The Consequences of Obamacare for Healthcare Fraud Enforcement

Over the last several years, the Patient Protection and Affordable Care Act of 2010 ("PPACA") has garnered significant interest from the press, the public, and the bar. Much of this attention has focused on ligation concerning the constitutionality of the law, but a lesser covered aspect of the law – the implications of PPACA for health care fraud enforcement – deserves some attention.

In particular, two provisions significantly affect the way the government may pursue, both criminally and civilly, cases that implicate the Anti-Kickback Statute ("AKS"). First, a provision of PPACA made a violation of the AKS a *per se* false claim under the False Claims Act ("FCA"), and the second change addressed a particular Ninth Circuit opinion on the meaning of "willfully" as it applies to the scienter standard for AKS cases.

Intent under the False Claims Act and Scienter under the Anti-Kickback Statute

Post-PPACA it is no longer necessary for the government or a relator to prove a connection between an alleged kickback and the submission of a false claim. The law obviated the need, in FCA cases predicated on an AKS violation, to proceed under "false certification" theories (*i.e.*, theories that claims implicitly and cost reports explicitly certify compliance with the AKS) by defining a claim that includes services resulting from a violation of the AKS to be "false."[1] However, PPACA is silent on the necessary intent standard that the government or a relator now must meet in order to prevail in an AKS-predicated FCA case. In particular, it is not clear whether the government or a relator must meet the AKS's "knowing and willful" scienter requirement as part of a *prima facie* False Claims Act case premised on an AKS violation. The FCA and the AKS contain distinct intent and scienter elements, and the question of the level of intent that the government must prove on an AKS-predicated FCA case has been decided in divergent ways by federal courts.

The FCA, a civil statute, and the AKS, a criminal statute, have distinct scienter and intent requirements, and the AKS's scienter requirement demands a more exacting level of proof than does the FCA's intent standard. The FCA, 31 U.S.C. §§ 3729-3733, imposes liability on a person or entity that knowingly presents a false claim to the government for approval or knowingly makes, uses or causes a false statement material to a false or fraudulent claim. "Knowingly" under the FCA is a statutorily defined term. The government or relator must show that the defendant, with respect to the relevant 'false' 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, and no proof of specific intent to defraud is required."[2] The FCA is not intended to punish "honest mistakes," and a claim premised on a reasonable difference in opinion regarding a disputed legal question does not prove scienter or intent under the FCA.[3]

In contrast, the AKS requires the government to show that the defendant acted "knowingly" and "willfully." Unlike the FCA's "knowing" intent standard, the AKS scienter standard has been developed through judicial interpretation of the requirements of criminal law. Generally, to satisfy the AKS's heightened intent requirement, to prove knowing conduct, the government must show that

[1] 42 U.S.C. § 1320a-7b(g).

[2] 31 U.S.C. § 3729(b).

[3] *See United States ex rel. Owens v. First Kuwaiti Gen. Trading Co.*, 612 F.3d 724, 729 (4th Cir. 2010); *U.S. ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 376–377 (4th Cir. 2008) (citing *United States ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1018 (7th Cir. 1999)); *United States ex rel. Morton v. A Plus Benefits Inc.*, 139 Fed. Appx. 980, 983 (10th Cir. 2005) ("Expressions of opinion, scientific judgments, or statements as to conclusions about which reasonable minds may differ cannot be false.") (quoting *United States ex rel. Roby v. Boeing Co.*, 100 F. Supp. 2d 619, 625 (S.D. Ohio 2000)).

the defendant "realized what he was doing and was aware of the nature of his conduct, and did not act through ignorance, mistake, or accident."[4] Additionally, in the First, Fifth, Eighth, Tenth, and Eleventh Circuits, the government also must prove that the defendant committed the act with an unlawful purpose in order to meet the AKS's willful conduct prong.[5]

The heightened scienter standard under the AKS is not accidental. The AKS's explicit requirement that the payment be made "knowingly and willfully" serves the critical functions of mitigating vagueness and providing fair and adequate notice concerning the permissibility of certain conduct.[6] This is particularly important in the context of criminal law, in which constitutionality is so often challenged. Such constitutional concerns are especially relevant with broad criminal statutes like the AKS, which by its plain language, encompasses countless health care arrangements that are not only innocuous, but even beneficial. In fact, the legislative history of the AKS reflects that the knowingly and willfully elements were added precisely to address this concern, because the "the literal language of the statute might otherwise encompass some types of innocent conduct" and that it would be improper to punish an "individual whose conduct, while improper, was inadvertent."[7] Requiring that a defendant act willfully "does not carve out an exemption to the traditional rule that ignorance of the law is no excuse [as] knowledge that conduct is unlawful [not that it is proscribed by a particular law] is all that is required."[8]

Must the Government or the Relator Satisfy the Anti-Kickback Act's Scienter Requirement to Prove an AKS-predicated False Claims Act Case?

