions'' to the sales agent in connection with the transactions. The relator alleged that non-regular commissions had been paid and that they should have been disclosed to the bank. In reversing the lower court, the D.C. Circuit held that ''the FCA does not reach an innocent, good-faith mistake about the meaning of an applicable rule or regulation. . . . Nor does it reach those claims made based on reasonable but erroneous interpretations of a defendant's legal obligations.''[25]

4) The Use of Statistical Sampling to Prove Liability and Damages Is Being Tested

Courts have been increasingly asked to consider the use of statistical sampling as a way of quantifying both liability and damages in cases involving a large number of claims.

In *United States ex rel. Paradies v. AseraCare, Inc.*, the U.S. District Court for the Northern District of Alabama denied defendants' motion for partial summary judgment on the government's use of sampling and extrapolation.[26] The government alleged that the defendant falsely certified certain patients as eligible for hospice care whose medical records did not support their qualification. The government's expert reviewed 233 out of 2,181 patient claims, found around 50 percent to be false, and extrapolated the findings over the universe of claims. The court found that statistical evidence ''*is* evidence'' and that a jury should determine the relative weight of the statistical findings.[27] Following the jury trial, on Oct. 26, 2015, the court granted the defendant's motion for a new trial and then announced on Nov. 3,

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certification . . . we decline to join them and instead join the Fifth Circuit.

[15] *Id.* at 712. The plaintiff's petition for rehearing *en banc* was denied on August 4, 2015.

[16] 793 F.3d 120 (D.C. Cir. 2015).

[17] *See id.* at 124–25.

[18] 31 U.S.C. § 3729(b)(1)(A).

[19] 2015 U.S. Dist. LEXIS 156924 (N.D. Ga. Oct. 30, 2015).

[20] The purpose of including overfill is to ensure that the individuals administering the drug will be able to extract the full labeled amount.

[21] *Id.* at *146–47. The court also contrasted mere negligence, noting that while the defendant ''may have been negligently unaware that overfill was considered 'free' and could not be billed, and negligently failed to inquire when it learned that at least some in the industry believed billing for overfill actually administered was impermissible,'' the FCA requires a greater showing of scienter beyond mere negligence. *Id.* at *147.

[22] 2015 U.S. Dist. LEXIS 109288 (E.D. Pa. Aug. 18, 2015).

[23] *Id.* at *33.

[24] 2015 U.S. App. LEXIS 20385 (D.C. Cir. Nov. 24, 2015).

[25] *Id.* at *13.

[26] 2014 U.S. Dist. LEXIS 167970 (N.D. Ala. Dec. 4, 2014).

[27] *Id.* at *25.

2015, that, prior to starting a new trial, it was going to consider granting summary judgment on its own accord.[28]

Similarly, in *United States v. Robinson*, the U.S. District Court for the Eastern District of Kentucky accepted the government's use of statistical sampling based on the theory that presenting individual evidence on each claim would have been ''unreasonable, likely impossible, and a waste of resources.''[29] The government alleged that the defendant falsely submitted for payment various nursing home examinations that did not meet the patient's medical needs. The district court cited a Sixth Circuit decision permitting statistical sampling techniques in ''complex situations,'' and held that the government could use its expert's 30-claim sample to extrapolate over the universe of 25,799 claims to determine which were medically necessary.[30] This testimony created a genuine issue of material fact that precluded summary judgment.[31]

However, statistical sampling is not universally accepted. In *United States ex rel. Michaels v. Agape Senior Community, Inc.*, the U.S. District Court for the District of South Carolina found statistical sampling inappropriate because it required ''highly fact-intensive'' investigations involving medical testimony and reviews of individual patient charts.[32] The relators alleged that the defendants, a network of 24 nursing homes, knowingly submitted false claims to various government programs for nursing-home-related services. While the court acknowledged that some cases are suitable for statistical sampling and ''in many cases that method is the only way that damages may be proved,'' it held that sampling would be permissible only if a seriatim analysis of billing claims was impossible, as opposed to merely time-consuming and expensive.[33] The district court certified the question of whether statistical sampling can be used to prove damages or liability for interlocutory appeal to the Fourth Circuit. This case is especially significant, as it will be the first time that a federal appeals court will address the issue of whether statistical sampling evidence may be used to prove FCA liability and damages.

5) The FCA's Public Disclosure Bar Continues to Be Heavily Litigated

The ''public disclosure'' bar, as amended by the ACA, is set forth in 31 U.S.C. § 3730(e)(4) and states, in relevant part, that ''[t]he 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'' in certain enumerated forums such as through the news media or a federal hearing, audit, or investigation, unless the plaintiff is the ''original source'' of the information.

