The Anti-Kickback Statute and the False Claims Act

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The United States government pays more than 40% of all retail prescription drug costs through Medicare, Medicaid and other health care programs. As a result, pharmacies are subject to potential liability under various federal statutes, including the Anti-Kickback Statute (AKS), the Civil Monetary Penalties Law (CMPL) and the False Claims Act (FCA). Different agencies address several recent developments that impact the potential scope of liability arising from claims for reimbursement submitted by pharmacies to government health care programs.

Bipartisan Budget Act of 2018 increased penalties

Industry that will be discernible funding provisions of the Bipartisan Budget Act of 2018 (the “Budget Act”) (P.L. 115-123) in addition to the potential criminal and civil penalties for violating the AKS. The AKS makes it a federal offense to offer, pay or accept anything of value in exchange for referrals for the provision of items or services that is submitted to a government health care program for reimbursement. The Budget Act doubled the maximum prison sentence for an AKS violation from five years to 10 years and increased the maximum civil monetary penalties for each AKS violation from $25,000 to $100,000.

The Budget Act also doubled the penalties available under the CMPL, which authorizes the Office of the Inspector General of the Department of Health and Human Services to impose civil money penalties for various forms of fraud and abuse involving the Medicare and Medicaid programs. Violations of the AKS previously subject to a civil penalty of up to $50,000 per violation under the CMPL now carry a potential penalty of $100,000 per violation. The enhanced criminal and civil penalties provided by the Budget Act cover violations committed after February 9, 2018.

False Claims Act cases

The FCA penalizes anyone presents, or causes to be presented, to the federal government a false or fraudulent claim for payment. A pharmacy may violate the FCA by billing a federal health care program for a prescription or service that was not provided, billing for a prescription or service that should not have been provided, billing an amount larger than that allowed, billing for an overpayment received from a government, or violating the AKS.

The FCA authorizes a private litigant, referred to as a “relator,” to file a claim on behalf of the government and receive a percentage of any recovery if the government chooses not to intervene. If the government elects not to intervene in a relator’s case, the court may indicate an increased likelihood that the Supreme Court will grant certiorari and hear the appeal.

DOJ guidance

There have been several recent indications that the Department of Justice is increasingly open to approaches that may moderate some of the harsh impacts of the AKS. On January 10, 2018, Michael Granston, the assistant U.S. attorney general, outlined his intention to decline to intervene in a case, DOJ attorneys should also consider whether the government’s interests are served by seeking dismissal of a relator’s case rather than simply declining to intervene and providing a nonexclusive list of issues that should be part of the analysis.

On January 25, 2018, Associate Attorney General Rachel Brand issued a blanket statement on the increase in AKS liability in the health care industry. The Department of Justice has taken to create meaningful DOJ Memos as well as formalizing issues that should be part of the analysis.

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