SUMMARY OF HHS REGULATIONS:
FINAL 2021 NOTICE OF BENEFIT AND PAYMENT PARAMETERS

As part of regulations issued annually to implement selected aspects of the Affordable Care Act (ACA), the U.S. Department of Health and Human Services (HHS) released the final Notice of Benefit and Payment Parameters for 2021 (the final 2021 NBPP) on May 7. These final rules address a number of issues relevant to plan sponsors, along with a number of issues outside that purview.

As we reported in the March 10 Benefits Byte, the American Benefits Council filed comments on the proposed 2021 NBPP, in support of modifications to rules regarding drug manufacturers’ coupons and the annual limitation on cost sharing, as well as in support of guidance regarding qualified small employer health reimbursement arrangements (QSEHRAs) and value-based insurance design. As described below, the final rules are consistent with our comments on those issues.

DRUG MANUFACTURERS’ COUPONS

Most notably, the final 2021 NBPP addresses the manner in which the value of drug manufacturers’ coupons are treated for purposes of the annual limitation on cost sharing under the ACA, including for self-funded and large group market health plans. This is an issue on which the Council has been advocating over the past year.

Background

The 2020 NBPP had provided that group health plans and issuers would be prohibited from excluding the value of drug manufacturers’ coupons when applying the annual limitation on cost sharing, unless a generic equivalent of the drug is available.

This would have imposed material additional costs on some plans and issuers that had been excluding the value of coupons for drugs without a generic alternative from counting toward the annual limitation on cost sharing. Further, as noted in the
Council’s comment letter, “the Treasury Department and the Internal Revenue Service, 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’ ability to contribute to an HSA.” The Council and other stakeholders raised these issues to HHS, Treasury and the U.S. Department of Labor (“the tri-agencies”) and, in August 2019, the tri-agencies released an Frequently Asked Questions document providing a non-enforcement safe harbor of the rule in the 2020 NBPP, pending the tri-agencies re-visiting this policy in the 2021 NBPP.

In the proposed 2021 NBPP, HHS proposed to revise the regulations on the annual limitation on cost sharing to provide that, to the extent consistent with applicable state law, amounts paid toward reducing the cost sharing incurred 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 the annual limitation on cost sharing. In addition, HHS stated that it proposed to interpret the definition of cost sharing not to include expenditures covered by drug manufacturers’ coupons, although HHS did not make any revisions to the regulation text defining cost sharing. The Council’s comment letter expressed support for these proposed changes, for the reasons noted above.

Final Rules: In General

Under the final 2021 NBPP, to the extent consistent with state law, amounts paid toward reducing the cost sharing incurred 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 the annual limitation on cost sharing. This aspect of the regulations is finalized consistent with the Council’s comments, with only a minor revision to the title of the regulatory provision.

HHS notes that it received many comments both in support of and opposed to this policy and states that “the flexibility provided under this policy will enable issuers and group health plans to continue longstanding practices with regard to how and whether direct drug manufacturer support accrues toward an enrollee’s annual limitation on cost sharing.” HHS goes on to say that it believes the impact on costs for consumers may be limited if plans and issuers continue their current practice, which it believes will be the case.

At the same time, HHS is not finalizing any change to the definition of cost sharing, in response to comments asserting that the interpretation in the proposed rule is inconsistent with the current regulation and raises questions about how the interpretation would impact other forms of patient assistance. HHS explains that a drug manufacturers’ coupon can be interpreted as falling within the existing definition of cost sharing in that it could be considered part of the overall charges incurred by the enrollee (as the consumer cannot obtain the drug without providing the full amount owed), but at the same time could be viewed as not representing costs incurred by or
charged to enrollees and instead as a reduction, by drug manufacturers, in the amount that the enrollee is required to pay at the point of sale to obtain the drug.

HHS has therefore “determined that the term ‘cost sharing’ is subject to interpretation regarding whether these amounts fall under this definition” and so the proposed interpretation to exclude these amounts from the definition of cost sharing is not finalized. This, however, does not undermine the fact that plans and issuers may decide whether to count the value of drug manufacturers’ coupons toward the annual limitation on cost sharing – for those who elect to count these amounts, the value would be considered part of the overall charges incurred by the enrollee, and for those who elect not to count these amounts, the value would be considered a reduction in the amount the enrollee incurs or is required to pay.

**HDHPs**

In the preamble to the final 2021 NBPP, HHS notes that it received a number of comments on the interaction of the drug manufacturers’ coupon policy and the rules for HSA-eligible HDHPs. HHS notes that some commenters expressed concern or disagreement with the purported conflict for HDHPs.

