AMERICAN BENEFITS COUNCIL

February 28, 2020

Submitted electronically at www.regulations.gov

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-9916-P
P.O. Box 8016
Baltimore, MD 21244-8016

Re: HHS Notice of Benefit and Payment Parameters for 2021 Proposed Rule (CMS-9916-P)

Dear Sir or Madam,

We write on behalf of the American Benefits Council ("the Council") to provide comments in connection with the HHS Notice of Benefit and Payment Parameters (NBPP) for 2021 Proposed Rule ("proposed regulations") published in the Federal Register on February 6, 2020, by the U.S. Department of Health and Human Services (HHS, or "the department") (85 Fed. Reg. 7088). The department proposed standards for exchanges, health insurance issuers, and group health plans. Notably, the department clarifies rules for group health plans and health insurance issuers relating to the treatment of drug manufacturers' coupons for purposes of the annual limitation on cost sharing in the Affordable Care Act (ACA). The regulations also propose, among other things, a special enrollment period in the individual market for individuals provided a non-calendar year qualified small employer health reimbursement arrangement (QSEHRA) and options to assist issuers of qualified health plans (QHPs) in designing value-based insurance plans.

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 support sponsors of health and retirement benefits for virtually all Americans covered by employer-provided plans.

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The Council appreciates the opportunity to provide comments on the proposed regulations.

SUMMARY OF COMMENTS

The following is a summary of our comments, each of which is discussed in more detail below:

- The Council supports restoring flexibility to employers in designing their benefit plans, including with respect to prescription drug benefits and the treatment of drug manufacturers' coupons in relation to the annual limitation on cost sharing. As such, the Council supports the department's modification of the regulations finalized in the NBPP for 2020 in order to allow, but not require, group health plans and issuers to count the enrollee's cost-sharing portion associated with the value of drug manufacturers' coupons toward the annual limitation on cost sharing. The Council appreciates the department's willingness to engage on the concerns we raised regarding requiring that drug manufacturers' coupons be counted toward the annual limitation on cost sharing in certain circumstances.

- The Council supports rules that facilitate the use of health reimbursement arrangements (HRAs) and other defined contribution health models, including QSEHRAs. Accordingly, the Council appreciates the department codifying that individuals provided a non-calendar year plan year QSEHRA would be entitled to a special enrollment period to enroll in or change their individual health insurance coverage through or outside of an exchange.

- The department proposes to offer issuers of QHPs options to assist in the design of value-based insurance plans that would empower consumers to receive high-value services at lower cost. While this proposal would only impact individual and small group health insurance coverage offered on an exchange, the Council is supportive of federal policies and rules that support and enhance value-based insurance design. The Council also emphasizes that employers are at the forefront of initiatives to lower health care costs and improve quality through various value-based design strategies and that increased plan sponsor access to pricing and claims data and meaningful and uniform quality measures are needed to facilitate the development and expansion of such programs.

SPECIFIC COMMENTS

I. Drug Manufacturers' Coupons and the Annual Limitation on Cost Sharing

The department is proposing to modify regulations finalized in the 2020 NBPP that would have limited employers' previous flexibility to determine whether drug

manufacturers' coupons should accrue towards 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). The department proposes to interpret the definition of "cost sharing" not to include expenditures covered by drug manufacturers' coupons. As a result, the department is also proposing that, to the extent consistent with applicable state law, amounts paid by an enrollee using any form of direct support offered by drug manufacturers for specific prescription drugs may be, but are not required to be, counted toward that enrollee's annual limitation on cost sharing.

The Council thanks the department for responding to the concerns we raised following finalization of the 2020 NBPP. The 2020 NBPP provided that for plan years beginning on or after January 1, 2020, plans and issuers would only be permitted to exclude the value of drug manufacturers' coupons from counting toward the annual limitation on cost sharing if a medically appropriate generic equivalent is available.

As the Council has previously expressed to the department,[1] the 2020 NBPP would have imposed material additional costs on group health plans and issuers that had been excluding the value of coupons for drugs without a generic alternative from counting towards the annual limit on cost sharing. Manufacturers' coupons are a form of assistance that patients use (both insured and uninsured patients) to reduce their out-of-pocket costs at the pharmacy. These amounts are not actually paid by the enrollee, and, as such, many plans do not count these amounts, as cost share paid by the enrollee, toward the annual limitation on cost sharing.

To the extent plans and issuers would have been required to count the value of drug manufacturers' coupons when administering the annual limitation on cost sharing, some enrollees would have satisfied the annual limitation on cost sharing sooner than they otherwise would. As a result, the issuer or plan would have incurred coverage liabilities sooner than if the manufacturers' coupon had not been applied. In such cases, the economic effect could have been higher plan and employer costs and potentially higher premiums for plan participants.

