

HHS Gives New Guidance on Drug Manufacturer Coupons and Out-of-Pocket Maximums

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Background

In April 2019, the Department of Health and Human Services (HHS) released guidance indicating that a health plan must include the value of financial assistance received from a drug manufacturer (often referred to as a “coupon” or “copay card”) when calculating a member’s annual out-of-pocket maximum if the coupon was used to purchase a specialty drug that had no generic equivalent available. In response to industry concerns over this rule and its impact on programs developed and utilized by pharmacy benefit managers (PBMs) to exclude such coupons from members’ cost-sharing amounts (e.g., out-of-pocket maximums, copays, and deductibles), HHS, the Internal Revenue Service, and the Department of Labor issued joint guidance in August 2019 (discussed [here](#)), providing that the new rule developed by HHS would not be enforced for the 2020 calendar year. The joint guidance also stated that HHS would revisit this subject and issue new guidance that would apply for 2021 and beyond.

Legal Development

In a proposed rule recently issued by HHS (available [here](#)), which would apply beginning in 2021, HHS appears to have backed away from its prior position. Specifically, HHS has now proposed that group health plans be permitted, *but not required*, to count the value of drug manufacturer coupons toward members’ annual cost-sharing limits. If the proposed rule is finalized, health plans and PBMs would be able to continue to utilize any current practices of excluding drug manufacturer coupons from members’ annual cost-sharing amounts (sometimes referred to as “copay accumulator programs” or “copay optimization programs”) in 2021 and beyond.

Note, however, that some states (e.g., Virginia and West Virginia) have passed insurance laws that *require* that the value of drug manufacturer coupons be credited to a member’s annual cost-sharing amounts in certain circumstances. While these state laws would not apply to self-funded group health plans, sponsors of fully insured group health plans and insurance carriers should be cognizant of any such restrictions imposed by state law.

Takeaway Message

For the remainder of 2020, health plans may continue to exclude the value of drug manufacturer coupons from a member's annual cost-sharing amounts. While nothing is finalized yet for 2021 and beyond, we expect that the recent rule proposed by HHS will be adopted in final form without many changes (and that, as a result, health plans would be permitted to continue to exclude drug manufacturer coupons from annual cost-sharing amounts in all cases). Please stay tuned for future developments.

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