

## Publications

## HHS Drops Appeal in Drug Coupon Case

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On January 16, 2024, the Department of Health and Human Services (“HHS”) dropped its appeal of the U.S. District Court for the District of Columbia’s September 29, 2023 decision that vacated a portion of the 2021 Notice of Benefit and Payment Parameters (“2021 NBPP”). The 2021 NBPP permitted (but did not require) plans and issuers to count direct support offered by drug manufacturers for prescription drugs (“Coupons”) toward the Affordable Care Act’s annual cost-sharing limit (“MOOP”). *HIV and Hepatitis Policy Inst. et al. v. U.S. Dep’t of Health and Hum. Svcs.*, No. 22-2604, 2023 WL 6388932 (D.D.C. Sept. 29, 2023). See our prior alert [here](#).

Although HHS dropped its appeal, HHS has adopted non-enforcement relief. Thus, until HHS issues further guidance, HHS will not take enforcement action against plans and issuers that do not count Coupons towards the MOOP.

## Non-Enforcement Relief

On November 27, 2023, the day before HHS filed its appeal, HHS filed a motion asking the court to clarify its order. HHS informed the court that it “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.” HHS also stated that “[p]ending 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.”

On December 22, 2023, the court ruled that the 2020 Notice of Benefit and Payment Parameters (“2020 NBPP”) is now in effect, but the court did not interpret the 2020 NBPP or rule on the legality of any nonenforcement policy because those issues were not before the court.

## 2020 NBPP

Based on the preamble language, the regulated community interpreted the 2020 NBPP to say that if there was not a generic equivalent available, then the plan or issuer was not required to count the Coupon toward the MOOP. However, the 2020 NBPP regulatory text itself does not specifically say that plans and issuers were required to count

Coupons toward the MOOP if there is not a medically appropriate generic. Instead, the regulatory text merely states that plans and issuers are not required to count coupons towards the MOOP where there is a medically appropriate generic available. It does not specify a rule where there is not a medically appropriate generic available.

## Potential HHS Rulemaking

**NOTE:** For context, the statute defines “cost-sharing” to include “(i) deductibles, coinsurance, copayments, or similar charges; and (ii) any other expenditure required of an insured individual which is a qualified medical expense (within the meaning of section 223(d)(2) of Title 26) with respect to essential health benefits covered under the plan.” 42 U.S.C. § 18022(c)(1).

The existing regulatory definition of “cost-sharing” is “any expenditure required by or on behalf of an enrollee with respect to essential health benefits; such term includes deductibles, coinsurance, copayments, or similar charges, but excludes premiums, balance billing amounts for non-network providers, and spending for non-covered services.” 45 C.F.R. § 155.20

Although HHS dropped its appeal, that does not end the matter. Because the court remanded the 2021 NBPP back to HHS, HHS must take some future action. Some examples of potential action are:

- *Only remove the 2021 NBPP rule that the court invalidated* – it seems unlikely that HHS will only take this action because HHS will likely want to clarify what the Coupon rule actually is since the 2020 NBPP has caused confusion. Also, the 2020 NBPP seems to present the exact same problems as the 2021 NBPP – that is, plans and issuers could apply either of two interpretations of identical statutory language, and that interpretation also may conflict with the preexisting regulatory definition of “cost sharing.”
- *Issue a new proposed rule that revises the definition of “cost-sharing” to more closely follow the statute* – HHS could interpret the statute to only include amounts actually paid by the participant and not amounts paid “on behalf of” the participants, like Coupons.
- *Issue a new proposed rule that requires plans and issuers to count Coupons towards the MOOP, even where there is a generic equivalent available* – HHS could leave the regulatory definition of “cost-sharing” as it is and interpret the “on behalf of” language to mean that all Coupons for drugs that are essential health benefits must count towards the MOOP.

**GROOM INSIGHT:** Any HHS action would need to take into account the issue that the HHS and the Departments of Treasury and Labor noted in [FAQ guidance](#) regarding HSA-compatible high deductible health plans.