The Council supports the rule contained in the proposed regulations that would allow, but not require, plans and issuers to count the enrollee's cost sharing portion associated with the value of drug manufacturers' coupons toward the annual limitation on cost sharing, regardless of the availability of a generic equivalent. As the department notes "this proposal would enable issuers and group health plans to continue longstanding practices with regard to how and whether drug manufacturers' coupons accrue towards an enrollee's annual limitation on cost sharing."[2] This policy will not prohibit patients from using coupons at the point of sale, but it will ensure that plans

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[1] https://www.americanbenefitscouncil.org/pub/?id=0A0495DF-1866-DAAC-99FB-C0EF14D0DDC3.

[2] 85 Fed. Reg. 7088, 7136.

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, and, as such the Council supports the department finalizing the regulations as proposed.

Moreover, as noted by the department in the preamble to the proposed regulations and in the related preceding tri-agency FAQ[3], the Treasury Department and the Internal Revenue Service (IRS), which have jurisdiction over health savings accounts (HSAs) and high deductible health plans (HDHPs), take the position that the 2020 NBPP could have created a conflict with a 2004 IRS notice concerning HDHP enrollees' eligibility to contribute to an HSA. In particular, IRS Notice 2004-50, Q&A 9, requires an HDHP to disregard discounts for health care services or products in determining if the minimum deductible for an HDHP has been satisfied and requires that individuals pay the cost of health care (taking into account the discount) until the HDHP deductible is satisfied. The 2021 NBPP indicates the Treasury Department and the IRS take the position that this Q&A also requires an HDHP to disregard manufacturers' coupons when determining if the deductible for an HDHP has been satisfied and to only count amounts actually paid by the individual.

The department states in the preamble to the proposed regulations, that the 2020 NBPP "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 manufacturers' 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." The ability to offer HSA-compatible HDHPs is an important option for employers. The Council appreciates that the department took this issue into account in the proposed regulations and then restored flexibility to allow, but not require, group health plans and issuers to count the value of drug manufacturers' coupons toward the annual limitation on cost sharing.

In addition, as part of the preamble discussion, the department states its expectation that issuers and group health plans should be transparent with enrollees and prospective enrollees regarding whether the value of drug manufacturers' coupons accrues to the annual limitation on cost sharing as such policies would affect enrollees' out-of-pocket liability under their plans. The department also states in the preamble that it expects issuers to prominently include this information on websites and in brochures, plan summary documents, and other collateral material that consumers may use to select, plan, and understand their benefits. The department does not mandate a new notice requirement.

[3] https://www.dol.gov/agencies/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-40.

The Council has long supported employee access to accurate cost-sharing information to ensure consumers have the information they need to seek out lower-cost, higher-value health care. The more consumers understand health care costs, the better informed consumers will be in making decisions about health care. Accordingly, the Council appreciates the department's interest in plans and issuers providing clear information to enrollees regarding how drug coupons are treated by the plan, including how they are treated for purposes of the annual limitation on cost sharing. We also support the way this issue is addressed by the department in that a new notice requirement is not imposed; plans and issuers are in the best position to determine how to communicate this information to participants and their flexibility as to how to do so should be retained.

II. Qualified Small Employer Health Reimbursement Arrangements

In a recent final rule establishing individual coverage HRAs,[4] HHS provided a special enrollment period to employees and dependents who *newly* gain access to an individual coverage HRA to enroll in individual health insurance coverage, or to change to other individual health insurance coverage in order to maximize the use of their individual coverage HRA. In addition, because employees and dependents with a QSEHRA generally must be enrolled in minimum essential coverage, and one category of minimum essential coverage is individual health insurance coverage, the HRA rule also provided that individuals who are *newly* provided a QSEHRA also qualify for the new special enrollment period.

In the preamble to the HRA final rule, HHS explained that, although the new special enrollment period only covers newly eligible employees, employees who are offered an individual coverage HRA year after year will have the ability to purchase or change their individual market health care coverage either through individual market open enrollment (for calendar year individual coverage HRAs) or through the existing special enrollment period for non-calendar year group health plans (for non-calendar year individual coverage HRAs). HHS also expressed its intent to treat a QSEHRA with a non-calendar year plan year as a group health plan for the limited purpose of qualifying for the non-calendar year group health plan special enrollment period, and to codify this interpretation in future rulemaking. Thus, in the proposed regulations, HHS is codifying this interpretation, specifically establishing that qualified individuals and dependents who are provided a QSEHRA with a non-calendar year plan year would qualify for the existing special enrollment period for individuals enrolled in any non-calendar year group health plan.

As noted above, the Council supports federal policy that facilitates employer use of HRAs, including QSEHRAs, as well as other defined contribution health strategies more generally. Accordingly, the Council appreciates the department codifying the

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[4] 84 Fed. Reg. 28888 (June 20, 2019).

interpretation expressed in the final HRA rule. The Council agrees that making the non-calendar year plan year special enrollment period available annually to individual market enrollees with a non-calendar year plan year QSEHRA appropriately provides employers with flexibility to provide QSEHRAs on a 12-month cycle that meets their needs. This also allows employees and their dependents the flexibility to re-assess their individual health insurance coverage options at the same time that the terms of their QSEHRA may change. The Council agrees that accessing this non-calendar year plan year special enrollment period may be important to some individuals, including those who wish to change their individual health insurance plan due to a change in the terms of their QSEHRA.

