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HHS Changes Rule Regarding Prescription Drug Manufacturer Coupons and Cost-Sharing Requirements

The Department of Health and Human Services (HHS) Centers for Medicare & Medicaid Services (CMS) has released the final Notice of Benefit & Payment Parameters for 2020. The notice announces a change to Code §156.130 (Cost-sharing requirements), which specifically permits plans to disregard manufacturer coupons when determining whether a participant has met their out-of-pocket maximum when generic equivalents of the drug are available.

BACKGROUND

Healthcare reform applies an overall "cost-sharing limit" on essential health benefits under non-grandfathered group health plans. Copays for prescription drugs that qualify as essential health benefits count toward this overall limit. To compete with available drug alternatives, drug manufacturers often offer coupons to individuals to reduce the copay the individual pays when purchasing the drug. On April 25, 2019, HHS released the final Notice of Benefit & Payment Parameters for 2020, which went into detail about concern over this practice's effect on overall drug prices, given that it provides an incentive to patients and providers to choose a more expensive brand-name drug over a more affordable generic option. In response to this concern, HHS updated Code §156.130 (Cost-sharing requirements) to include the following:

> *"(h) Use of drug manufacturer coupons. For plan years beginning on or after January 1, 2020:*
>
> *(1) … amounts paid toward cost sharing using any form of direct support offered by drug manufacturers to enrollees to reduce or eliminate immediate out-of-pocket costs for specific prescription brand drugs that have an available and medically appropriate generic equivalent are not required to be counted toward the annual limitation on cost sharing…."*

NO AVAILABLE GENERIC ALTERNATIVE

The new text of the rule clarifies that plans can decide to disregard manufacturer coupons for purposes of cost-sharing limitations when a generic alternative is available. However, the rule does not specifically state that plans are required to count coupons toward the out-of-pocket maximum when no generic alternative is available.

Although the updated regulation itself does not specifically state that plans are required to count coupons toward an individual's out-of-pocket limit when there is no general alternative, language to this effect does appear in the text of the Notice of Benefits & Payment Parameters for 2020:

> *"…Where there is no generic equivalent available or medically appropriate… amounts paid toward cost sharing using any form of direct support offered by drug manufacturers must be counted toward the annual limitation on cost sharing..."*

Although this text is non-binding, it is does illustrate the position taken by HHS: that in cases where no generic alternatives are available, coupons must be counted toward an individual's out-of-pocket maximum.

SUMMARY

Cost-sharing regulations have been updated to include a paragraph that explicitly permits a plan to disregard drug manufacturer coupons when determining whether an individual has met their out-of-pocket maximum.

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Although the agency does not explicitly state it in the regulations, HHS has been clear about viewing drug manufacturer coupons as counting toward an individual's out-of-pocket maximum when a generic alternative is not available. Your Parker, Smith & Feek Benefits Team will discuss this new development with your Pharmacy Benefits Manager, carrier, and/or TPA to determine how to handle drug-manufacturer coupons beginning January 1, 2020.

As always, should you have any questions, please contact your Parker, Smith & Feek Benefits Team. While every effort has been taken in compiling this information to ensure that its contents are totally accurate, neither the publisher nor the author can accept liability for any inaccuracies or changed circumstances of any information herein or for the consequences of any reliance placed upon it.