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Fraud and Compliance

Affordable Care Act Repeal and Impact on False Claims Act Liability and Defenses

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In 2010, the Patient Protection and Affordable Care Act (ACA) amended key portions of the False Claims Act (FCA) and related federal fraud and abuse statutes. These amendments punched holes in common defense strategies for fending off FCA actions. Most prominently, the ACA put into place statutory provisions that have (i) eased the burden of proof regarding FCA claims premised on Anti-Kickback Statute^[1] (AKS) violations; (ii) created a FCA claim premised on the easily violated 60-day "return and report" rule; and (iii) diluted the public disclosure/original source bar for relators and, relatedly, provided the Department of Justice (DOJ) with a purported "veto" over an otherwise valid public disclosure defense. While at this point, it is unknown whether a potential repeal of the ACA would be a broad roll-back or a more surgical endeavor, it is clear that repealing the FCA-related portions of the law would bring some breathing room to the health care industry.

ACA Amendment of the AKS

Prior to the ACA, courts disagreed over whether an FCA claim could be based simply on an underlying violation of the AKS.^[2] While numerous courts held that violations of the AKS could be the predicate for FCA claims where the defendant had expressly certified compliance with the AKS, others indicated that absent such a certification, it could not. In 2010, however, the ACA amended the AKS by adding Section 1320a-7b(g), which provides, "a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA]." One of the sponsors of the AKS amendment stated that the amendment was to "ensure that all claims resulting from illegal kickbacks are considered false claims for the purpose of civil action under the False Claims Act, even when the claims are not submitted directly by the wrongdoers themselves."^[3] Since the ACA, some courts have taken this amendment many steps further than what the sponsor suggested, ruling that the amendment supported an implied-certification theory of falsity, i.e., that AKS-premised FCA claims are "false" even where there is no express certification of compliance with the AKS.^[4]

In addition, the ACA included a second amendment to the AKS, which now provides that to establish a violation "a person need not have actual knowledge of [the AKS] or specific intent to commit a violation of [the AKS]."^[5] This amendment reduced the intent standard under the AKS, specifically overruling the Ninth Circuit's holding in *Hanlester Network v. Shalala*^[6] that to establish scienter, the AKS requires showing the defendant knew of the AKS and specifically intended to violate the statute.

If a repeal eliminates these AKS amendments, the case law would likely revert to pre-ACA precedent, which gave defendants substantially expanded defenses against AKS-premised FCA claims. For instance, a repeal could prove a setback to the government's "implied certification" arguments in the AKS context. Before the ACA, the government generally relied on express certifications (e.g., invoices, claim forms, provider agreements, hospital cost reports) to establish the existence of a false statement in AKS cases. With the passage of the ACA, however, the government has had a stronger "implied" certification argument, allowing it to bypass some of the intricacies involved in using express certifications to show falsity, which sometimes were a barrier to successfully pleading a violation of the FCA. In one case involving Medicaid, pre-ACA FCA claims

failed under an express certification theory because actual, state Medicaid certifications were not properly pled, whereas the very same FCA claims survived for the time period after the ACA became law under an implied certification theory.[7] Further, a repeal would breathe new life into arguments regarding the nature and sufficiency of the certification language itself. Repeal also would give defendants more leverage on the issue of whether the level of intent could be established—an issue that would generally be very important in civil FCA cases where the facts underlying kickback allegations can frequently reflect complex, industry norms. In short, defense counsel would have a larger quiver of arrows to attack the critical questions of falsity and intent in FCA claims.

ACA Amendments Affecting Reverse False Claims and Creation of the 60-day Rule

As the health care industry is well aware, the ACA created a highly particularized "report and return" requirement for Medicare and Medicaid overpayments. Specifically, the ACA provided that a person who has "received an overpayment" must report and return such overpayment within "60 days after the date on which the overpayment was *identified*." [8] Further, the ACA provided that an "overpayment retained by a person after the deadline" is an "obligation" under the FCA. [9] In short, the knowing failure to return an "identified" overpayment in accord with the 60-day "report and return" provisions of the ACA could result in a violation of the FCA. Since the enactment of the "60-day rule," much ink has been spilled—in litigation and in the Centers for Medicare & Medicaid Services (CMS') rulemaking effort—on how to determine when an overpayment has been "identified" and the 60-day clock starts running. The 2014 and 2016 CMS rules in this area helped lessen the uncertainty to some extent, [10] but it is clear that the 60-day rule imposes additional compliance burdens and enforcement risks on an already heavily regulated industry.