III. Value-Based Insurance Design

The department proposes to offer issuers of QHPs options to assist them in designing value-based insurance plans that would empower consumers to receive high-value services at lower cost. Specifically, the department outlines a ''value-based'' model QHP that contains consumer cost-sharing levels aimed at driving utilization of high value services and lowering utilization of low value services when medically appropriate. Offering a value-based insurance design QHP would be voluntary, the proposed regulations do not change the current rules for the design of cost-sharing structures, and the department encourages issuers to select services and cost sharing that work best for their consumers.

While this proposal would only impact individual and small group health insurance coverage offered on the exchange, we nevertheless want to take this opportunity to reiterate our support for value-based insurance designs generally, which ensure value, quality, and access to evidence-based health care. Although we aren't providing specific comments on the proposal, we commend the department for its continued efforts on this issue. Many employer plan sponsors currently use value-based insurance design strategies, such as reducing copayments for select high value providers, drugs or participation in disease management, and the Council is a member of the Smarter Health Care Coalition,[5] which works to support value-based insurance design. Studies have indicated that the numbers of employers using or considering such strategies will grow, and such strategies result in an overall reduction on spending.[6] Accordingly, the Council supports the department providing flexibility to allow innovation in the structure and use of value-based insurance design to encourage the utilization of appropriate high-value lower cost health care services.

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[5] *See* https://www.smarterhc.org/.

[6] *Assessing the Evidence for Value-Based Insurance Design*, Health Affairs 29:11 November 2010. Citing Mercer National Survey of Employer Sponsored Health Plans, 2007-2008; Evaluation of Value-Based Insurance Design for Primary Care, Qinli Ma, PhD; Gosia Sylwestrzak, MA; Manish Oza, MD; Lorraine Garneau; and Andrea R. DeVries, PhD, Am J Manag Care. 2019;25(5):221-227.

In response to HHS' more general solicitation of comments on value-based insurance design, we also emphasize that additional public policy changes are needed to support these efforts, including for employer-sponsored coverage. Employers play a critical role in the health care system and provide health coverage to over 178 million Americans. Further, employers are on the forefront of initiatives to lower health care costs and improve quality through various value-based design strategies.[7] Many employers that have had success in decreasing the rate of health care spending have done so by analyzing their plan data to better understand how much is being spent on specific health care services. However, plan sponsors increasingly face difficulties in accessing claims data and pricing data regarding their own plans. Ensuring employers have access to their own plan data is an important priority for the Council and, as such, the Council is supportive of legislative efforts, in particular those outlined in the Lower Health Care Cost Act, that would prohibit restrictions on employers' access to and use of this information. Employers want to ensure they can use their data to inform creation of the most efficient and effective benefit designs that steer patients to the highest-value providers operating in the highest-value settings. Increased transparency will be necessary to meet that goal.

In addition, meaningful and uniform quality measures are a foundation of value-based purchasing decisions. As more large employers implement innovative payment reforms, like direct contracting or accountable care organizations, a uniform set of standardized quality measures is critical. To that end, we note that that the Council is a member of the Core Quality Measures Collaborative (CQMC), a broad-based coalition of health care leaders, including the Centers for Medicare and Medicaid Services (CMS), insurance providers, medical providers, consumers and purchasers, promoting alignment of quality measures across public programs and the private sector.[8] The Council commends CMS for its participation in the CQMC and encourages the department to support and promote the work of CQMC.[9]

Programs that are focused on value-based benefit design and value-based payment reform have the potential to transform our system by realigning incentives that keep participants healthier – while at the same time lowering costs. We urge the Administration to advance policies that support these efforts with respect to large group and self-funded plans as well as in the individual and small group markets.

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[7] This is the message of *Leading the Way: Employer Innovations in Health Coverage*, a report from the Council and Mercer showing how employer providers of health coverage are succeeding at lowering costs and improving quality through innovation. *See* https://www.americanbenefitscouncil.org/pub/16e9bbe3-9b27-d7aa-ec7c-e9f86419c786.

[8] https://www.qualityforum.org/cqmc/.

[9] The Council also recently submitted comments in response to a request for information regarding quality reporting, as part of the proposed rule "Transparency in Coverage" issued by the Departments of Labor, the Treasury and HHS. *See* https://www.americanbenefitscouncil.org/pub/?id=7BF19916-1866-DAAC-99FB-43AFBB87FE4E.

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Employers are on the front lines of implementing innovative strategies to get more out of every health care dollar they spend, including relating to prescription drugs. As such, it is very important to our members that they be provided adequate flexibility to design their plans/policies, including in deciding how to treat drug manufacturers' coupons for the annual limitation on cost sharing. We greatly appreciate the efforts by the department to support employers' flexibility in this regard.

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,

Ilyse Schuman
Senior Vice President, Health Policy