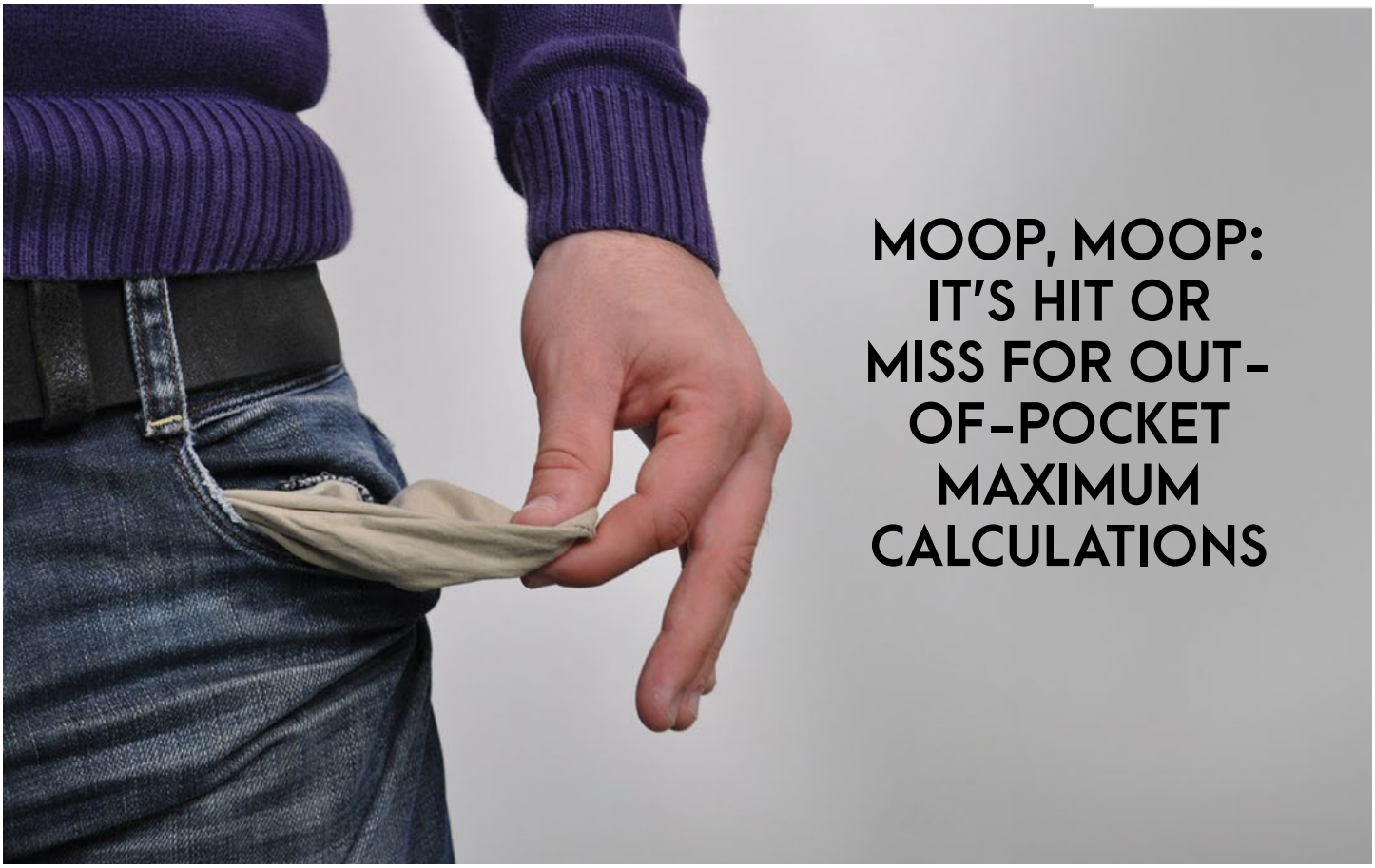

MOOP, MOOP: IT'S HIT OR MISS FOR OUT-OF-POCKET MAXIMUM CALCULATIONS

Written By Alston & Bird, LLP Health Benefits Practice

Many health plans have adopted the practice of excluding the value of drug manufacturer rebates and coupons (collectively coupons) from counting toward deductibles and out-of-pocket maximums (MOOP). Others may apply coupons towards the deductible and/or out-of-pocket maximum, but as noted below, such practice may cause compliance concerns under the IRS rules applicable to HSA-compliant HDHPs. In this month's article, we trace through recent agency (HHS) guidance and court developments and the challenges such rulings create for health plan administration. Although the Notice of Benefit and Payment Parameters (NBPPs) are issued by HHS, the rulemaking likely indicates how the tri-agencies may view the issues for self-insured plans (even if such rules are not directly applicable through portions of the Public Health Service Act incorporated into ERISA).


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BACKGROUND

HHS first addressed the practice of excluding the value of drug manufacturer coupons from MOOP through copay accumulator programs in the 2020 Notice of Benefits and Payment Parameters (2020 NBPP). However, the language in the regulatory text of the 2020 NBPP created confusion over whether counting the value of the coupons in MOOP was required or discretionary. The text of the rule itself permitted plans and issuers to disregard the value of the coupons as long as a medically appropriate generic equivalent was available (and as long as the practice was consistent with state law), but the rule did not codify any requirement to include the value of the coupons in MOOP if a generic equivalent was not available. In response to the confusion over the 2020 NBPP and potential conflict with the IRS HDHP requirements applicable to HSA-compatible HDHPs, federal regulators issued nonenforcement relief (through FAQs Part 40) until the 2021 NBPP could be issued and put into effect, stating that no enforcement action would be initiated if a plan or issuer excluded the value of the coupons, even if no generic equivalent was available. The 2021 Notice of Benefit and Payment Parameters ("2021 NBPP") clarified that plans and issuers had total discretion (subject to state law applicable to insured plans) to decide whether to count the value of these coupons towards MOOP, regardless of the availability of any generic equivalent.

