

The False Claims Act and the Health Care Industry: 2014 Year in Review

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December 2014

On Nov. 20, 2014, the U.S. Department of Justice (“DOJ”) announced settlements and judgments for False Claims Act (“FCA”) cases totaling \$5.7 billion (compared to \$3.8 billion in fiscal year 2013), \$2.3 billion of which was derived from the health care sector.¹ Earlier this fall, the DOJ announced that all new FCA *qui tam* complaints will be automatically reviewed by both the DOJ’s criminal division and its civil division—the criminal division no longer being reliant on referrals for potential prosecution.² With this enforcement background, 2014 is marked by a number of key FCA developments that are significant to the health care industry.

Failing to Timely Return Government Overpayments: Reverse False Claims

As part of the Affordable Care Act (“ACA”), Congress adopted the requirement that any person or entity that has received an overpayment from the federal (or a state) government must report and return the overpayment within 60 days after the date such overpayment was “identified.” Failure to timely return an overpayment may constitute a “reverse false claim.” Although the 60-day repayment rule went into effect approximately three years ago, cases based on this provision began to emerge in 2014. For example, in *United States ex rel. Kane v. Continuum Health Partners*, the DOJ for the first time intervened in an FCA action alleging solely a violation of the 60-day overpayment rule.³ The complaint alleges that the defendant hospitals received government payments for claims wrongly billed to Medicaid and that the defendants

¹ DOJ Press Release Justice, 11/20/2014 “Department Recovers Nearly \$6 Billion from False Claims Act Cases in Fiscal Year 2014,” available at <http://www.justice.gov/opa/pr/justice-department-recovers-nearly-6-billion-false-claims-act-cases-fiscal-year-2014>.

² DOJ Justice News, 9/17/2014 “Remarks by Assistant Attorney General for the Criminal Division Leslie R. Caldwell at the Taxpayers Against Fraud Education Fund Conference,” available at <http://www.justice.gov/criminal/pr/speeches/2014/crm-speech-140917.html>.

³ Case No. 11-2325 (S.D.N.Y. June 27, 2014). The FCA’s reverse false claims provision is located at 31 U.S.C. § 3729(a)(1)(G).

received notice of these overpayments by the New York Office of the State Comptroller in September 2010, and by the employee/relator's investigation in February 2011. The employee/relator's investigation revealed approximately 900 specific overpayments totaling over \$1 million, which the defendants eventually repaid in full. However, instead of reimbursing the overpayments within the required 60-day period, the defendants are alleged to have repaid the claims in "small batches" over the next two-plus years. The parties are currently litigating a motion to dismiss.

Pleading with Particularity Under Federal Rule of Civil Procedure 9(b)

Rule 9(b) provides that "[i]n alleging fraud," a "party must state with particularity the circumstances constituting fraud." Although courts generally agree on Rule 9(b)'s theoretical implications—namely, that the plaintiff must marshal facts sufficient to show the "who, what, when, where and how" of the alleged fraud—circuit courts of appeal are divided on what factual detail must be alleged at the FCA pleading stage to satisfy this standard.⁴

Although the Eighth Circuit has historically endorsed a more stringent application of Rule 9(b), the court's 2014 decision in *United States ex rel. Thayer v. Planned Parenthood of the Heartland* appears to relax that position.⁵ In this case, a former Planned Parenthood center manager sued the organization for allegedly submitting false or fraudulent claims to Medicaid. The relator did not provide any specific instances of fraud in her complaint—simply alleging that Planned Parenthood violated the FCA by filing claims for, inter alia, unnecessary quantities of birth control pills, seeking reimbursement for abortion-related services (in violation of federal law) and upcoding. Planned Parenthood moved to dismiss on Rule 9(b) grounds. The district court granted the motion, finding that the relator failed "to provide a single specific example of a particular fraudulent claim Planned Parenthood submitted to the government, let alone any representative examples." The Eighth Circuit reversed as to particular allegations, holding that a relator need not provide a specific example of a false claim if the relator provides specific facts about the underlying fraud and sufficient "indicia of reliability" to support the "strong inference" that false claims were actually submitted. In this case, the relator's particularized allegations, such as names of individuals participating in the scheme, the timeframe of the scheme and the methods for its perpetration were sufficient to satisfy Rule 9(b).

This year the Third Circuit also endorsed a more flexible Rule 9(b) application in *United States ex rel. Foglia v. Renal Ventures Management LLC*.⁶ In this case, the plaintiff alleged that the defendant violated the FCA by falsely certifying to Medicare

⁴ The traditional circuit split has been as follows. The Fourth, Sixth, Eighth and Eleventh Circuits apply a "stringent" construction of Rule 9(b) that requires detailed allegations about specific claims actually submitted for government payment. The First, Fifth, Seventh, Ninth and Tenth Circuits traditionally apply a more "relaxed" and permissive construction of Rule 9(b) that merely requires "reliable indicia" that false claims were submitted.

⁵ Case No. No. 13-1654 (8th Cir. Aug. 29, 2014).

