NATIONAL HEALTH COUNCIL
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BY ELECTRONIC DELIVERY

Seema Verma, Administrator
Centers for Medicare & Medicaid Services Department of Health and Human Services
7500 Security Blvd
Baltimore, MD 21244

RE: Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2021 CMS-9916-P

Dear Administrator Verma:

The National Health Council (NHC) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS') Proposed Rule entitled, "HHS Notice of Benefit and Payment Parameters for 2021; Notice Requirement for Non-Federal Governmental Plans" (the NBPP).

Created by and for patient organizations 100 years ago, the National Health Council (NHC) brings diverse organizations together to forge consensus and drive patient-centered health policy. We promote increased access to affordable, high-value, sustainable health care. Made up of more than 140 national health- related organizations and businesses, the NHC's core membership includes the nation's leading patient organizations. Other members include health-related associations and nonprofit organizations including the provider, research, and family caregiver communities; and businesses representing biopharmaceutical, device, diagnostic, generic, and payer organizations.

The NHC recognizes that the long-term viability of the Patient Protection and Affordable Care Act (PPACA) is dependent on stability of the individual health plan marketplaces and supports policies that balance long-term program stability with our primary commitment to ensuring that individuals with chronic conditions have access to affordable, high-value, sustainable health care.

Our comments focus on the NBPP provisions most likely to facilitate or impede our goal of ensuring that all Americans, particularly those with chronic diseases and disabilities, can access the health care they need at a cost they can afford. Specifically, the NHC:

- Urges CMS to reconsider its proposal to modify automatic re-enrollment processes;
- Urges CMS to withdraw the proposed changes related to manufacturer coupons and leave in place the provision established in the 2020 NBPP; and
- Supports value-based insurance design with carefully considered guardrails and requirements.

The NHC urges CMS to reconsider its proposal to modify automatic re-enrollment processes.

Despite substantial divergence on a variety of issues related to PPACA implementation since its enactment, stakeholder comments on the 2020 NBPP were unanimously in support of retaining automatic re-enrollment processes[1]. Yet, CMS has proposed to remove the application of Advance Premium Tax Credits **(**APTCs) to pay premiums upon automatic re-enrollment of an individual with an APTC that fully covered the premium for the previous year. The NHC is concerned that this policy will place an insurmountable obstacle between America's poorest workers and health care access. Specifically, we are concerned that re-enrolling an individual (or family) in their existing plan without applying the appropriate APTC for the enrollee will present the enrollee with an immediate monthly premium invoice that could reach or exceed their total monthly income.

Because beneficiaries who are not receiving an APTC only have a 30-day grace period for paying versus the 90-day grace period for those that receive an APTC, beneficiaries would be put further at risk. The NHC firmly believes that the logistical challenges of receiving notice, understanding required next steps, gathering the documents needed for a new APTC determination, completing the necessary forms, and receiving a determination are too substantial to be resolved within a 30-day grace period, and could even present challenges within a 90-day grace period. The working individuals impacted by this proposal, and their families will, for the most part, find themselves unexpectedly uninsured and may find it impossible to resume comprehensive coverage under the PPACA.

We strongly urge CMS to not move forward with this proposal and solicit feedback from stakeholders on mechanisms that can be applied to address any verifiable fraud and abuse risks not mitigated through existing programmatic safeguards.

The NHC urges CMS to withdraw the proposed changes related to manufacturer coupons and leave in place the provision established in the 2020 NBPP.

The current system subjects patients to high out-of-pocket costs, particularly for drugs used to treat complex and chronic conditions. Patients requiring branded medications without an available generic substitute often rely on copay coupons, discount cards, charitable assistance, and other assistance as the only means to afford the medication they need.

[1] HHS Notice of Benefit and Payment Parameters for 2021; Notice Requirement for Non-Federal Governmental Plans, 85 FR 7088 at 7119.

CMS' 2020 NBPP included provisions to permit plans and issuers to exclude any form of direct manufacturer cost-sharing support from calculations toward applicable annual limitations on out-of-pocket costs *only when* offered for a specific brand prescription drug that has a generic equivalent. The NHC supported this provision, noting the distinction between these instances and those where there is no generic equivalent and stating the 2020 NBPP struck the right balance between eliminating inappropriate use of copay coupons and allowing assistance to help people afford their needed medications. We also noted an important distinction that individual patient response to some generics may differ from branded products, sometimes with significant risk, and there may be instances in which generic products are either not on a plan's formulary or do not offer significant savings.