However, repeal could carry its own perils. Doing away with the 60-day rule would *not* do away with the risk of FCA liability for knowing retention of an overpayment. However, repeal *would* likely revive uncertainty about what triggers the obligation to return an overpayment, what qualifies as an "overpayment," and what the timing should be. In 2009, Congress passed the Fraud Enforcement and Recovery Act [11] (FERA), which extensively amended the FCA. FERA—not the ACA—dusted off the largely neglected "reverse false claims" provision and brought knowing retention of overpayments into the ambit of FCA liability. [12] Repeal of the ACA would not alter FERA's expansion of the reverse false claims provision, but at the same time could nullify CMS' rules and guidance on "report and return" and remove the "overpayment" definition from the Social Security Act. While CMS' rules are a source of new obligations and uncertainty, they also give providers and plans some breathing room between receipt of credible information regarding a potential overpayment and the deadline to report and return any actual overpayment. The rules also provide some certainty regarding the actual mechanics of returning overpayments and other matters. With repeal, that breathing room and clarity could evaporate absent a judicial gloss or further rulemaking by the agency, which may well be distracted by other changes put in motion by the new administration.

ACA Amendments to Public Disclosure and Creation of the "Government Veto"

Prior to the ACA, the public disclosure bar served as a first line of defense against parasitic qui tam actions where the government chose not to intervene. Generally speaking, the public disclosure bar required courts to dismiss a FCA claim where the underlying qui tam complaint allegations were based on a "public disclosure" by someone other than the relator. The ACA amendments undercut the bar by (1) removing express "jurisdictional" language regarding the nature of the bar, (2) creating the so-called "government veto" over public-disclosure based dismissals, (3) limiting what constitutes a "public disclosure," and (4) easing the standards for qualifying as an "original source."

Taken collectively, these amendments substantially diluted the value of the public disclosure bar for defense counsel litigating non-intervened FCA claims. For instance, while some courts have construed the post-ACA bar as jurisdictional—thus allowing defendants to raise the defense at any point in the proceedings, including through trial and appeal—numerous circuit courts have ruled the

bar is no longer jurisdictional.[13] While there is less case law on the "government veto," that provision has been held as valid and controlling with respect to a motion under the public disclosure bar.[14]

The ACA public disclosure amendments also have worked to the disadvantage of the defense bar in other significant ways. Previously, public disclosure dismissals were brought under Fed. R. Civ. P. 12(b)(1), where courts can review evidence beyond the pleadings—indeed, limited discovery for the defendant on jurisdictional issues is sometimes possible. However, motions for dismissal have now been increasingly construed as being made under Fed. R. Civ. P. 12(b)(6), limiting the court's review to the allegations in the complaint and creating risks that the public disclosure defense is waivable. Similarly, the ACA limited the sources of information that could constitute a "public disclosure" In determining whether a "public disclosure" has been made, a court may only consider sources enumerated in the FCA's "exclusive list,"[15] which the ACA dramatically shortened to include only *federal* criminal, civil, and administrative proceedings in which the government is a party; *federal* reports, hearings, audits, and investigations; and the news media. Repeal would reverse these limitations, and thus expand the protections of this defense.

Original Source

The ACA also made it easier for parasitic relators to sidestep dismissal even where the facts of their case had been "publicly disclosed." Relators can avoid dismissal under the public disclosure bar if they show they are an "original source." Before the ACA, a relator was an "original source" only if he or she had direct and independent knowledge "obtained from actually viewing source documents, or firsthand observation of the fraudulent activity that provides the grounds for the qui tam suit." [16] This requirement was not satisfied if a third party was the source of the core information upon which the qui tam complaint was based [17] or if the relator's knowledge was derived from public disclosures. [18]

The ACA eliminated this knowledge requirement, allowing relators to meet the original source standard if they have "knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions." As the Third Circuit recently observed in *Moore*, [19] the focus has shifted to "what independent knowledge the relator has added to what was publicly disclosed." Indeed, *Moore* is a case in point about what repeal could mean for FCA defenses—the court held relator would not have qualified under the pre-ACA provision as an original source, but that he *did* qualify as an original source under the post-ACA version. [20]

At this point, what any repeal of the ACA might look like or when it might occur is highly uncertain. In particular, whether repeal would capture the ACA's non-"Obamacare" statutory revisions is anyone's guess. It is not guesswork, however, that repealing the provisions discussed above would shift some advantages back to the defense side in the FCA arms race.

