AMERICAN BENEFITS COUNCIL

February 19, 2019

Submitted electronically via http://www.regulations.gov

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-9926-P
P.O. Box 8016
Baltimore, MD 21244-8016

Re: Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020

Dear Sir or Madam:

I write on behalf of the American Benefits Council ("Council") to provide comments in connection with the Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020 Proposed Pule published in the *Federal Register* on January 24, 2019 by the Centers for Medicare and Medicaid Services ("CMS"), U.S. Department of Health and Human Services ("HHS") (84 Fed. Reg. 227).

The rule proposes several changes with respect to prescription drugs, including the application of cost-sharing requirements and annual and lifetime dollar limitations specifically relating to brand name prescription drugs and drug manufacturer coupons. The Council appreciates the opportunity to provide comment with respect to the proposed rule, in particular provisions predicated on bringing down the cost of prescription drugs, an issue of critical importance for employers who sponsor health benefits plans and their employees and families.

The Council is a public policy organization representing principally Fortune 500 companies and other organizations that assist employers of all sizes in providing benefits to employees. Collectively, the Council's members either sponsor directly or provide services to health and retirement plans that cover more than 100 million Americans. The Council provided extensive comments regarding employer innovations and strategies to lower

drug costs and related issues on the "HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs" issued last year.[1]

Pharmaceutical drug therapies have played a significant role in treating and curing injury, illness and disease. They allow millions of Americans to overcome debilitating conditions, return to work after injury, illness or disease, and to live longer, healthier, more productive lives. Although the benefits of pharmaceutical drug therapies are substantial, these benefits often come with significant financial costs – to both participants and to payers in the health care system, including employer-sponsored plans. As evidenced in 2016 alone, private health plans spent more than $142 billion on prescription drug coverage – more than ever before.[2] From 2013 to 2016, spending on prescription drug coverage grew more than any other category of health care expenses for individuals with employer-sponsored health coverage.[3] These costs continue to increase across plans. Of note, among employers with 500 or more employees, prescription drug costs increased by 7.6% in 2017 and are projected to rise by another 7.8% in 2018.[4]

The Council appreciates HHS' efforts to address issues related to increasing prescription drug costs and the need to provide additional flexibility for health plans to implement innovations and strategies designed to manage overall drug costs and encourage consumers to use more cost-effective generic drugs.

Cost Sharing Requirements and Annual and Lifetime Dollar Limits

Under the proposed rule, beginning with the 2020 plan year, CMS would permit plans to impose lifetime and annual dollar limits on a brand prescription drug if an enrollee selects the brand drug when a medically appropriate generic equivalent is available. This is because the brand drug would no longer be considered an essential health benefit ("EHB") subject to the prohibition on such dollar limits under Section 2711 of the Public Health Service Act.

The Council supports the proposal to allow plans to treat a brand prescription drug as not an EHB where there is a medically appropriate generic equivalent available on the plan's formulary. This proposal, in particular, would provide group health plans the necessary flexibility to design pharmacy benefits to encourage enrollees to use a lower-cost generic equivalent drug, when medically appropriate, and positively impact a plan's prescription drug costs and premiums.

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[1] *See* the American Benefits Council's July 16, 2018, comment letter to the U.S. Department of Health and Human Services, https://www.americanbenefitscouncil.org/pub/?id=9460eae0-a95e-7eef-cc02-81b549ce389f.
[2] *See* Peterson-Kaiser Health System Tracker, *Health Spending Explorer*, https://tinyurl.com/y9moy7qq.
[3] *See* Health Care Cost Institute, 2016 Health Care Cost and Utilization Report 14 (2018) (hereinafter "2016 Health Care Cost and Utilization Report"), http://www.healthcostinstitute.org/report/2016-health-care-cost-utilization-report.
[4] *See* Mercer's National Survey of Employer-Sponsored Health Plans, *Mercer National Health Survey: Employer's Finding New Ways to Hold the Line on Health Benefit Cost Growth*, Mercer (Nov. 2, 2017), https://www.mercer.com/newsroom/mercer-national-health-survey-employers-finding-new-ways-to-hold-the-line-on-health-benefit-cost-growth.html.

The proposed rule would also permit plans to not count certain cost-sharing toward the Affordable Care Act's maximum out-of-pocket limit if an enrollee selects a brand prescription drug when a medically appropriate generic equivalent drug is available. If an enrollee selects the brand drug when the generic equivalent drug is available and medically appropriate, CMS proposes that the issuer and the group health plan would be permitted to not count the difference in cost sharing between that which is paid for the brand drug and that which would be paid for the generic equivalent toward the maximum out-of-pocket limit, but would still be required to attribute the cost sharing that would have been paid for the generic equivalent drug. CMS is also considering an alternate proposal, under which an issuer and a group health plan would be permitted to except the entire amount paid for a brand prescription drug for which there is a medically appropriate generic drug from the maximum out-of-pocket limit.

