



AMERICAN BENEFITS

COUNCIL

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Submitted via electronic mail

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Services
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**Re: Drug Manufacturers' Coupons and the Annual Limitation on Cost-Sharing; HHS
Notice of Benefit and Payment Parameters for 2021 (CMS-9916-P)**

Dear Ms. Weiser, Ms. Rivers and Mr. Pate,

I write on behalf of the American Benefits Council ("the Council") regarding the treatment of drug manufacturers' coupons for purposes of the annual limitation on cost-sharing in the Affordable Care Act (ACA). The Council very much appreciates the willingness of the departments of the Treasury, Labor and Health and Human Services ("the Departments") to work with the Council on this issue over the past year, as well as the related enforcement safe harbor that the Departments provided in response to

concerns raised by the Council and other stakeholders. We write now to reiterate the Council's position, as we expect that the HHS Notice of Benefit and Payment Parameters (NBPP) for 2021 Proposed Rule, currently under review at the Office of Management and Budget's Office of Information and Regulatory Affairs, will address this issue.

The American Benefits Council is a Washington D.C.-based employee benefits public policy organization. The Council advocates for employers dedicated to the achievement of best-in-class solutions that protect and encourage the health and financial well-being of their workers, retirees and families. Council members include over 220 of the world's largest corporations and collectively either directly sponsor or administer health and retirement benefits for virtually all Americans covered by employer-sponsored plans. The Council provided comments regarding the 2020 NBPP, including on the provision regarding drug manufacturers' coupons and the annual limitation on cost-sharing.¹

As the Departments are aware, the 2020 NBPP contained a rule regarding how drug manufacturers' coupons must be treated by plans and issuers when applying the annual limitation on cost-sharing under the ACA and under Public Health Service Act Section 2707(b) (as incorporated into the Employee Retirement Income Security Act and the Internal Revenue Code) ("Rx Drug Rule"). Specifically, the Rx Drug Rule provided that for plan years beginning on or after January 1, 2020, plans and issuers would be permitted to exclude the value of drug manufacturers' coupons from counting toward the annual limitation on cost-sharing when a medically appropriate generic equivalent is available.²

As the Council has previously expressed to the Departments, as finalized in the 2020 NBPP, the Rx Drug Rule would have imposed material additional costs on group health plans and issuers. This is because it generally would have prohibited plans and issuers, when applying the annual limitation on cost-sharing, from excluding the value of drug manufacturers' coupons unless a generic equivalent of the drug is available. These are amounts that are not actually paid by the participant, and, as such, these are amounts that many plans do not count as amounts paid by the participant toward the annual limitation on cost-sharing. To the extent plans and issuers were required to take account of drug manufacturers' coupons when administering the annual limitation on cost-sharing, participants would have satisfied the annual limitation on cost-sharing sooner than they otherwise would under the plan's terms, which would then result in the plan having to pay "first-dollar" for any covered medical expenses incurred by the participant thereafter. The practical economic effect of the Rx Drug Rule would have been to significantly increase plan costs, with resulting increased costs for employers and potential premium increases for plan participants and beneficiaries.

¹ Council letter to the Centers for Medicare & Medicaid Services Re: Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020, February 19, 2019.

² See 84 FR 17454, 17544-17546.

It is very important to our employer and carrier members that they be permitted to design their plans to continue to disregard drug manufacturers' coupons when applying the annual limitation on cost-sharing, without regard to whether there is a medically appropriate generic equivalent of the drug available. To that end, as noted above, we greatly appreciated the Departments speaking with Council staff last summer to hear about our members' concerns with respect to this issue. And the Council was both appreciative and greatly relieved when the Departments issued an FAQ on August 26, 2019, effectively rescinding the Rx Drug Rule to allow for further consideration by the Departments.³

As was also noted by the Departments in the FAQ, the Rx Drug Rule would have created a conflict with certain Internal Revenue Service (IRS) rules for high deductible health plans (HDHPs) and eligibility to contribute to a health savings account (HSA). In particular, IRS Notice 2004-50, Q&A 9, requires an HDHP to disregard drug discounts and other manufacturers' and providers' discounts in determining if the minimum deductible for an HDHP has been satisfied and only allows amounts actually paid by the individual to be taken into account for that purpose. As discussed in the FAQ, the Rx Drug Rule "could put the issuer or sponsor of an HDHP in the position of complying with either the requirement under [the 2020 NBPP] for limits on cost sharing in the case of a drug manufacturer coupon for a brand name drug with no available or medically appropriate generic equivalent or the IRS rules for minimum deductibles for HDHPs, but potentially being unable to comply with both rules simultaneously."

As part of the Departments' reconsideration of the Rx Drug Rule, and for the foregoing reasons, the Council reiterates its request that plans and issuers be permitted to disregard the value of drug manufacturers' coupons when administering the annual limitation on cost-sharing, regardless of the availability of a generic equivalent. This will not prohibit patients from using coupons at the point of sale, but will allow plans to administer benefit features like deductibles as designed and in compliance with HDHP rules. More generally, this will ensure that plans and issuers remain free to design plans that provide for meaningful drug coverage, while also ensuring the application of certain cost-sharing tools and strategies designed to manage utilization of, and the costs associated with, prescription drug benefits.

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³ The FAQ provides that "[u]ntil the 2021 NBPP is issued and effective, 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 Council is grateful for the opportunity to engage with the Departments directly on this issue and for the Departments' responsiveness in issuing the FAQ and delaying implementation of the Rx Drug Rule.

Thank you for considering this letter. If you have any questions or would like to discuss further, please contact us at (202) 289-6700.

Sincerely,

Ilyse Schuman

A handwritten signature in black ink that reads "Ilyse Schuman". The signature is written in a cursive, flowing style.

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