

Court Vacates HHS Rule for Prescription Drug Coupons

November 1, 2023

Quick Facts

- The interaction of high deductible health plan (HDHP) compliance with drug manufacturer coupon assistance has been a source of confusion for plan sponsors for quite some time.
- Previous guidance from the Department of Labor (DOL), the Department of Health and Human Services (HHS) and the Internal Revenue Service (IRS), collectively known as “the Departments,” attempted to provide clarity on this ambiguous issue.
- A recent court order vacated the rule and remanded it to the Departments to provide further clarity for plan sponsors.

Background

The 2020 Affordable Care Act (ACA) [Notice of Benefit and Payment Parameters \(NBPP 2020\)](#), published in April 2019, stated that the value of drug manufacturer coupons offered to reduce out-of-pocket costs for brand name prescription drugs that have a generic equivalent are not required to be counted towards a plan participant’s out-of-pocket maximum (OOPM) limit. Most group health plans interpreted this rule to mean that if no generic equivalent is available, then coupons from manufacturers for prescription drug payment assistance must be counted toward the OOPM.

Since NBPP 2020 was released, there have been many concerns raised about the implications of including the value of drug coupon amounts in OOPMs and the ambiguity of the NBPP rules. A recent court decision out of the Federal District Court in the District of Columbia directs the Departments to provide an interpretation of key definitions and hopefully shed light on this ambiguous requirement.

Temporary Limit on Enforcement Action

Following the release of this rule, concerns about interaction with high deductible health plans (HDHPs) and health savings account (HSA) eligibility were raised. In August 2019, the Departments released [Frequently Asked Questions \(FAQs\) Part 40](#), which addressed confusion about whether the NBPP requires plans and issuers to count the value of coupons toward the annual OOPM limit in situations other than when a generic equivalent is available. In that FAQ, the Departments stated they would not take enforcement action against plans and issuers that exclude the value of coupons when there is no available generic equivalent until additional guidance was provided.

Interaction with HDHPs

As part of [FAQ 40](#), the Departments concede that the NBPP requirement could create a conflict with eligibility rules for individuals participating in HDHPs with HSAs. The Departments reference IRS Notice 2004-50 which states that the provision of drug discounts will not disqualify an individual from being an eligible individual if the individual is responsible for paying the costs of any drugs (taking into account the discount) until the deductible of the HDHP is satisfied. The Departments state in FAQ 40,

that per IRS Notice 2004-50, an HDHP must disregard drug discounts and other manufacturers' discounts when determining whether the HDHP minimum deductible has been satisfied, and states that only amounts paid by the individual covered by the HDHP can be counted toward satisfying the deductible.

Following the FAQ guidance, NBPP 2021 amended the statute, stating that drug manufacturer coupons "may be, but are not required to be" counted towards OOPM limits. The amendment intended to resolve ambiguity and avoid compatibility issues for HDHPs with HSAs.

Recent Court Ruling

In September 2023, the United States District Court for the District of Columbia (the Court), vacated the NBPP 2021 provision in the case [*HIV and Hepatitis Policy Inst. V. HHS*](#). The Plaintiffs challenged the provision, stating that the definition of the term "cost-sharing" in NBPP 2021 conflicts with the ACA and with the HHS regulatory definition of "cost-sharing" and that NBPP 2021 is arbitrary and capricious. Arbitrary and capricious is a legal standard meaning that there is no reasonable standard for the decision. When a ruling is arbitrary and capricious it can later be invalidated when there is no reasonable rational connection between the facts of the case and the decision.

The Court vacated and remanded the rule to HHS to determine the definition of cost-sharing. The court stated that ACA's definition of cost-sharing "does not speak clearly" as to manufacturer assistance and agreed with the Plaintiffs that the NBPP conflicts with the HHS regulatory definition of cost-sharing. Additionally, the Court held that the NBPP provision is arbitrary and capricious as it interprets the term as having two different meanings, leaving too much to the discretion of the regulated parties.

Summary

At this point, it is unknown whether the case will be appealed, or the decision will be stayed. This could be a significant ruling if plans will be required to count drug manufacturer's assistance coupons towards the OOPM, but the practical effect is not clear. There are currently no immediate implications for plans or issuers. EPIC will continue to monitor the issue and watch the outcome of this decision closely.

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