In the preamble to the proposed rule, CMS notes that large group market health insurance issuers and self-funded group health plans already have flexibility relating to the maximum out-of-pocket limit for an individual's out-of-pocket costs for a brand drug when a generic equivalent is available and medically appropriate.[5] Based on the current FAQ guidance, this would allow large group market health insurance issuers and self-funded group health plans to choose not to count toward the maximum out-of-pocket limit *some or all of the amounts* paid toward the brand drugs that are not an EHB, if the participant or beneficiary selects a brand name prescription drug in circumstances in which a generic equivalent was available and medically appropriate. The FAQ notes that the Summary Plan Description ("SPD") must explain which covered benefits will not count towards an individual's maximum out-of-pocket limit out-of-pocket maximum and in determining whether a generic is medically appropriate, a plan may use a reasonable exception process.

The Council supports the proposal to allow plans to not count the cost share for a brand prescription drug against the maximum out-of-pocket limit where a generic equivalent drug is available and medically appropriate. The Council recommends that all plans be permitted flexibility to choose not to count toward the maximum out-of-pocket limit *some or all of the amounts* paid toward the brand drugs that are not an EHB, if the participant or beneficiary selects a brand name prescription drug in circumstances in which a generic equivalent was available and medically appropriate, consistent with the current FAQ guidance.

Cost Sharing Requirements and Drug Manufacturers' Coupons

Under the proposed rule, amounts paid toward cost sharing using any form of direct support offered by drug manufacturers to patients to reduce or eliminate immediate out-of-pocket costs for specific prescription brand drugs that have a generic equivalent are not required to be counted toward the maximum out-of-pocket limit.

[5] FAQs About Affordable Care Act Implementation (Part XIX). May 2, 2014. Available at https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-xix.pdf.

As noted in the preamble, drug manufacturers may offer coupons for various reasons, including competing with a lower cost generic equivalent drug when released. The preamble also recognizes that the availability of a coupon may cause physicians and beneficiaries to choose an expensive brand name drug when a less expensive and equally effective generic or other alternative drug is available. Finally, the preamble notes that the use of coupons can add significant long-term costs to the health care system that may outweigh the short-term benefits of allowing coupons, and counter balance efforts to point enrollees to more cost-effective drugs.

The Council supports a change that would allow plans the flexibility to not count amounts paid with a drug manufacturer coupon toward the maximum out-of-pocket limit. Notably, ERISA group health plans have discretion to determine whether the plan will accept drug manufacturer coupons, according to plan terms. However, if a plan does accept drug manufacturer coupons (or any other type of drug coupon) to reduce an enrollee's cost sharing, plans should have flexibility to not count amounts paid with a drug manufacturer coupon (or any other type of drug coupon) toward the maximum out-of-pocket limit.

Mid-Year Formulary Changes

Under the rule, CMS proposes to allow individual market, small group market, and large group market health insurance issuers to adopt mid-year formulary changes to incentivize greater enrollee use of lower-cost generic drugs. CMS proposes, however, that this would only apply when adding a generic equivalent drug, removing the equivalent brand drug or moving the equivalent brand drug to a different cost share tier on the formulary. The proposal provides that enrollees should have the option to request coverage for the brand drug through appeals or exceptions process and requires 60 days notification prior to change.

It is important for plans and issuers to have flexibility in maintaining a drug formulary to promote the use of cost effective, high value care. The interpretation of guaranteed renewability under the proposed rule could disrupt certain current industry practices by limiting the circumstances under which mid-year formulary changes could be made.

The Council recommends that HHS further engage with stakeholders to better understand the implications of this proposed change with respect to certain current industry practices related to mid-year formulary changes. The Council recommends that CMS reconsider finalizing the mid-year formulary proposed rule at this time and continue to work with stakeholders on this issue to avoid any unintended consequences that could interfere with the goal of achieving more affordable, high value care. If the rule is finalized, we recommend that it be broadened to take into account current industry practices with regarding to mid-year formulary changes.

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The Council applauds HHS' efforts to make changes that will help bring down the cost of prescription drugs, changes that will benefit the health care system as a whole, including for employer plan sponsors, employees and their families.

For the reasons discussed above, we strongly urge CMS to adopt proposals that will provide additional flexibility to facilitate the use of lower-cost prescription drugs, such as generics, when medically appropriate for enrollees. It is vital that this flexibility be granted to the maximum extent to help incentivize consumers to choose lower-cost generic drugs, when medically appropriate.

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

Sincerely,

Kathryn Wilber
Senior Counsel, Health Policy
American Benefits Council