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Compliance Implications for Healthcare Companies Post-First Circuit Decision

May 14, 2025

The US Court of Appeals for the First Circuit's landmark decision in *United States v. Regeneron Pharmaceuticals* will have some implications for healthcare compliance and defense strategies. In the case, the First Circuit adopted the more stringent "but-for" causation standard for claims under the False Claims Act (FCA) predicated on violations of the Anti-Kickback Statute (AKS). This approach aligns with the Sixth and Eighth circuits and cements the Third Circuit's outlier status. While the Third Circuit's more lenient "causal link" standard requires only some causal connection between the kickback and the false claim, most circuits now require the government to prove that the alleged kickback or improper payment was the direct cause of the false claim being submitted.

Implications for compliance programs

While the First Circuit's decision does not fundamentally alter how compliance programs should be structured, and compliance requirements under the AKS remain largely unchanged, the prevalence of the more robust "but-for" standard opens up potential defenses for individuals and companies facing AKS allegations. To bolster these defenses, it is essential that healthcare providers and companies review their compliance processes to ensure that evidence of medical necessity is well documented.

1. Emphasize medical necessity

To avoid false claims liability under the "but-for" causation standard, companies should emphasize and be prepared to present evidence of medical necessity. This is crucial because where there is clear evidence that services or supplies were medically necessary, it is less likely that the government (or relator's counsel) will be able to prove "but-for" causation – in other words, that those claims would not have been submitted absent an improper financial arrangement.

For pharmaceutical companies, it may also be wise to implement a formal monitoring program to review medical necessity of orders by healthcare professionals (HCPs) with whom the company has a separate financial relationship (e.g., through a speaker program). Additionally, for other companies, requiring certification that a test is medically necessary when ordering or processing it can significantly bolster a company's defense against subsequent allegations of wrongdoing. This could involve a statement alongside the order affirming that the patient meets all conditions for the prescribed test.

2. Importance of recordkeeping

The First Circuit's decision similarly reinforces the importance of maintaining clear, accurate documentation at all stages of interactions between pharmaceutical companies and HCPs. Whether it is the contractual language between the company and HCPs with whom they have financial arrangements or internal records surrounding specific arrangements, well-maintained records will be crucial in defending against false claims allegations if they arise. In addition, companies should consider implementing stronger provider attestation requirements, according to which HCPs with whom the company has separate financial relationships affirm that the services they ordered were medically necessary and not influenced by outside factors. These measures can help strengthen a company's defense if faced with allegations of improper kickbacks or false claims.

3. Speaker program selection

The First Circuit's decision also has potential implications for how companies structure their speaker programs and manage provider attestations. For example, while it may seem counterintuitive, when selecting potential speakers, it may now be beneficial to focus on doctors who have consistently prescribed or ordered services in the past. Their involvement could suggest that their prescribing behavior is independent of any financial

incentives. In other words, there is evidence that these providers would still have prescribed “but for” their compensation as speakers. For speakers who have no experience with a drug, it is harder to establish that they are not ordering it because of their payment as a speaker.

This is no time to rest on compliance laurels

The First Circuit’s decision is the latest in a series of rulings reshaping the legal landscape for healthcare compliance in the false claims space. While the decision may make the government’s job harder in some cases, it should not drastically alter compliance protocols, as it does not impact the underlying kickback analysis. At the same time, the “but-for” causation standard in FCA cases increases the emphasis on maintaining strong documentation and clear lines of evidence for medical necessity in case a defense is necessary.

As the circuit split deepens, healthcare companies should be prepared for potential future US Supreme Court review and should continue taking proactive steps to ensure their compliance programs pass muster. A robust compliance framework that emphasizes medical necessity, maintains thorough recordkeeping and scrutinizes relationships with healthcare providers will help minimize the risk of violating the AKS and FCA.

For more insights into how the First Circuit’s decision may impact your healthcare compliance practices, or for assistance in making them more robust, please contact any of the lawyers listed below.

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