In *United States ex rel. Whipple v. Chattanooga-Hamilton County Hospital Authority*, the Sixth Circuit held that a relator's claims were not barred on public disclosure grounds because information disclosed to the government through audit or investigation is not ''in the public domain.''[34] The relator alleged that the hospital violated the FCA by knowingly submitting false or fraudulent claims to the government for various hospital services. Unbeknownst to him, an anonymous hotline tip reported that the hospital was engaging in similar misconduct, which triggered a government investigation and led both parties to retain third-party contractors to audit various claims. The findings from both contractors were shared with the government, and the matter was resolved administratively in September 2009, once the hospital refunded the government. The relator subsequently disclosed his *qui tam* claims to the government in October 2010 and filed a complaint under seal in March 2011. In reversing the lower court, the Sixth Circuit held that the allegations were *not* publicly disclosed, as they were not disseminated beyond the participants in the administrative audit and investigation process. The Sixth Circuit noted that ''[i]f a disclosure to the government in an audit or investigation would be sufficient to trigger the bar, the term 'public' would be superfluous.''[35]

In *United States ex rel. Osheroff v. Humana, Inc.*, the Eleventh Circuit affirmed the dismissal of an FCA case where the relator alleged that certain health clinics and health plans either knew of or promoted a variety of free services for patients and health plan members, including transportation, meals, and entertainment services.[36] The Eleventh Circuit found that the incentives were repeatedly mentioned in court filings, news articles, and newspaper advertisements. While the relator argued that the public disclosures in the newspapers were different because that information did not connote any wrongdoing, the Eleventh Circuit held that the contested information had a ''significant overlap'' with the publicly available information and did not ''materially add to the public disclosures.''[37]

In *United States ex rel. Antoon v. Cleveland Clinic Found.*, the Sixth Circuit affirmed the dismissal of an FCA action against a hospital alleging violations of the

[28] *United States ex rel. Paradies v. AseraCare, Inc.*, No. 2:12-cv-245 (N.D. Ala., Nov. 3, 2015).

[29] 25 U.S. Dist. LEXIS 41123, at *32 (E.D. Ky. Mar. 31, 2015).

[30] *See Mich. Dep't of Educ. v. U.S. Dep't of Educ.*, 875 F.2d 1196, 1205 (6th Cir. 1989) (affirming the validity of random sampling as acceptable evidence of the validity of various vocational rehabilitation expenditures when an individual audit of the thousands of cases at issue would be impossible).

[31] *See also United States ex rel. Ruckh v. Genoa Healthcare, LLC*, 2015 U.S. Dist. LEXIS 55384 (M.D. Fla. Apr. 28, 2015). In this case, the U.S. District Court for the Middle District of Florida issued an order in connection with the relator's motion *in limine* to admit expert testimony on statistical sampling. Relying in part on *Robinson*, the court found the relator's motion *in limine* premature, since the expert's analysis was incomplete and therefore no margin of error had been calculated. However, the court noted there was no ''universal ban'' on statistical sampling in FCA cases and that such evidence may be admissible in future proceedings. *Id.* at *12–13.

[32] Order Resolving Two Interrelated Issues and Certification for Interlocutory Appeal, *United States ex rel. Michaels v. Agape Senior Community, Inc.*, 2015 U.S. Dist. LEXIS 82379, at *24 (D.S.C. June 25, 2015).

[33] *Id.* The court estimated that the review of a single patient's file would cost between $1,600 and $36,000 using the relator's experts who receive $400 per hour to review files. *Id.* at *3.

[34] 782 F.3d 260 (6th Cir. 2015).

[35] *Id.* at 268. The Supreme Court denied the hospital's petition for a writ of certiorari on Oct. 2, 2015.

[36] 776 F.3d 805 (11th Cir. 2015).

[37] *Id.* at 812, 815.

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FCA stemming from misrepresentations about which physician performed the relator's robotic surgery.[38] The Sixth Circuit found that the relator had made a prior public disclosure of the alleged fraud by filing a state court complaint two years before the federal one (triggering a CMS investigation). Moreover, the local newspaper published an article on the relator's allegations and the CMS investigation, and the relator's pleadings contained information from Freedom of Information Act (FOIA) requests. Because the relator's allegations were already publicly disclosed and since he was not an original source (the court found the claims to be based on mere speculation that his physician was lying), the case was dismissed.

[38] 788 F.3d 605 (6th Cir. 2015).

What to Expect in 2016

Following a year of notable FCA developments, heightened enforcement and a rise in the number of cases pursued post-declination by *qui tam* relators is expected to continue in 2016. Particular areas to follow include the DOJ's increased focus on individual liability in criminal and civil investigations as well as the use of an implied false certification theory, which it is anticipated will be clarified by the Supreme Court next summer.