Several post-PPACA judicial opinions have addressed the required intent needed in an AKS-predicated FCA case. Some opinions have ignored the AKS's separate scienter requirement, essentially deciding AKS-predicated FCA cases without fully considering whether the government or relator must meet the AKS' separate intent requirement. In *United States ex rel. Nunnally v. West Calcasieu Cameron Hospital*, the relator alleged a scheme in which the defendant hospital charged reduced test fees to physicians in return for the physician referring to the hospital patients in need of laboratory tests.[9] The hospital would then charge Medicare significantly higher fees than charged to non-Medicare patients for the same tests, resulting in the government paying thousands of "false claims" generated by the illegal inducements.[10] On appeal, the Fifth Circuit affirmed the motion to dismiss the allegations.[11] More importantly, the Court noted in passing that the AKS requires the relator to plead that the defendant "knowingly paid remuneration to specific physicians in exchange for referrals" without separately considering the "willfully" element of the AKS.[12]

However, the majority of courts that have interpreted this issue—and that have considered it in detail—have concluded that the government or relator must prove that a defendant in an AKS-predicated FCA case acted "knowing and willfully."

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[4] *Klaczak ex rel. United States v. Consol. Med. Transp.,* 458 F. Supp. 2d 622, 674 (N.D. Ill. 2006).

[5] *See e.g., United States v. Davis*, 132 F.3d 1092, 1094 (5th Cir. 1998); *United States v. Jain*, 93 F.3d 436, 440-41 (8th Cir. 1996); *United States v. McClatchey,* 217 F.3d 823, 829 (10th Cir. 2000); *United States v. Starks*, 157 F.3d 833, 837–38 (11th Cir. 1998).

[6] Congress added the "knowingly and willfully" elements to the AKS in 1980 to address concerns "that criminal penalties may be imposed under current law to an individual whose conduct, while improper, was inadvertent." H.R. Rep. No. 1167, 96th Cong., 2d Sess. 59 (1980), reprinted in 1980 U.S.C.C.A.N. 5526, 5572.

[7] *Jain*, 93 F.3d at 440 (internal citations and quotations omitted).

[8] *Bryan v. United States*, 524 U.S. 184, 191–95 (1998); *United States v. Entin*, 750 F. Supp. 512, 518 (S.D. Fla. 1990) ([Under the 1986 amendments the] "scienter standard was eased in order to preclude 'ostrich' type situations, where an individual has 'buried his head in the sand' and failed to make any inquiry which would have revealed the false claim.").

[9] 519 F. App'x 890, 892 (5th Cir. 2013)).

[10] *Id.*

[11] *Id.* at 895.

[12] *Id.* at 894.

One notable case to adopt this interpretation of the PPACA amendments is *Gonzalez v. Fresenius Medical Care North America*.[13] In *Gonzalez*, one of the defendants was a provider of dialysis services who allegedly submitted false claims to Medicare in violation of the FCA.[14] The relator further alleged that this defendant was involved in a referral scheme with another doctor in private practice in violation of the AKS.[15] The Fifth Circuit confirmed that the use of the AKS as a predicate offense for the FCA required the relator to prove that the defendant satisfied the AKS's heightened scienter requirement.[16] The Fifth Circuit held that the relator did not demonstrate a violation of the FCA based on an alleged AKS violation because she could not show that the defendants "knowingly and willfully" entered into an illegal kickback scheme.[17] Additionally, the Fifth Circuit favorably cited to the district court's observation that the relator failed to point to any evidence "that would promote the inference of criminal intent to induce referrals."[18]

Similarly, in *United States ex rel. Osheroff v. Tenet Healthcare Corp.*, the Southern District of Florida decided the relator must allege that the defendant offered or paid remuneration to induce illegal referrals "knowingly and willfully" in an AKS-predicated FCA matter. [19] Further, the Court defined "willfully" to mean "'with knowledge that [defendant's] conduct was unlawful'"[20] In *United States ex rel. Klaczak v. Consolidated Medical Transport*, the Northern District of Illinois granted the defendant's motion for summary judgment in the AKS-predicated FCA case because relators failed "to create a triable case with respect to the [AKS's] heightened *scienter* requirements – *i.e.*, 'knowingly' and 'willfully' engaging in criminal misconduct."[21] In *United States ex rel. Sharp v. Consolidated Medical Transport*, the Northern District of Illinois stated that the AKS requires a greater showing of intent than the FCA.[22]

Courts that have required the government and relators to demonstrate that an FCA defendant acted "knowingly and willfully" under the AKS have the better end of the argument. The text of PPACA and its legislative history never suggest that anything less than proof as to every element of the AKS would be required to prove an FCA case predicated on an AKS violation. More specifically, PPACA amended the AKS to add an explicit statement that proof of a violation of that statute is legally sufficient to satisfy the falsity element of an FCA claim.[23] The change clarified and even streamlined the government's obligations when using the AKS as the predicate offense to an FCA claim. This amendment did not, however, alter any element of the underlying AKS violation, instead plainly stating that this satisfaction of the FCA is only applicable upon a showing of a "violation of this section [of the AKS]."

