Compliance Readiness – Law Firms

The False Claims Act & The Anti-Kickback Act: Potential Conundrums Against The Health Care Industry And Growing Even Stronger?

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As those in the health care industry undoubtedly know, the past decade has seen an explosion in the number of health care actions brought under the civil False Claims Act. Originally enacted during the Civil War to combat the bilking of the government by unscrupulous vendors, the False Claims Act (“FCA”) was amended in 1986 to encourage more private "qui tam" lawsuits and to spur the federal government to prosecute more actions.1 The government and whistleblowers complained. In 1992, the Department of Justice reported that since the 1986 amendments, the federal government has recovered over $15 billion from FCA convictions, much of it from the health care industry, and $1.4 billion in 2005 alone.2 If that were not enough, it was noted that the industry, in recent years, private whistleblowers and the government have successfully pursued a new type of FCA claim – based on the Anti-Kickback Statute.3 This shows a significant development in health care litigation, and one that means even greater financial exposure for health care providers.

The False Claims Act is a civil statute that prohibits the knowing submission of false or fraudulent claims or requests for payment.4 It provides for a civil penalty of not less than $5,500 and not more than $11,000 for each claim submitted.5 It also authorizes “qui tam” suits, allowing private plaintiffs referred to as “relators,” receive a share of any recovery from the defrauder.6 The false claims statutes are an important enforcement tool in the health care industry, and whistleblowers have already pursued Anti-Kickback Statute claims – for example, where pharmaceutical companies pay kickbacks to physicians to prescribe their products.7

The Anti-Kickback Statute ("AKA") is a criminal statute that bans as a felony any person who knows or recklessly忽略 any person who knows or recklessly ignores the fact that the services or items were furnished in violation of the Anti-Kickback Statute or that the payments were paid to or accepted on behalf of a claimant.8 It provides for a criminal penalty of imprisonment of up to 5 years, fine, and mandatory exclusion from federal health care programs.9

The AKA also provides for administrative remedies, authorizing the Office of Inspector General of Health and Human Services to impose a civil monetary penalty and seek to exclude any person who knowingly or willfully pays or receiving remuneration in exchange for referrals or the purchase of any item or service that may be paid for by a federal health care program.10 It is a felony offense that carries with it the penalties of imprisonment of up to five years, fines, and mandatory exclusion from federal health care programs.11 The AKA also provides for administrative remedies, authorizing the Office of Inspector General of Health and Human Services to impose a civil monetary penalty and seek to exclude any person who knowingly or willfully pays or receiving remuneration in exchange for referrals or the purchase of any item or service that may be paid for by a federal health care program.12 It is a felony offense that carries with it the penalties of imprisonment of up to five years, fines, and mandatory exclusion from federal health care programs.13

The Anti-Kickback Act contains no private right of action. A private plaintiff may not sue a health care provider unless authorized by the AKA.14 Nor does the AKA state that payment from the government is conditioned upon compliance with the statute. Nevertheless, the government and qui tam plaintiffs have successfully argued across the country that violations of the AKA, a criminal statute, can serve as the basis for a claim under the False Claims Act.15 Under this theory, a claimant is necessarily and knowingly responsible for violations for purposes of the FCA if the medical services or items were furnished in violation of the Anti-Kickback Act notwithstanding the fact that the services or items provided were themselves appropriate and proper.

In so doing, the court in Thompson v. Columbia/HCA Healthcare Corporation, 238 F.Supp.2d 258, 263-64 (D.D.C. 2003)., held that a violation of the AKA can serve as the basis for an FCA claim. A former employee brought the case against related medical services companies based on allegations that the companies paid kickbacks to physicians.16 The government intervened and argued that the defendants’ AKA violations were actionable as “false” claims because the defendants had certified in their Medicare enrollment applications that they would comply with the AKA, and that this compliance was a prerequisite to payment.17 This is the same certification that the court in Pogue II relied on in concluding that the relator’s FCA claims were actionable. After half-heartedly denying the defendants’ motion to dismiss, the district court certified the issue for interlocutory appeal given its significance.18 With little discussion, the Eighth Circuit accepted the government’s argument, finding that it had alleged sufficiently that compliance with the AKA is a condition of payment, that the defendants were aware of this condition, and submitted claims “knowing that they were ineligible for payments demanded.”19

For the health care industry, the implications of McNutt are alarming.20 The Medicare enrollment form upon which both the government and whistleblowers rely requires providers to certify that they will comply with “all Medicare laws, regulations and program instructions” and that they understand such compliance is a condition of payment.21 Followed to its logical conclusion, the Eighth Circuit held that the Eleventh Circuit’s McNutt decision is of no consequence.22 The McNutt case recognized the potential draconian consequences of accepting the government’s position. It warned, “If one of the purposes of the United States in drafting the enrollment form and in intervening in qui tam suits like this one is to discourage people from becoming whistleblowers, it may succeed, especially if it wins a few.”23

Only time will tell what the government’s success in McNutt will mean for the health care industry. Given the number of contexts in which the government and whistleblowers have already pursued Anti-Kickback Act FCA claims – for example, disguised physician referral fees; Stark self-referral violations; below market rent; consulting agreements; unsupported discounts; and various pharmaceutical company marketing practices – health care providers must be ever vigilant in reviewing their financial arrangements with other health care entities and professionals. A strong compliance program is essential.

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1 See United States v. McNinch, 256 F.3d 595 (5th Cir. 2001.)
3 See United States v. McNinch, 256 F.3d 595 (5th Cir. 2001.)
4 See 31 U.S.C. § 3729 et seq.
5 See id. at 3757(b).
6 See id. at 3757(a).
8 See 42 U.S.C. § 1320a-7b(c) (1998).
9 See id. at 1320a-7b(b) or (c) (1998).
10 See id. at 1320a-7b(a).
15 See id. at 1320a-7b(b) or (c) (1998).
21 See United States ex rel. McNutt v. Haleyville Medical Group, Inc., the Third Circuit also permitted

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