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DOJ Intervenes in False Claims Case Involving Copay Subsidies

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The Department of Justice (DOJ) recently intervened in a False Claims Act (FCA) lawsuit involving allegations of kickbacks for prescription drug copays. The DOJ says the lawsuit makes "clear that the Department will hold accountable drug companies that pay illegal kickbacks to facilitate increased drug prices." The DOJ "will not allow drug companies to use so-called charitable patient assistance funds to do what they otherwise cannot do – pay patients' copays to circumvent these safeguards and increase their profits."

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DOJ Continues To Pursue Health Care Fraud

The FCA, which allows private persons ("relators") to bring private ("*qui tam*") actions on behalf of the US government, provides that the DOJ may elect to intervene in an action or bring a related action. Last year, the total amount the DOJ recovered in *qui tam* cases in which it intervened or otherwise pursued reached almost $2 billion, with health care fraud claims accounting for the majority of the recoveries.

Copay Subsidies Under Scrutiny

In this matter, according to the DOJ's announcement, the defendant paid illegal kickbacks in the form of copayment subsidies for one of its drugs. This allowed the defendant to raise continually the price but market the drug as "free," which the DOJ alleged then shifted the drug's increasing cost to Medicare.

The defendant allegedly paid the copay subsidies through a foundation under an agreement only to cover copays for the defendant's drug, to the exclusion of other drugs. The DOJ's complaint alleges that the agreement between the defendant and the foundation falsely stated, however, that the fund would provide financial assistance "with any medically appropriate therapy." The copay scheme allegedly contributed to significant growth in the drug's sale and in corporate revenue. Documents cited in the DOJ's complaint indicate that the defendant believed that covering the drug's copay was the most significant "motivating factor" that would increase the drug's usage.

Defendant's Alleged Knowledge of Illegality

The complaint also alleges the defendant knew about the FCA, the Anti-Kickback Statute (AKS), and other healthcare fraud and abuse laws. The complaint describes a compliance training that warned employees never to provide anything of value as an inducement for prescribing, using, or recommending the defendant's products. A corporate policy also allegedly specified that it was a violation of the AKS to offer reimbursement assistance to induce the use or purchase of a drug. Another allegation of knowledge included the circulation of trade publications among employees that described Medicare Part D copays as illegal under the AKS.

HHS Views AKS Compliance as Material When Paying Medicare Claims

According to the DOJ, the defendant's scheme circumvented Congress's "design of the Medicare system, which requires a copay, in part, to act as a market constraint against increasing drug prices." The DOJ's complaint

emphasized that the AKS is a "*per se* prohibition against the payment of kickbacks in any form." The DOJ claims that any Medicare claim that includes items or services resulting from a violation of the AKS constitutes a false or fraudulent claim under the FCA. Perhaps having its eye on the Supreme Court's 2016 decision in *Universal Health Services v. United States ex rel. Escobar*, the DOJ alleged in its complaint that "[c]ompliance with the AKS is material to the agency's decision to pay a Medicare claim." Such centrality, the DOJ's complaint states, is demonstrated by the fact that Congress determined that any Medicare claim including items or services that resulted from a violation of the AKS constitutes a false or fraudulent claim under the FCA. Moreover, "HHS-OIG has made clear that compliance with the AKS is material," by providing guidance on the issue of drug companies paying copay subsidies.