Advocacy groups challenged the 2021 NBPP in the D.C. district court, arguing that its treatment of drug manufacturer coupons conflicted with the statutory definition of "cost-sharing" under the Affordable Care Act ("ACA") and with the pre-existing regulatory definition. In its September 2023 ruling in HIV and Hepatitis Policy Institute et al. v. HHS, the D.C. district court agreed with the advocacy groups, vacating 2021 NBPP and remanding it back to HHS. This ruling meant that the 2020 NBPP was now in effect again.

The Department of Health and Human Services ("HHS") initially appealed the ruling but dropped its appeal of the D.C. district court's order in mid-January 2024. The immediate consequence of this ruling was that the previous rule announced sprang back into effect. Under that 2020 NBPP, plans and issuers were not required to count the drug manufacturer coupons towards MOOP as long as a medically appropriate generic equivalent was available (and the practice was consistent with state law). Although this rule implies that the coupons must be counted if no generic equivalent is available, the text did not expressly state any such requirement, leaving plans and issuers in a state of confusion. Until HHS issues a new rule or other binding guidance, plans and issuers are left guessing whether it is permissible to exclude the value of the coupons from MOOP when a generic equivalent is not available.

Practice Pointer: It is important to note that self-insured, non-grandfathered ERISA plans need to be mindful of Affordable Care Act rules for cost-sharing limits on essential health benefits ("EHBs"). If the drug at issue is not considered an EHB under the plan, then the plan is likely free to include or exclude the value of the coupon or discount. But if the drug is considered an EHB under the plan, then HHS' rulemaking in the NBPPs for these copay accumulator programs is likely relevant. Self-insured plans should review the terms of their programs to ensure compliance with the EHB rules.

