

Weekly Checkup

HHS Secretary Becerra in Need of (Copay) Assistance

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Last Friday, Department of Health and Human Services (HHS) Secretary Xavier Becerra testified on the department's fiscal year 2025 budget before the Energy and Commerce Subcommittee on Health. While the discussion was wide-ranging, one exchange regarding HHS' position on the use of copay assistance cards raised both eyebrows and questions. Specifically, Secretary Becerra repeatedly responded to questions regarding HHS' approach to copay assistance cards by confirming the department's commitment to protecting prescription drug access for Medicare beneficiaries...who are prohibited by federal law from using copay assistance cards under the anti-kickback statue. While this could be a simple case of government-official misspeak, it is useful to clarify the complex dynamics driving the use of copay assistance cards are, who can use them, the actions HHS has taken on them to date – and why the secretary may have avoided directly answering questions related to the department's approach to these cards.

What Are Copay Assistance Cards? Drug manufacturers typically offer copay assistance cards to patients for high-cost branded medications. Patients use these copay assistance cards to cover the out-of-pocket costs at the pharmacy counter when filing a prescription. Many patients assumed that the copay assistance card discount would be applied to their yearly deducible, but that was not always the case as some plan sponsors elect to use either or both a pharmacy benefit manager's (PBMs) copay accumulator or copay maximizer. A copay accumulator would allow a patient to redeem their copay assistance card without any balance being applied to the yearly deductible. A copay maximizer would have any unused balance from the copay assistance card provided to the health plan or employer. For example, if a patient has a \$100 copay assistance card, but the out-of-pocket payment is \$80, the plan sponsor would then "maximize" the full amount of the copay assistance card by amending the out-of-pocket payment to \$100.

Copay accumulators and maximizers are implemented by PBMs on behalf of plan sponsors to control costs. Typically, drugs redeemed by patients with a copay assistance card are not preferred on a drug formulary (meaning that a cheaper brand or generic was available). Moreover, plan sponsors tend to pay more for drugs redeemed with a copay assistance card as no additional drug manufacturer rebates are offered. **Some even argue that repeat use of copay assistance cards by patients ends up circumventing the PBM rebate negotiation process since patients get through their deducible faster.** Regardless of plan sponsors' motivations for accepting or denying a copay assistance card – patients often get caught in the middle.

Who Can Use Copay Assistance Cards? Typically, patients with commercial insurance (self-insured or fully insured) are allowed to use copay assistance cards. According to Avalere, as of June 2023, 19 states banned the use of copay accumulators in the individual, fully insured, large-group and small-group markets (approximately 19 percent of the total U.S. commercial market).

Medicare, Medicaid, TRICARE military insurance, and Veterans Health Administration programs beneficiaries cannot redeem copay assistance cards.

What Action Has HHS Taken on Copay Assistance Cards? In September 2023, the U.S. District Court for the District of Columbia vacated part of a rule (2021 Notice of Benefit and Payment Parameters) that did not require plan sponsors apply copay assistance balances to a patient's yearly deducible (also known as a cost-sharing obligation). In short, this ruling was a victory for the Biden Administration which has focused on reducing out-of-pocket costs as key policy priority. Unexpectedly – and in response to this court action – HHS released a statement that the agency "intends to address, through rulemaking, the issues left open by the Court's opinion, including whether financial assistance provided to patients by drug manufacturers qualifies as 'cost sharing' under the Affordable Care Act. Pending the issuance of a new final rule, HHS does not intend to take any enforcement action against issuers or plans based on their treatment of such manufacturer assistance." Surprisingly, HHS and the Centers for Medicare and Medicaid Services appealed the court's decision to vacate the 2021 rule but abandoned the case in January 2024. Some have speculated that HHS ended its legal appeal because the agency intends to issue a rule on copay assistance cards.

This all brings us back to HHS Secretary Becerra's unrelated answers on Medicare rather than clear responses about the department's approach to copay assistance cards. Certainly one could assume he was part of the conversation to both appeal the 2023 District Court ruling as well as abandoning further litigation in 2024. If not, it raises the question of who is driving the policies at HHS at a time when the Biden Administration is taking significant regulatory action that will have long-term harmful effects on overall health costs and medical innovation.