

Accused of Kickback Scheme, Pfizer Pays \$23M to Resolve False Claims Act Case

Under the federal Anti-Kickback Statute of the False Claims Act, a drug company may not offer anything of value (not limited to money) in order to persuade Medicare beneficiaries to buy the company's products. Earlier this month, the U.S. Attorney's Office for the District of Massachusetts, announced that the drug giant Pfizer agreed to resolve the case against it by paying \$23.85 million. The pharmaceutical company had been accused of violating the False Claims Act when it allegedly paid Medicare enrollees illegal kickbacks via an ostensibly independent charitable foundation.

Case sends a message to pharma companies: just say no to kickbacks

"Kickbacks undermine the independence of physician and patient decision-making, and raise healthcare costs," Acting Assistant Attorney General Chad A. Readler of the Justice Department's Civil Division said in a press release announcing the case's resolution. "As today's settlement makes clear, the Department will hold accountable drug companies that pay illegal kickbacks—whether directly or indirectly—to undermine taxpayer funded healthcare programs, including Medicare."

High deductibles and costly medications are a reality for many people nowadays, no matter what type of insurance they're covered under. But when Medicare patients are prescribed a drug covered by Medicare Part B or D, they may be responsible for paying a deductible, co-payment, or co-insurance before their prescriptions are filled. Especially in the case of specialty pharmaceuticals, the patient responsibility can be exceedingly high or even out-of-reach for many people on a fixed income.

The government's case zeroed in on billing practices for three Pfizer drugs: Sutent and Inlyta (both treatments for renal cell carcinoma), and Tikosyn (treatment for certain types of arrhythmia). The Department of Justice (DOJ) alleged that Pfizer circumvented its own free drug program intended to provide Sutent and Inlyta to patients demonstrating a financial need, and instead, steered some of those patients to a 501(c)(3) foundation for co-pay coverage. This in turn triggered Medicare claims for the medications, and ultimately government reimbursement.

Additionally, the government's case alleges that Pfizer made charitable donations to the foundation to be kept in the loop, so that it could speak, and attest to the fact that the foundation covered the co-pays for Medicare patients prescribed Sutent and Inlyta.

Alleged behavior "violates the basic trust patients extend to the healthcare system"

Harold H. Shaw, Special Agent in Charge, FBI Boston Division, said the settlement "demonstrates the FBI's commitment to making sure patients receive, and the government pays for, health care that is not compromised by kickbacks. What Pfizer is accused of doing in this case—masking charitable contributions to increase company profits—violates the basic trust patients extend to the healthcare system and threatens the financial integrity of the Medicare program."

Regarding Tikosyn, the government alleges that the drug company worked with the foundation to develop a fund for Medicare patients in treatment for arrhythmia (specifically with atrial fibrillation or atrial flutter, which are the indications for Tikosyn). Toward the end of 2015, Pfizer hiked the wholesale price of the drug by nearly 50%. The DOJ alleges that the drug giant was aware that the cost increase was likely to result in a corresponding hike in Medicare patients' out-of-pocket responsibility, which in turn motivated Pfizer to allegedly begin bankrolling and referring patients to the fund it co-created with the foundation when the cost increase went into effect. Records revealed that Medicare enrollees prescribed Tikosyn represented the vast majority of those awarded fund assistance for the first nine months of the fund's operation.

Settlement punishes Pfizer, but gov't "commends" drug

company for settling

Although the settlement agreed to by Pfizer does not involve an admission of guilt, it does resolve the case. And the government is pleased with Pfizer's decision to settle.

"Pfizer used a third party to saddle Medicare with extra costs," said U.S. Attorney Andrew E. Lelling in a government press release. "According to the allegations in today's settlement agreement, Pfizer knew that the third-party foundation was using Pfizer's money to cover the co-pays of patients taking Pfizer drugs, thus generating more revenue for Pfizer and masking the effect of Pfizer's price increases. The Anti-Kickback Statute exists to protect Medicare, and the taxpayers who fund it, from schemes like these. At the same time, we commend Pfizer for stepping forward to resolve these issues in a responsible manner."

Pfizer now in 5-year corporate integrity agreement with HHS-OIG

In addition to the settlement payment, Pfizer has agreed to enter a five-year corporate integrity agreement (CIA) with the Department of Health and Human Services Office of Inspector General (HHS-OIG). In addition to putting in place systems that will verify that any patient assistance programs involving a third party are fully compliant with the law, the pharmaceutical company must undergo periodic reviews by an independent organization, and its Board members and executives must achieve certifications demonstrating compliance.

"Our corporate integrity agreement promotes independence between Pfizer and any patient assistance programs to which it may donate," said Gregory E. Demske, Chief Counsel to the HHS-OIG. "Without true independence, as we have seen in this case, drug companies may use patient assistance programs as conduits for improper payments that harm Medicare."

This article is provided for educational purposes only and is not offered as, and should not be relied on as, legal advice. Any individual or entity reading this information should consult an attorney for their particular situation. For more information/questions regarding any legal matters, please email info@nelsonhardiman.com or call 310.203.2800.