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TRENDS IN HEALTH CARE ENFORCEMENT AND COMPLIANCE

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The Department of Justice (DOJ), in connection with the Health and Human Services Office of Inspector General (OIG), has taken an aggressive stance in connection with alleged health care fraud and abuse in the past few years, and the expectation is that the Department's enforcement efforts will continue to increase. The DOJ's focus on health care fraud is bolstered by its recovery of billions of dollars stemming largely from settlements with the health care industry.

In fiscal year 2011, the DOJ recovered more than $3 billion in civil cases involving alleged fraud against the government.[1] Of the $3 billion total, $2.8 billion was recovered under the whistleblower provisions of the False Claims Act (FCA).[2] In addition to the FCA cases, the DOJ obtained $1.3 billion in criminal fines, forfeitures, restitution, and disgorgement under the Federal Food, Drug, and Cosmetic Act. Assistant Attorney General Tony West, who oversees the DOJ's Civil Division, recently stated that 28% of the recoveries in the last 25 years were obtained since President Obama took office. According to West, "[t]hese record-setting results reflect the extraordinary determination and effort that this administration, and Attorney General Eric Holder in particular, have put into rooting out fraud, recovering taxpayer money and protecting the integrity of government programs."[3]

The Rise of the Whistleblower

Qui tam actions have seen a tremendous increase, as demonstrated by the $2.8 billion recovered in whistleblower cases in 2011. The qui tam provisions of the FCA allow private citizens, known as relators, to file lawsuits on behalf of the United States against those who are alleged to have falsely or fraudulently claimed federal funds. The DOJ then decides whether to intervene or allow the relator to pursue the case. Recovery under the FCA includes three times the government's loss plus a civil penalty of $5,500 to $11,000 per claim. Of this recovery, a relator may be awarded 15% to 25% if the government intervenes or up to 30% if the government declines to intervene.

In the 25 years since the False Claims Act was substantially amended, whistleblowers have filed more than 7,800 actions under the qui tam provisions.[4] The number of qui tam suits peaked at 638 in 2011, after numbering around 300 to 400 a year for much of the previous decade. This increased activity is in part the result of the Affordable Care Act (ACA),[5] passed in 2010, which amended the False Claims Act to provide additional incentives for whistleblowers to report fraud to the government and strengthened the provisions of the federal health care Anti-Kickback Statute (AKS). Broad publicity of whistleblower awards (such as the $96 million dollars awarded to the relator in the GlaxoSmithKline case)[6] and an increasingly sophisticated qui tam bar are also driving this increase.

CMS and Its New Technology

Health care providers should expect increased oversight from government contractors and the Centers for Medicare & Medicaid Services (CMS) utilizing new technology aimed at fraud detection. Medicare Administrative Contractors have initiated widespread probe audits directed at medical record documentation, including incomplete documentation, lack of physician order, lack of substantiation for the procedure billed, and services not supported by medical records. The Recovery Audit Contractors continue to mine billing data using the same software utilized by credit card companies to uncover areas of abuse or noncompliance.

In November 2011, CMS announced that it is

implementing predictive modeling technology known as the Fraud Prevention System (FPS) to identify potentially fraudulent Medicare claims and, in some instances, to suspend suspect payments before they are made.[7] The FPS uses a scoring system to identify suspect providers and to rate those providers based on a series of metrics designed to identify billing abnormalities or outliers. CMS can then assess each provider based on the abnormalities and determine whether further investigation is necessary or payment suspension is appropriate. In some instances, the leads generated by the FPS will be shared with the FBI, OIG, DOJ, and other law enforcement organizations. The FPS is currently screening all Medicare fee-for-service claims, and CMS plans to expand the program to include Medicaid claims by 2015.

