In trend, court limits drug rebate AKS charges to easier 'but-for' standard

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Effective Mar 6, 2025
Published Mar 10, 2025
Last Reviewed Mar 6, 2025

Compliance

A recent ruling on the False Claims Act (FCA) implications of the anti-kickback statute (AKS) appears to be part of a trend that may protect you from escalated penalties if you're charged with AKS violations.

The AKS, a federal law, "prohibits the knowing and willful payment of 'remuneration' to induce or reward patient referrals or the generation of business involving any item or service payable by the federal health care programs," according to HHS.

A prime area of concern for AKS is drug rebate programs (or sometimes "prebate" or other discount mechanisms) in which pharmaceutical companies help low-income patients, sometimes through third-party entities and with the cooperation of their providers, to get expensive drugs with lower co-insurance costs (*PBN 10/17/22*). This can be a problem because Medicare still has to pay most of the cost of the drug, opening pharmaceutical companies and providers to charges that they have engaged in a kickback that the government, having been involved as a payer, has a right to address.

Regeneron was accused by the government in 2024 of violating the AKS by devising such a plan to partially cover costs for their Eyelea drug for treatment of neovascular age-related macular degeneration, so that Medicare could still be charged for it while patient co-insurance was minimized.

The Department of Justice (DOJ) sought to extend Regeneron's liability beyond AKS and into False Claims Act territory based on a 2010 amendment to the AKS that states a "claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA]." This would also expand potential penalties for the alleged kickbacks to triple damages and civil monetary penalties under the FCA.

But the U.S. District Court for Massachusetts, mirroring previous findings in similar cases by the Sixth and Eighth Circuit Courts, said that the general understanding of "resulting from" was insufficient to prove the fraudulence of claims, and called for a "but-for causation requirement" instead. On appeal, the First Circuit affirmed their logic.

Paul Werner of the Buttaci, Leardi and Werner law firm in Princeton, N.J., explains that, while the presumption had been that a claim coming after an inducement meant that the claim had been induced and was therefore false, the "but-for" standard means "not only did the inducement have to exist, the provider [also] needed to have been induced to do something other than what they would have done but for that inducement. For example, a patient wouldn't have gotten the medication apart from the fact that they could get cost-sharing assistance via a rebate program."

In other words, if it can't be proven that the kickbacks by themselves caused the physician to prescribe the drug, then the FCA is not implicated.

What it means for you

The ruling takes some of the AKS heat off if you're within the jurisdiction of the First Circuit, and also in the Sixth and Eighth Circuits, owing to their similar findings. (The Third Circuit has settled on a slightly more forgiving standard.)

"Every time a Circuit Court of Appeals makes a ruling like this, there is the potential that district courts in other Circuits which have not yet addressed the issue can be influenced to follow the court's ruling," says Geoffrey R. Kaiser, senior counsel in the compliance, investigations and white collar and health services practices of Rivkin Radler in Uniondale, N.Y. "District courts within Circuits which have addressed the issue are of course bound by their own Circuit Court's ruling." This being a "circuit split," Kaiser and others expect the Supreme Court to settle it eventually, which would nationalize the standard.

Werner says he has seen an uptick in AKS-to-FCA cases, "so this could be an important potential reining-in of that."

This isn't a license to take kickbacks, obviously. Khaled J. Klele, a partner with the McCarter & English law firm in Newark, N.J., reminds you there are AKS safe harbors — some of these laid out in a 2020 HHS/OIG final rule — of which you should be mindful whenever you consider a drug rebate program for your patients (*PBN 3/30/23*). "If a party is presented with an arrangement involving a discount or rebate, the party should do a compliance review to make sure that it falls within a safe harbor under the anti-kickback statute," he adds.

Sean B. O'Connell, a shareholder and member of the government enforcement and investigations group at Baker Donelson in Washington, says that you should be wary of any scheme in which "a financial incentive, such as co-pay assistance, is tied to prescribing behavior, rather than a neutral patient support program; [or] the prescribing decision appears to be financially driven rather than clinically justified; [or] the provider has a financial relationship with the supplier that could be seen as influencing prescribing habits."

RESOURCES

Ruling, U.S. Court of Appeals for the First Circuit, U.S. v. Regeneron Pharmaceuticals, Inc., Feb. 18, 2025: https://fcablog.sidley.com/wp-content/uploads/sites/5/2025/02/Regeneron-1st-Cir.-2.18.25.pdf

HHS/OIG, final rule, "Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements," Dec. 2, 2020: www.federalregister.gov/documents/2020/12/02/2020-26072/medicare-and-state-health-care-programs-fraud-and-abuse-revisions-to-safe-harbors-under-the

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