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# Beware of Offers Too Good to Be True: Recent Federal Lawsuit Highlights Kickback and False Claims Risks

As of February 18, 2025, the First Circuit Court of Appeals requires the government to prove “but-for” causation in Anti-Kickback Statute (AKS)-based False Claims Act (FCA) cases. The court reasoned in *United States v. Regeneron Pharmaceuticals* that the 2010 AKS amendment—which declares any claim for government payment “resulting from” an AKS violation as automatically false or fraudulent under the FCA—requires the government to prove the strict “but-for” causation standard. Though the court placed a higher burden on the government in future AKS-based FCA cases, providers should remain cautious if negotiations and transactions with vendors appear too good to be true.

## Statutory basis and but-for causation in *Regeneron*

The AKS prohibits individuals from offering, paying, soliciting, or receiving any remuneration to induce or reward referrals for services covered by federal healthcare programs. Individuals who violate the AKS may incur criminal liability unless the transaction satisfies one of the applicable exceptions. Under the FCA, an individual will incur civil liability if they “knowingly present, or cause to be presented, a false or fraudulent claim for payment” to the government. Pursuant to the 2010 AKS amendment, claims resulting from a violation under the AKS are also fraudulent within the purview of the FCA. Therefore, the 2010 AKS amendment creates a separate pathway for FCA claims.

In *Regeneron*, the court reasoned that the 2010 AKS amendment contains a default presumption that AKS-based FCA claims impose the “but-for” causation standard. Accordingly, the court concluded that the government

must prove that an illicit kickback was the “actual causality” of a false Medicare or Medicaid claim.

## **Key takeaways for healthcare providers**

Despite the court’s adoption of the “but-for” causation standard, healthcare providers should continue to thoroughly review potential transactions with their vendors. In the 2024 National Health Care Fraud Enforcement Action, the U.S. Department of Justice (DOJ) announced that it filed criminal charges against 76 different healthcare providers for their participation in various healthcare payment schemes. Some of the improper kickbacks committed by the healthcare providers that were discussed in the 2024 Action included:

**Laboratory fraud:** Clinical laboratory owners in Texas and New Jersey received kickbacks in exchange for referring patients for unnecessary genetic testing.

**Amniotic wound graft:** Two defendants in Arizona received over \$600 million from Medicare within 16 months for administering unnecessary amniotic grafts on elderly patients.

Moreover, the DOJ continues to scrutinize a variety of healthcare provider transactions including managed care organization investment arrangements, product discounts, and facility ownership arrangements in California, Massachusetts, New York, Texas, and numerous other states as AKS-based FCA claims. Despite efforts by healthcare providers to avoid incurring civil or criminal liability, the DOJ continues to allege that product discounts and other arrangements are covert schemes by providers to benefit from illegal referrals and kickbacks. Healthcare providers must remain vigilant because vendors marketing representations for these circuitous arrangements are likely to increase as a result of the strict “but-for” causation standard.

In light of the *Regeneron* decision, healthcare providers should be wary of any offers from vendors that appear too good to be true. Vendors may seek to take advantage of the increased burden placed upon the government in the *Regeneron* case to entice providers to accept kickbacks and bribes in exchange for unnecessary referrals. However, healthcare providers must recall that they may incur liability under the FCA for any payment claim resulting from a kickback under the AKS.

## **What this means to you**

As a result, it is essential for healthcare providers to ensure that their practices continue to comply with the AKS and FCA to avoid potentially incurring fines and penalties, reputational damage, and legal scrutiny. If an offer from a vendor appears too good to be true, then healthcare providers should thoroughly investigate it and seek legal counsel before proceeding.

## **Contact us**

If you have any questions about controlling risks in new or ongoing arrangements for people, products, ownership, or profits; the implications of these risks; ways to control risks under the AKS and FCA; or other healthcare issues, please contact Brian Flood, Robert Blaisdell, Taylor White, or your Husch Blackwell attorney.