IMPACT OF COUPONS ON THE PLAN'S ADMINISTRATION OF THE MOOP

At first glance, this might all seem like much ado about nothing; however, a closer look reveals challenges for health plans. For all health plans, applying coupons to the out-of-pocket maximum increases the plan's cost. And for HDHP plans, it likely creates HSA eligibility issues in the absence of sophisticated administrative systems that can exclude the coupons from the deductible but not the out-of-pocket maximum. The following example illustrates the issue with counting (or not counting) coupons and

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discounts towards MOOP: If a participant uses a coupon with a value of $150 for each month's supply of a prescription drug, the annual value of the coupon is $1800. If the plan counts the value of the coupon, then $1800 of the participant's deductible and MOOP is funded by the drug manufacturer. If the plan excludes the value of that coupon, then $1800 would not be counted towards MOOP, and the participant would be left to make up the $1800 by paying for other medical expenses out-of-pocket.

HOW DRUG MANUFACTURER COUPONS ARE TREATED UNDER THE 2020 NBPP

The 2020 NBPP grants discretion to plans and issuers to count the value of a drug manufacturer's coupon towards MOOP if a medically appropriate generic equivalent is available (and if consistent with state law). The preamble to the 2020 NBPP goes on to add that the value of such coupons must be counted towards MOOP when no medically appropriate generic drug is available. Although the preamble states, "We have added language to the regulation text to address this clarification," the addition was never actually made, and the regulators did not include this requirement in the text of the regulation itself. This glaring omission led to confusion over whether there really was any requirement to count the value of the coupons when no medically appropriate generic equivalent is available. That said, the wording of the text that did make it into the regulation—that plans and issuers "are not required" to count direct support from drug manufacturers when a generic equivalent is available—strongly implies that such direct support is required to be counted when no generic equivalent is available.

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NONENFORCEMENT RELIEF: FAQS PART 40 AND THE HDHP/HSA PROBLEM

In August 2019, in response to the confusion over 2020 NBPP, the tri agencies released FAQ Part 40, in which they reconsidered the policy on how to count drug manufacturer coupons, taking into consideration the conflict that applying the coupons to the out-of-pocket maximum might have on HSA eligible, as described in IRS Notice 2004-50. In order to be eligible to contribute to an HSA, an individual must be enrolled in an HDHP and have no other disqualifying health coverage that would pay for medical care before the HDHP deductible is reached. Any coverage or benefits received prior to meeting the HDHP deductible could disqualify a person from being eligible to contribute to an HSA (unless an exception exists). IRS Notice 2004-50 stated that the value of a discount from a drug manufacturer will not lead to disqualification as long as the individual is otherwise responsible for paying costs until the deductible is met. In other words, the value of the drug discount would apparently be disqualifying if it were counted towards the individual's HDHP deductible, and therefore, the discount must be excluded from the calculation in order for the individual to maintain HSA eligibility.

Interestingly, the conflict between the 2020 NBPP and the HSA rules highlights an administrative issue. The 2020 NBPP only requires that the coupons be applied to the out-of-pocket maximum –not the deductible. HSA eligibility is only impacted if the coupons are applied to the deductible. This suggests that the two rules could co-exist in theory; however, such is not the case in practice. First, plan administrators are simply not able to apply a cost share to the out-of-pocket maximum without also applying it to the deductible. Second, the coupons would likely exhaust the out-of-pocket maximum before the participant incurred significant other

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deductible expenses necessary to satisfy the HSA rules.

Consequently, regulators announced relief from complying with 2020 NBPP in FAQs Part 40, stating that no enforcement action would be initiated if a plan were to exclude drug manufacturer assistance from MOOP, even if no medically appropriate generic drug is available. This nonenforcement relief was set to expire once the 2021 NBPP was issued and in effect.