Expansion of Statutory Tools

The reach of the FCA under an implied false certification theory to enforce violations of the AKS[8] and the physician referral prohibition statutes,[9] collectively known as the Stark Laws, has been expanded. The AKS is a criminal statute that prohibits manufacturers and providers from offering or receiving anything of value in return for patient referrals or the ordering of goods or services. In submitting a claim for reimbursement to Medicare, a healthcare provider impliedly certifies that it has not violated any Medicare statutes and regulations, including the AKS.

There was an open question as to whether AKS violations were sufficient to trigger FCA liability if payment was made by the healthcare provider as an inducement to refer Medicare patients or to order goods or services reimbursable by Medicare. The ACA, however, provided that Medicare or Medicaid claims that include items or services that result in an AKS violation are a predicate for an FCA claim.[10] Thus, even if the healthcare provider delivered the services for which it billed Medicare, and Medicare paid the proper amount of reimbursement, the services can be considered tainted by the AKS violation, and thus the reimbursement claims can be considered false. This theory has allowed DOJ to pursue large civil penalties for AKS violations without charging or proving a violation under the criminal law standards of proof applicable to the AKS.

In 2011, the Seventh Circuit Court of Appeals joined four other judicial circuits in adopting the "one purpose test" for assessing business arrangements under the AKS.[11] This test provides that if at least one purpose of the provision of remuneration is to induce use of product or referrals, the AKS has been violated. In recent cases pharmaceutical and device companies as well as the receiving provider have been pursued.

Proactive efforts to ensure compliance remain essential. Key areas of AKS risk mitigation include independent procurement programs and good compliance around the provision of medical education, equipment, consulting, advisory boards, research funding, donations, rebates, and honoraria. Finally, solid fair market value determinations and documentation are vital in acquisition transactions and compensation arrangements.

Medical Necessity Reviews

Another area that has seen an increased focus of enforcement activity is the medical necessity of procedures. Federal health programs only pay for medically necessary procedures — a determination that is not always clear. This scrutiny is often initiated by Medicare contractors and qui tam relators. Recent activity has focused on Cardiology procedures and provision of Durable Medical Equipment. While physicians have the responsibility for medical necessity determinations, hospitals face allegations that they knew or should have known medically unnecessary procedures were being performed at their facilities. The DOJ and OIG are pursuing investigations of many health care systems around the country focusing on the medical necessity of services.

Mitigation of risk related to compliance with medical necessity standards for health care systems involves good documentation in the medical records, medical staff appointment and credentialing processes, peer review processes, quality indicators and utilization trends, and medical staff bylaws. Compliance personnel involvement on medical staff quality committees can also be helpful.

Conclusion

There is no let up in sight for the aggressive enforcement environment facing the health care community. Providers can mitigate their risks by — as always — sound compliance programs, continued emphasis on quality and outcomes, and whistleblower management.

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[1] DOJ Press Release. Justice Department Recovers $3 Billion in False Claims Act Cases in Fiscal Year 2011. December 19, 2011. http://www.justice.gov/opa/pr/2011/December/11-civ-1665.html.
[2] 31 USC 3729-3733.
[3] DOJ Press Release. Justice Department Recovers $3 Billion in False Claims Act Cases in Fiscal Year 2011. December 19, 2011. http://www.justice.gov/opa/pr/2011/December/11-civ-1665.html.
[4] Id.
[5] H.R. 3590
[6] DOJ Press Release. GlaxoSmithKline to Plead Guilty & Pay $750 Million to Resolve Criminal and Civil Liability Regarding Manufacturing Deficiencies at Puerto Rico Plant. October 26, 2010. http://www.justice.gov/opa/pr/2010/October/10-civ-1205.html
[7] Public speeches at the National Health Care Anti-Fraud Association and the National Medicare RAC Summit, November, 2011.
[8] 42 U.S.C. § 1320a-7b.
[9] 42 C.F.R. §§ 411.350-89.
[10] Pub. L. 111-148 § 6402(f)(1).
[11] *United States v. Borrasi,* 2011 U.S. Ap