How PPACA Overruled the Ninth Circuit's Interpretation of the "Willfulness" Requirement for an AKS Violation

PPACA also sought to address the Ninth Circuit's jury instruction on the "willfully" element of the AKS. Prior to PPACA, many circuits required the government to prove that a criminal defendant acted with specific intent to do something the law forbids.[24] In *Hanlester Network v. Shalala*, the Ninth Circuit required the government to prove both that

[13] 689 F.3d 470 (5th Cir. 2012).
[14] *Id.* at 473.
[15] *Id.*
[16] *Id.* at 476.
[17] *Id.*
[18] *Id.*
[19] 09-22253-CIV, 2012 WL 2871264, at *8 (S.D. Fla. July 12, 2012)
[20] *Id.* (*quoting United States v. Starks,* 157 F.3d 833, 838 (11th Cir. 1998)).
[21] 458 F. Supp. 2d at 626–627.
[22] *See* No. 96 C 6502, 2001 U.S. Dist. LEXIS 13923, *30–31 (N.D. Ill. Aug. 31, 2001) (comparing the criminal intent standard of the AKS to the negligent conduct civil standard of the FCA).
[23] *See* 42 U.S.C. § 1320a-7b(g) ("a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim . . .").
[24] *See Davis*, 132 F.3d at 1094; *Starks*, 157 F.3d at 837–38 (affirming district court instruction defining willfully as "the act was committed voluntarily and purposely, with specific intent to do something the law forbids, that is with a bad purpose, either to disobey or disregard the law").

a defendant knew that the AKS "prohibits offering or paying remuneration to induce referrals" and that a defendant acted with the *specific intent* to violate the AKS itself.[25] In other words, pre-PPACA, the Ninth Circuit required the government to show that the defendant knew about the AKS's requirements and had specific intent to violate those requirements, while other circuits did not require proof of the defendant's actual knowledge of the AKS. Through PPACA, Congress modified the AKS to explicitly state that a defendant does not need a *specific intent* to violate a particular provision of the AKS.[26] The PPACA amendments added a clarifying subsection to the AKS; it did not delete or alter any of the pre-existing elements codified in the AKS. This addition does not eliminate (or, outside of the Ninth Circuit, even reduce) the generally acknowledged scienter requirements under either the AKS or the FCA. Thus, Congress abrogated this aspect of *Hanlester*, while leaving untouched court decisions that defined willfulness as intent to act unlawfully. As a result, the prevailing pre-PPACA understanding of the AKS's willfulness requirement from the other circuits remains good law.[27]

One clear example of this pre-PPACA jurisprudence that remains good law today is the "middle ground" approach taken in *United States v. Jain*.[28] In *Jain*, the defendant psychologist was convicted of violating the AKS by receiving money for referring patients to a psychiatric hospital.[29] On appeal, the defendant challenged the trial court's jury instruction defining "willfulness" within the AKS, arguing that it "means the voluntary, intentional violation of a known legal duty" as applied in criminal tax cases.[30] The Eighth Circuit upheld the district court's decision that the government must meet a heightened *mens rea* burden and "willfully" means "unjustifiably and wrongfully [and is] known to be such by the defendant."[31] This middle ground interpretation continues to inform AKS jury instructions in the Eighth Circuit following the enactment of PPACA.[32] Thus, there is little question that PPACA did not alter the AKS's willfulness requirement outside of the Ninth Circuit.

Conclusion

PPACA gave no indication of any intent to undo a scienter requirement carefully constructed through prior amendments. Neither the government nor a relator can, in effect, amend the AKS to eliminate one of its elements when proceeding under the FCA. As such, the government bears the burden of proving every element of both the AKS and the FCA in order to obtain the benefits of the PPACA amendments. Both pre- and post-PPACA, the government must show that a defendant proceeded with knowledge that his actions were unlawful. While PPACA linked the AKS more closely to the FCA and clarified the substance of the AKS's scienter requirement, the intent standard for FCA claims predicated on the AKS must be the heightened "knowing and willful" criminal standard.

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[25] 51 F.3d 1390, 1400 (9th Cir. 1995) (emphasis added).
[26] 42 U.S.C. § 1320a-7b(h) ("[a] person need not have actual knowledge of this section or specific intent to commit a violation of [the AKS]") (emphasis added).
[27] *See, e.g., Davis*, 132 F.3d at 1094; *Starks*, 157 F.3d at 837–38.
[28] 93 F.3d at 440.
[29] *Id.* at 438.
[30] *Id.* at 440. (*citing Cheek v. United States*, 498 U.S. 192, 201 (1991).
[31] *Id.*
[32] *See United States v. Yielding*, 657 F.3d 688, 708 (8th Cir. 2011) (analyzing (and eventually upholding) the district court's instruction to ensure consistency with *Jain* where the district court had instructed the jury that a "defendant acts willfully if he knew his conduct was wrongful or unlawful").