2021 NBPP: A "FIX" THAT FELL FLAT

HHS issued the 2021 NBPP in May 2020, marking the end of the nonenforcement relief once 2021 NBPP went into effect. Rather than imposing any specific practice on plans, the 2021 NBPP simply granted permission for plans to choose whether to apply the value of drug manufacturer assistance to MOOP. As long as the plan's actions were consistent with state law, the 2021 NBPP placed no mandate on how to treat drug manufacturer coupons for MOOP, regardless of whether a medically appropriate generic equivalent was available. Regulators explained in the preamble of 2021 NBPP that the term "cost-sharing," which is defined in the statute and further interpreted by regulations, is "subject to interpretation" when it comes to whether to include or exclude drug manufacturer coupons in MOOP. And the interpretation for this purpose is left not to regulators but to plans and issuers. Advocacy groups challenged the discretion granted to plans and issuers in 2021 NBPP in HIV and Hepatitis Policy Institute et al. v. HHS and were ultimately victorious, but the victory only reinstated the 2020 rule, which was not clear to begin with. However, as discussed below, the arguments raised in the lawsuit may force HHS to be more decisive in its next round of rulemaking.

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COURT CHALLENGE TO 2021 NBPP

In 2022, several advocacy groups filed a lawsuit against HHS for, among other things, conflicts between HHS's interpretation of "cost-sharing" in the 2021 NBPP and the statutory and regulatory definitions (see HIV and Hepatitis Policy Institute et al. v. HHS):

> The ACA defines "cost-sharing" to include the catch-all "any other expenditure required of an individual which is a qualified medical expense."
>
> The regulatory definition from 2012 defines cost sharing as "any expenditure required by or on behalf of an enrollee […]." [45 CFR Section 155.20]

Although some may parse the difference between the phrases "required of (statutory) and "required by" (regulatory) and conclude that the two mean the same thing, it could be argued that the additional phrase "or on behalf of" in the regulatory definition tilts in favor of including coupons in MOOP. In either case, the advocacy groups argued that opposing interpretations based on the same statutory and regulatory language could not both be true; that is, it cannot be true that the value of the coupons is cost-sharing for one plan but is not cost-sharing for another, absent any difference in state law or other legal limitations.

In its September 2023 opinion, the D.C. district court agreed with the advocacy groups that the exact same statutory and regulatory text cannot have two opposing meanings when applied to drug manufacturer coupons and that the discretion to choose between the two opposing meanings cannot be left to the discretion of the parties being regulated. The court set aside 2021 NBPP and remanded it back to HHS. The vacatur meant that the 2020 NBPP was back in effect, but the court refused to weigh in on the legality of the nonenforcement relief in FAQs Part 40.

WHERE DO WE GO FROM HERE?

So, what can we expect from HHS? Leaving plans and issuers to decide for themselves whether direct support from drug manufacturers is "cost-sharing" under the ACA is now apparently off the table. HHS may go back to its regulatory definition of "cost-sharing" and propose removing the problematic "on behalf of" language and provide an interpretation that is closer to the statutory language. Or HHS may make a decisive statement that drug manufacturer support must or must not be included in cost-sharing calculations. If HHS were to issue a decisive rule that all drug manufacturer assistance had to be included in MOOP, such a rule would have to take into account IRS rules for HDHPs, and self-insured plans would need to address potential compliance

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issues with the EHB and MOOP rules.

For now, 2020 NBPP is technically in effect, which apparently means the following for plans and issuers:

- State law is controlling for plans and issuers subject to state law.
- Plans and issuers are apparently not required to include direct support from a drug manufacturer coupon in MOOP if a medically appropriate generic drug is available.

What about that nonenforcement relief in FAQs Part 40 from 2019? Did the D.C. district court opinion that revived the 2020 NBPP also revive the nonenforcement relief? In a motion for clarification on the ruling, HHS stated that it does not intend to take any enforcement action against plans based on treatment of manufacturer assistance. Although advocacy groups pushed for the court to rule that the non-enforcement policy was illegal, the court stated that the non-enforcement policy was not an issue before the court. So far, we have not seen any recent enforcement activity in this area from the agencies. ■

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