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- [1] 42 U.S.C. § 1320a-7b(b).
- [2] See, e.g., *United States ex rel. King v. Solvay S.A.*, 823 F. Supp. 2d 472, 504-06 (S.D. Tex. 2011) (collecting cases).
- [3] 155 Cong. Rec. S10852-01 (Oct. 28, 2009) (statement of Sen. Leahy), 2009 WL 3460582, at * S10854 (Westlaw).
- [4] See, e.g., *Hericks v. Lincare Inc.*, No. 07 Civ. 387, 2014 WL 1225660, at *4 (E.D. Pa. Mar. 25, 2014); *United States ex rel. Kester v. Novartis Pharmaceuticals Corp.*, 23 F. Supp. 3d 242, 267 (S.D.N.Y. 2014); *United States ex rel. Parikh v. Citizens Med. Ctr.*, 977 F. Supp. 2d 654, 685 fn. 3 (S.D. Tex. 2013).
- [5] 42 U.S.C. § 1320a-7b(h).
- [6] 51 F.3d 1390, 1400 (9th Cir. 1995).
- [7] See *United States ex rel. Kester v. Novartis Pharmaceuticals Corp.*, 41 F. Supp. 3d 323, 338-39 (S.D.N.Y. 2014) (AKS-premised FCA claims failed pre-ACA under (i) implied certification because AKS did not expressly condition payment on compliance and (ii) express certification because government failed to plead actual state Medicaid provider certifications; same AKS-premised FCA claims survived for time period after effective date of ACA under implied certification theory).
- [8] 42 U.S.C. § 1320a-7k(d)(1)-(2) (emphasis added).
- [9] 42 U.S.C. § 1320a-7k(d)(3).
- [10] For instance, the ACA did not define what it means to "identify" an overpayment and whether such identification required *actual knowledge* or whether a different knowledge standard might apply. In 2014 and 2016, CMS issued regulations providing that a Medicare overpayment has been "identified" "when the [entity] has determined, or should have determined through the exercise of reasonable diligence, that [it] has received an overpayment." See 42 C.F.R. §§ 401.305, 422.326, 423.360. CMS further detailed what "reasonable diligence" meant and that, for instance, a provider, in most circumstances, could take up to six months to investigate whether an overpayment had been received before the 60-day clock began to run. See CMS, Medicare Program; Reporting and Return of Overpayments, 81 Fed. Reg. 7654, 7662 (Feb. 12, 2016).
- [11] Pub. L. No. 111-21, 123 Stat. 1617 (2009).
- [12] FERA added a definition of "obligation" to the FCA, providing that an "obligation" included an "established duty" arising from "retention of an overpayment," 31 U.S.C. § 3729(b)(3), and further provided that is a violation of the FCA for a person to knowingly conceal or knowingly and improperly avoid or decrease an "obligation" to the government. 31 U.S.C. § 3729(a)(1)(G).
- [13] See, e.g., *United States ex rel. Advocates for Basic Legal Equal., Inc. v. U.S. Bank, N.A.*, 816 F.3d 428, 433 (6th Cir. 2016) (no longer jurisdictional), *petition for cert. filed*, (U.S. July 25, 2016) (No. 16-130); *United States ex rel. Moore & Co., P.A. v. Majestic Blue Fisheries, LLC*, 812 F.3d 294, 300 (3d Cir. 2016) (same); *United States ex rel. Beauchamp v. Academic Training Ctr., LLC*, 816 F.3d 37, 40 (4th Cir. 2016) (same); *United States ex rel. Osheroff v. Humana, Inc.*, 776 F.3d 805, 810 (11th Cir. 2015) (same); *but see United States ex rel. Kirk v. Schindler Elevator Corp.*, 601 F.3d 94, 103 n. 4 (2d Cir. 2010) (amended § 3730(e)(4) is jurisdictional bar), *rev'd on other grounds*, 563 U.S. 401 (2011); *United States ex rel. Kester v. Novartis Pharmaceuticals Corp.*, 43 F. Supp. 3d 332, 345 (S.D.N.Y. 2014) (McMahon, J.) (ACA amendments did not affect jurisdictional nature of bar).
- [14] *United States ex rel. Conroy v. Select Med. Corp.*, No. 12-cv-00051, 2016 WL 5661566 (S.D. Ind. Sept 30, 2016).
- [15] *Kirk*, 601 F.3d at 104.
- [16] *United States ex rel. Ping Chen v. EMSL Analytics*, 966 F. Supp. 2d 282, 300 (S.D.N.Y. 2013) (quoting *Stennett v. Premier Rehab., LLC*, 479 Fed. Appx. 631, 635 (5th Cir.2012)).
- [17] *United States v. N.Y. Med. Coll.*, 252 F.3d 118, 121 (2d Cir. 2001) (citation omitted).
- [18] See *Stennett*, 479 Fed. Appx. at 635.

[19] 812 F.3d at 299.

[20] *Id.* at 305.

- See more at:

<https://www.healthlawyers.org/News/Health%20Lawyers%20Weekly/Pages/2016/December%202016/December%202016/Affordable-Care-Act-Repeal-and-Impact-on-False-Claims-Act-Liability-and-Defenses-.aspx#sthash.X1OZm8SJ.dpuf>