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Publications

Court Ruling Calls Into Question Whether Plans and Issuers Can Exclude Drug Coupons Towards the MOOP

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On September 29, 2023, the U.S. District Court for the District of Columbia vacated the 2021 Notice of Benefit and Payment Parameters ("2021 NBPP") amendments to Affordable Care Act regulations. The amendments permitted (but did not require) plans and issuers to count direct support offered by drug manufacturers for prescription drugs 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). The court invalidated the 2021 NBPP regulations because the court concluded that the 2021 NBPP's interpretation of "cost sharing" conflicts with the statutory and regulation definition of "cost sharing" under the ACA

The Court remanded the amendments in the 2021 NBPP back to the department of Health and Human Services ("HHS") for further consideration. In the meantime, plans and issuers will need to determine whether or not to count the drug coupon assistance towards the MOOP.

Background

The use of drug coupons has been a controversial practice for plans and issuers. Coupons can have the effect of impacting carefully planned formularies that are intended to encourage participants to use lower cost, efficacious drugs. As such, many plans and issuers have preferred not to count coupons toward participant cost sharing.

The amendments to the 2020 Notice of Benefit and Payment Parameters ("2020 NBPP") (in 45 C.F.R. § 156.130(h)) provided that amounts offered by drug manufacturers to reduce or eliminate out-of-pocket costs for certain prescription brand drugs (e.g., coupons) that have an available and medically appropriate generic equivalent are not required to be counted towards the MOOP. Based on the preamble language, the regulated community interpreted this rule to say that if there was not a

generic equivalent available, then the drug manufacturer assistance was required to count toward the MOOP.

As a result of stakeholder concerns that this would raise issues for HSA-compatible High Deductible Health Plans ("HDHPs"), the Departments of Labor, Health and Human Services, and the Treasury (collectively, the Departments) published FAQ guidance to address the ambiguity in the regulation and potential conflict with prior IRS guidance for HDHPs. The guidance stated that "the Departments will not initiate an enforcement action if an issuer of group or individual health insurance coverage or a group health plan excludes the value of drug manufacturers' coupons from the annual limitation on cost sharing, including in circumstances in which there is no medically appropriate generic equivalent available."

The 2021 NBPP amended 45 C.F.R. § 156.130(h) to say that drug manufacturer assistance coupons "may be, but are not required to be," counted toward the MOOP. The effect of this amended language is to make it expressly permissive for plans and issuers to not count the drug manufacturer support toward the MOOP, which resolved the "confusion" and avoided a conflict with the HSA-compatible HDHP guidance.

Legal Challenge and Court Ruling

Plaintiffs challenged the 2021 NBPP's changes to 45 C.F.R. § 156.130(h) on three grounds:

1. It conflicts with the ACA's statutory definition of "cost-sharing" and is not entitled to *Chevron* deference.
2. The 2021 NBPP changes clash with HHS' preexisting regulatory definition of "cost sharing."
3. The 2021 NBPP is arbitrary and capricious because: (a) it gives the same statutory and regulatory language different meanings; (b) the sole justification for the rule is based on an erroneous view of the law; (c) the rule's analysis of costs to patients is irrational; (d) HHS failed to justify their reversal from the 2020 NBPP and failed to consider reliance interests; and (e) the rule treats similarly situated cases differently without adequate justification.

The court vacated the rule and remanded it to the HHS based on the first two arguments, without addressing whether the 2021 NBPP is arbitrary and capricious.

The court focused on how the ACA defines "cost-sharing," which is "(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."

ACA § 1302(c)(3)(A). The court concluded that:

[T]he ACA's definition of "cost sharing" does not speak clearly as to the treatment of manufacturer assistance. And "[i]n a suit challenging agency action, 'it is not for the court to choose between competing meanings' of an ambiguous statute when the agency charged with its administration has not weighed in first."

The court vacated the rule and remanded it to the HHS "to interpret the statutory definition in the first instance," but cautioned that "whatever interpretation the agencies adopt on remand cannot conceivably 'rehabilitate' the 2021 NBPP, because the 2021 NBPP rests on two contradictory interpretations of the statute." *Id*.

The court also agreed with the plaintiffs that the 2021 NBPP conflicts with the regulatory definition of cost sharing, but noted that there are "difficult interpretive questions as to this definition that were not raised by the parties." The 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 (emphasis added). The plaintiffs argued that, on its face, this definition includes drug manufacturer assistance because it is an expenditure made on behalf of an enrollee. HHS offered three rebuttals, each rejected by the court:

- The 2021 NBPP's authorization of copay accumulators may be a reduction in the amount the enrollee is required to pay under the statutory definition of "cost sharing." The court reasoned, however, that nonetheless, this is an expenditure under the regulatory definition because it is an expenditure on behalf of the enrollee.

- The regulatory definition is better understood as referring to the economic impact on the drug manufacturer akin to a price reduction rather than an expenditure on behalf of an enrollee. The court said that contrary to this assertion, however, both the statutory and regulatory definitions center the experience on an enrollee rather than a third-party.
- At least in some instances, manufacturer assistance does not involve an expenditure on anyone's behalf because it may be a reduction in price paid by the purchaser, such as a payment to a pharmacy. The court said that, even if this were true sometimes, it is also true that at other times manufacturer assistance is an expenditure on behalf of an enrollee.

Even though the court dispensed with HHS' arguments, it noted several thorny issues for consideration on remand:

- Although the court agreed with the plaintiffs' implicit assumption that the intent of the regulation likely was to define "cost sharing" as costs that are: (1) required of an enrollee and (2) paid by "or on behalf of" that enrollee, that is not what the actual text of the regulation says. Instead, "cost sharing" is "any expenditure required by or on behalf of an enrollee." On the plaintiffs' reading, this means *any expenditure* either "required by" or "on behalf of" an enrollee.
- An equally plausible reading of the regulation, however, is any expenditure "required by" or "required … on behalf of" an enrollee. The court noted that "[t]his raises thorny questions about what it might mean for an expenditure to be required'—whether by law, by an insurance plan, by contractual arrangement, or otherwise—'on behalf of' an enrollee."
- And, further, the regulation refers to an expenditure "required by" an enrollee, instead of tracking the statutory "required of." The word "by" implies that it is the enrollee "requiring" the expenditure.

The court observed, "there are interpretive depths to this regulation that have yet to be plumbed."

Practical Effect

At this point, we believe that plans and issuers need to carefully monitor the decision and any subsequent guidance. We do not know if the case will be appealed, the vacatur will be stayed, or if HHS will issue any clarifying guidance.

Notably, if the court's ruling merely vacates the 2021 NBPP's amendment to 45 C.F.R. § 156.130(h)—i.e., that plans are permitted, but not required to, count the assistance towards the MOOP—then it might restore the 2020 NBPP version of the rule. But, the 2020 NBPP version itself permitted plans and issuers to exclude the value of drug manufacturers' coupons from the MOOP where there is a medically appropriate generic equivalent available. And, some read the 2020 NBPP version to also be permissive and allow plans and issuers to decide whether to include or exclude the value of the coupons from the MOOP, even where there is not a generic equivalent available. That is, the 2020 NBPP seems to present the exact same problems as the 2021 NBPP: 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." It is not clear, however, if the effect of the 2021 NBPP was to remove the 2020 NBPP so that *neither* currently are in effect.

While we wait to see if there is an appeal or stay, or if HHS issues further guidance, plans and issuers should monitor this situation carefully and be ready to make changes if there is more certainty.