In response, HHS states that an “HDHP is not permitted to credit to the deductible in a manner that does not reflect the actual cost of the medical care to the individual.” The preamble goes on to provide that if a drug manufacturer coupon applies, “the true economic cost to the individual is the net amount incurred” and “[a]ccordingly, to meet the requirements of section 223 of the Code, an HDHP may only take into account that net amount when determining whether the individual has satisfied the deductible. Therefore, a conflict between the HHS policy finalized in the 2020 Payment Notice and the provisions of Section 223 of the tax code and IRS guidance may exist for issuers who elect to include drug manufacturer support amounts towards the consumer’s deductible and annual limitation on cost sharing if the consumer is enrolled in an HDHP coupled with an HSA.” HHS further notes that Treasury and the IRS continue to review comments received on various related HDHP/HSA administrative issues to determine if additional guidance is needed.

**Notice Requirements**

Consistent with discussion in the proposed 2021 NBPP, HHS states that it is important for issuers and plans to be clear and transparent with consumers regarding whether drug manufacturers’ coupons will count toward the annual limitation on cost sharing. However, although several commenters supported a notice requirement, the final rule, like the proposed rule, does not impose a specific notice requirement on plans and issuers. This is consistent with the Council’s comments, which asked that HHS decline to impose a specific notice requirement, noting that plans and issuers are in the best position to determine how to communicate this information to participants and asking that their flexibility be retained. HHS notes it will continue to monitor this issue.
OTHER RELEVANT PROVISIONS

The final 2021 NBPP also contains some other provisions relevant to employers and group health plans.

QSEHRAs

The final 2021 NBPP also addresses Qualified Small Employer Health Reimbursement Arrangements (QSEHRAs), which are a type of health reimbursement arrangement (HRA) available only to small employers (see the November 2, 2017, Benefits Blueprint). As was proposed, the final 2021 NBPP provides a special enrollment period to individuals and dependents in a QSEHRA with a non-calendar year plan year to enroll in or change their individual health insurance coverage through or outside of an exchange for each new QSEHRA plan year. Individuals provided a calendar year QSEHRA can already enroll in the individual market during open enrollment. This issue was teed up in the June 2019 individual coverage HRA final rules. The Council’s comment letter expressed support for this rule, noting that we support rules that facilitate the use of HRAs and other defined contribution health models, including QSEHRAs. HHS notes that commenters were generally supportive of this provision and finalizes it as proposed.

Maximum annual limitation on cost-sharing

The maximum annual limitation on cost-sharing, under the ACA, for 2021 increases to $8,550 for self-only coverage and $17,100 for other than self-only coverage. (The maximum annual limitation on cost-sharing for 2020 was $8,150 for self-only coverage and $16,300 for other than self-only coverage). This aspect of the 2021 NBPP is being finalized as proposed.

Excepted benefit HRAs

As in the proposed rules, the final 2021 NBPP requires excepted benefit health reimbursement arrangements (HRAs) sponsored by non-federal governmental plan sponsors to provide a notice to participants that contains specified information about the benefits available under the excepted benefit HRA. Rules allowing excepted benefit HRAs were finalized in June 2019 (see the June 17, 2019, Benefits Blueprint), and in the preamble to those rules, the administration noted that long-standing notice requirements under ERISA already apply to private-sector, employment-based plans. As such, the HRA regulations did not separately impose a notice requirement on excepted benefit HRAs. However, HHS, which has jurisdiction over non-federal governmental plans, noted it intended to impose a notice requirement similar to the one under ERISA for non-federal governmental plan excepted benefit HRAs, which it did in the proposed 2021 NBPP. The final 2021 NBPP finalizes the notice requirement as proposed, except that it extends the applicability date to plan years beginning on or
after 180 days following the effective date of the final rules (rather than 30 days, as was proposed), in response to comments.

**ACA employer mandate and PTC annual indexing**

As it does each year, the final 2021 NBPP provides the amounts used to adjust the employer mandate penalty for 2021 and the amount used to adjust the premium tax credit (PTC) affordability percentage for 2021 (which carries over to affordability under the employer mandate rules). These amounts are being finalized as proposed. We expect that IRS will provide employer mandate penalty and affordability percentage amounts for 2021 shortly, as they do each year following the finalization of the NBPP. See IRS FAQ #40 for prior year adjustments to the PTC affordability percentage and IRS FAQ # 55 for prior-year adjustments to the employer mandate penalty.

**Value-based insurance design**

In the 2021 proposed NBPP, HHS proposed to offer issuers of qualified health plans options to assist in the design of value-based insurance plans that would empower consumers to receive high-value services at lower cost. In the final 2021 NBPP, HHS finalizes the options as proposed and notes that these are just options for issuers and HHS will not be pursuing or requiring the development of a value-based standardized option. While these options only impact individual and small group health insurance coverage offered on the exchange, the Council’s comment letter noted that we are supportive of federal policies and rules that support and enhance value-based insurance design. We also emphasized 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.