⁶ Case No. 12-4050 (3d Cir. June 6, 2014).

that it was in compliance with state regulations regarding quality of care, falsely submitting claims for reimbursement for a particular drug and by reusing the remainder of single-use drug vials while charging Medicare for the full content of the vial. In reviving the dismissed complaint, the Third Circuit downplayed the rigorous Rule 9(b) pleading standard by stating that “the purpose of Rule 9(b) is to ‘provide[] defendants with fair notice of the plaintiffs’ claims” and holding that the plaintiff’s complaint met the Rule 9(b) standard because it “suffice[d] to give Renal notice of the charges against it, as is required by Rule 9(b).”

Public Disclosure Bar and Original Source Requirement

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.⁷ The public disclosure bar precludes whistleblower suits based on information that has already been publicly disclosed unless the whistleblower was the “original source” of the information.

In *United States ex rel. Guardiola v. Renown Health*, the court upheld its own jurisdiction to hear an FCA complaint over objection that the relator was not the original source of the information and that her allegations were already publicly disclosed and therefore barred by statute.⁸ The relator was Renown’s director of clinical compliance, who alleged that Renown improperly submitted short-stay inpatient claims (“zero-day stays” and “one-day stays”) to Medicare, which should have been properly billed as outpatient claims. These stays were also reported in audits conducted by recovery audit contractors (“RACs”) and those results were shared both internally and externally with nonemployee Renown providers and their staff. The defendants moved to dismiss for lack of subject-matter jurisdiction, arguing that the RAC audit and their external disclosure of that audit constituted public disclosures. The court disagreed and held that the disclosures were not publicly disclosed because the nonemployee providers who had access to the RAC audit were “economically linked to Renown” and were therefore not outsiders; they had an “economic incentive” to protect the information from disclosure to outsiders.

⁷ The ACA modified the public disclosure bar in several critical respects. First, the term “publicly disclosed” now includes only information from federal sources and the news media—not state or local proceedings. Second, the “original source” exception is now broadened to include persons who have knowledge that is “independent of and materially adds” to publicly disclosed information. And, third, the ACA provides that the court shall dismiss a case if there has been public disclosure unless “opposed by the Government.” In other words, the amended version of the law provides the federal government with “veto” power over a defendant’s motion to dismiss based on public disclosure.

⁸ Case No. 3:12-CV-00295-LRH-VPC (D. Nev. Oct. 16, 2014). Although the court did not need to address the original source issue (finding that the relator’s information had not been publicly disclosed) it nevertheless commented that it would have jurisdiction because the relator met the original source exception by alleging “direct and independent knowledge of the information” and because she “voluntarily disclosed this information to the government before filing her complaint.”

Scope of Liability for FCA Retaliation

The FCA's anti-retaliation provision prohibits an employer from retaliating against an employee "because of lawful acts done by the employee, contractor, agent or associated others" in furtherance of an FCA action.⁹ When the FCA was amended by the Fraud Enforcement and Recovery Act of 2009 one of the most significant alterations was that the new version no longer expressly prohibits retaliation from "his or her employer" but more broadly provides that the aggrieved employee, contractor or agent "shall be entitled to all relief necessary to make that employee, contractor, or agent whole." Although courts were once divided on whether 3730(h) as amended provided for individual liability—such as whether supervisors can be personally liable for whistleblower retaliation—there is now an emerging district court consensus against individual liability.¹⁰ For example, in *United States ex rel. Sadr v. Pediatric Cardiology Associates PC*, the U.S. District Court for the Eastern District of Virginia definitively addressed the issue for the first time within the Fourth Circuit, holding that "the 2009 FERA amendments were not intended to create individual liability for retaliation under § 3730(h)."¹¹

Judicial Assessment of Satisfaction of the Anti-Kickback Statute's Safe Harbors

Given the significant expense associated with discovery, courts play a critical gatekeeping role at the motion-to-dismiss stage. There have recently been two divergent decisions regarding whether courts assess fraud and abuse safe harbors on a motion to dismiss or summary judgment. In *United States v. Millennium Radiology Inc. et al.*, the court denied a motion to dismiss and refused to consider the defendants' argument that they met the "Personal Services Arrangement Safe Harbor" to the Anti-Kickback Statute—concluding that safe harbors are affirmative defenses and are therefore to be considered at summary judgment.¹² The court did not assess whether compliance with a safe harbor could be used to show a lack of scienter. In contrast, in *United States ex rel. Fox Rx Inc. v. Dr. Reddy's Inc. et al.*, the

⁹ See 31 U.S.C. § 3730(h).

¹⁰ See, e.g., *Lipka v. Advantage Health Grp. Inc.*, Case No. 13-CV-02223 (D. Kan. Sept. 20, 2013); *Russo v. Broncor Inc.*, Case No. 13-CV-348 (S.D. Ill. July 24, 2013); and *Aryai v. Forfeiture Support Assocs.*, Case No. 10-CV-8952 (S.D.N.Y. Aug. 27, 2012).

