CLIENT ALERTS & INSIGHTS

Third-Party Co-Pay Assistance Program Kickback Scheme Results in $450 Million DOJ Settlement

OCTOBER 16, 2024

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Teva Pharmaceuticals, the largest generic drug manufacturer in the United States, has agreed to pay $450 million to resolve allegations of violating the False Claims Act and Anti-Kickback Statute arising from purported copayment and price-fixing misconduct.[1] Teva's payment includes a criminal penalty pursuant to a deferred prosecution agreement. The government determined the aggregate settlement value based on Teva's ability to pay.

In 2020, the United States Department of Justice filed a complaint alleging that, for nearly a decade, Teva manipulated the co-pay foundation assistance system to induce more Medicare patients to purchase its sclerosis drug, Copaxone. To do this, Teva funneled hundreds of millions of dollars to co-pay assistance foundations through donations. These foundations would then pay the co-pays for the Medicare patients with donations Teva structured specifically to benefit only itself and not competitor drugs. At the same time, Teva utilized data from a specialty pharmacy, Advanced Care Scripts (ACS), to track patient prescriptions and ensure that it was donating enough to cover the cost of its drug.

By utilizing data from ACS and virtually eliminating patient co-pay costs through its donations, Teva was able to raise the price of Copaxone without losing market share to other sclerosis drugs. Over time, Teva raised Copaxone's price at 19 times the inflation rate, from approximately $17,000 a year to over $85,000 a year.

Both the foundations[1] and ACS[2] previously settled their cases with the United States. Teva's settlement is the latest in a string of other enforcement actions against pharmaceutical companies that allegedly used third-party foundations to pay kickbacks.[3]

From a legal perspective, co-pay assistance programs reduce the out-of-pocket cost burden for Medicare patients purchasing prescription medication covered under Medicare Part B or D. Pharmaceutical manufacturers have significant financial interests in Medicare coverage and receiving favorable tier-status for their drugs. Accordingly, co-pay assistance programs can present legal issues if donations, like in Teva's case, are used to influence the purchase of drugs by Medicare patients.

Among other things, the Anti-Kickback Statute criminalizes the knowing and willful offer of payment of remuneration "directly or indirectly . . . to any person to induce such person" to buy a good, item, or service for which Medicare may pay.[4] Claims to Medicare that result from Anti-Kickback Statute violations trigger liability under the False Claims Act.[5] Violations of either statute can result in civil and criminal penalties.

Notwithstanding the potential exposure, pharmaceutical manufacturers can still contribute cash donations to bona fide charitable assistance programs-the caveat being that the program must not "function as a conduit for payments by the pharmaceutical manufacturer to patients and must not impermissibly influence beneficiaries' drug choices." [6]

As a practical matter, this case demonstrates the Justice Department's commitment to prosecuting health care fraud. While pharmaceutical companies should be aware of these issues, others operating in the healthcare industry should take notice of the potential pitfalls associated with Medicare co-pay assistance programs. Because of the possible exposure coupled with the Justice Department's enforcement prioritization in this area, decisions involving compliance with federal law and OIG guidance should be made with experienced legal counsel.

Prompt and competent responses to healthcare fraud investigations are essential to mitigating damage and achieving positive outcomes. If you are a healthcare organization or medical professional who is struggling with these issues or would like to discuss developing corporate policy, contact Benesch's White Collar, Government Investigations & Regulatory Compliance group for consultation.

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[1] https://www.justice.gov/usao-ma/pr/third-foundation-resolves-allegations-it-conspired-pharmaceutical-com
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[2] https://www.justice.gov/usao-ma/pr/specialty-pharmacy-advanced-care-scripts-agrees-pay-35-million-reso
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[3] *See, e.g.*, https://www.justice.gov/opa/pr/patient-services-inc-agrees-pay-3-million-allegedly-serving-conduit-pharma
; https://www.justice.gov/opa/pr/two-pharmaceutical-companies-agree-pay-total-nearly-125-million-resolve-
.

[4] 42 U.S.C. § 1320a-7b(b)(2).

[5] 42 U.S.C. § 1320a-7b(g).

[6] Publication of OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70,623, 70,626, & 70,672 (Nov. 22, 2005).