¹¹ Case No. 1:13-CV-00077 (E.D. Va. Jan. 23, 2014). Epstein Becker & Green, P.C., served as defense counsel in this matter. Another district court within the Fourth Circuit has also recently held that there can be no individual liability under § 3730(h). In *Rangarajan v. Johns Hopkins Health System Corp. et al.*, Case No. 1:12-CV-01953 (D. Md. Nov. 21 2014), the U.S. District Court for the District of Maryland held on a motion to dismiss that, "Following the majority of courts that have ruled on the issue, this Court concludes that 31 U.S.C. § 3730(h) does not create a cause of action against supervisors in their individual capacity."

¹² Case No. 1:11-CV-00825 (S.D. Ohio Sept. 30, 2014). The Anti-Kickback Statute, 42 U.S.C. § 1320a, prohibits the exchange (or offer to exchange), of anything of value, in an effort to induce or reward the referral of federal health care program business. The ACA modified the language of the Anti-Kickback Statute to provide that claims submitted in violation of the statute automatically constitute false claims under the FCA. See 42 U.S.C. § 1320a-7b(g).

court dismissed a complaint alleging an unlawful kickback scheme, finding that the “[c]laim fails because the rebates allegedly accepted by Omnicare fall within the regulatory safe harbors for discounts, and therefore do not constitute a violation of the Anti-Kickback Statute.”

Good Faith Disputes and the Government Knowledge Defense

In FCA litigation, the “government knowledge” doctrine provides for an inference that a defendant lacked the required scienter when there is evidence of government knowledge and approval of the facts underlying an allegedly false claim. In *United States ex rel. Gonzalez v. Planned Parenthood of Los Angeles et al.*, the Ninth Circuit affirmed dismissal of a complaint alleging that Planned Parenthood overbilled state and federal governments more than \$200 million for contraceptives. The relator attached various letters between Planned Parenthood and state officials to the complaint, which the court found “fatally undercut” the claims because they demonstrated that—even if the claims submitted were false—there could be no knowing falsity due to the “explicit statements addressing this subject made by the State of California ... and the State’s silence after being told what procedures Planned Parenthood was following.”

Can Poor Quality of Care Constitute a Violation of the FCA?

Over the past several years, the government has once again been attempting to assess liability under the FCA under the “worthless services theory.” Under this theory, when a provider bills the federal government for a service that the provider knows, or should know, has no value, the provider is essentially billing for something that was not provided—a false claim. Although circuit courts of appeal are divided on whether the worthless services theory is a cognizable basis for FCA liability, the Seventh Circuit recently chipped away at it.¹³ In *United States ex rel. Absher v. Momen Meadows Nursing Center Inc.*, plaintiffs alleged that the defendant nursing center provided substandard care to its residents while receiving full per diem reimbursement from the federal government.¹⁴ The relators secured a \$9 million jury verdict based on evidence that the nursing home had violated regulations to the point of providing “woefully inadequate care.”¹⁵ Specifically, the relators presented evidence of problems relating to infection and pest control (including scabies outbreaks), pressure sore management, dangerous food and water temperatures and a litany of other deficiencies. On appeal the Seventh Circuit vacated the judgment,

¹³ To date, the worthless services theory has been adopted by the Second, Sixth, Eighth and Ninth Circuits. See *Mikes v. Straus*, 274 F.3d 687, 703 (2d Cir. 2001); *Chesbrough v. VPA PC*, 655 F.3d 461, 468–69 (6th Cir. 2011); *United States ex rel. Roop v. Hypoguard USA Inc.*, 559 F.3d 818, 824 (8th Cir. 2009); and *United States ex rel. Lee v. SmithKline Beecham Inc.*, 245 F.3d 1048, 1053 (9th Cir. 2001).

¹⁴ The consolidated cases are case nos. 13-1886 and 13-1936 (7th Cir. Aug. 20, 2014).

¹⁵ The jury awarded the U.S. over \$3 million in compensatory damages and imposed about \$19 million in fines for the *qui tam* claims. Pursuant to the FCA, the compensatory damages were trebled to over \$9 million. However, the district court set aside the fines on the grounds that they violated the Excessive Fines Clause of the Eighth Amendment.

finding that the jury instructions did not accurately reflect the applicable law. The court held that “[s]ervices that are ‘worth less’ are not ‘worthless.’” Thus, even assuming the viability of the worthless services theory in the Seventh Circuit (an issue the court “saved for another day”), the court explained that it would be “absurd” to contend that the nursing home’s services were “truly or effectively ‘worthless’”—as it was undisputed that the nursing home was allowed to continue providing services despite regular visits by government surveyors, and one of the relators admitted that her mother received “good care” at the facility.

What to Expect in 2015

After a year of significant FCA activity in the health care sector, *qui tam* activity is expected to continue rising in 2015. And with the DOJ now reviewing all *qui tam* complaints for criminal liability, an attendant increase in criminal enforcement is also to be expected.

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