We understand that CMS has received feedback expressing concerns that the 2020 NBPP policy may conflict with certain rules for high-deductible health plans (HDHPs) with health savings accounts (HSAs). In response to these concerns, CMS proposes to revise its regulations to give plans and issuers the flexibility to determine whether to include or exclude manufacturer coupon amounts from the annual limitation on cost sharing, regardless of whether a generic equivalent is available. The NHC continues to believe that the 2020 NBPP policy represents a pragmatic, nuanced approach to eliminating inappropriate use of copay discount cards and other direct manufacturer assistance. **The 2021 proposal, if implemented, would result in certain patients paying much higher out-of-pocket costs than under the 2020 proposal. We urge CMS to revise this proposal to be consistent with the 2020 NBPP and clarify that it does not conflict with rules relating to HDHPs with HSAs.**

Further, we reiterate that even if CMS returns to its 2020 policy, specific patient guardrails are needed to ensure the provision has the intended effect of eliminating inappropriate use of manufacturer assistance while protecting people who rely on assistance to afford their medications. Specifically, the NHC urges CMS to:

- Refrain from expanding this proposal to charitable assistance;
- Clarify that the provision only applies to manufacturer assistance where the copayment support is connected to a specific, brand product, and generic substitution is appropriate for the specific patient;
- Only apply this policy when a generic is available on the formulary on a lower cost sharing tier than the branded product;
- Require the issuer to inform the enrollee in advance that copayment assistance will be excluded from calculations toward annual out-of-pocket limits;
- Exclude therapeutic classes where there is documented variability in patient response to different versions of a brand or generic drug; and
- Ensure that patients have an opportunity to appeal the issuer's determination to exclude manufacturer support from out-of-pocket limit calculations in a manner similar to that extended to patients seeking a formulary exception.

Transparency

CMS also seeks stakeholder input on whether plans should be required to inform enrollees and prospective enrollees on whether the value of drug manufacturer coupons accrues to the annual limitation on cost sharing. The NHC consistently advocates for policies that increase and improve the relevancy of information that may impact decisions on health care plans, providers, and treatment options. Thus, we agree that this information is crucial for people needing access

to medications, especially those currently receiving financial assistance, and would impact enrollee decision making and financial planning. We do, however, note that if CMS revises its policies as proposed and requires plan transparency at the time of plan selection, there is a potential for an unintended consequence of adverse selection by discouraging people with chronic conditions and disabilities from enrolling in plans that present their information about how they consider manufacturer assistance in certain ways to discourage enrollment. This must be managed as part of any transparency requirements.

The NHC supports value-based insurance design with carefully considered guardrails and requirements.

The NHC supports CMS' efforts to promote value-based insurance design (VBID) and has prioritized implementation of VBID within our Policy Recommendations for Reducing Health Care Costs, released in 2017[2]. We support VBID efforts that structure patient cost-sharing and other benefit-design elements to encourage patients to consume higher-value clinical services or utilize higher-performing providers. The NHC appreciates that CMS provided plan sponsors and other stakeholders with a ''value-based'' model Qualified Health Plan (QHP) containing examples of consumer cost-sharing levels designed to drive utilization of high-value services and lower utilization of low-value services when medically appropriate. The "low-" and "high-" value categories were derived from an exemplar work provided by the Center for Value-based Insurance Design at the University of Michigan.[3] The high-value services that would be associated with a zero copayment include items and services that would likely be useful to, and promote value in, patients with diabetes, cardiac disease, and other common chronic conditions.

While very supportive of the VBID concept, the NHC encourages CMS to implement this proposal in a manner that reduces the risk for discriminatory plan design so that the transparency required to inform plan selection does not facilitate issuer cherry-picking of the healthiest patients. Patients with complex care needs due to serious and/or chronic conditions may find the care that is considered "low-value" from a population health perspective may be high-value for them and would be associated with a higher copayment in a VBID than in a traditional QHP. Similarly, the model may designate as low-value the high-volume services that would be disproportionately used by patients with chronic diseases and disabilities and those associated with higher cost sharing such as outpatient services, outpatient surgical services, and non-preferred name branded drugs.

To ensure VBID is implemented in the Marketplaces in a way that best benefits patients without leading to discriminatory plan design or selection, we recommend that CMS put the following protections in place:

- Evaluate which services in emerging VBID models have a meaningful impact on health outcomes and costs;
- Limit VBID plan entry to issuers with at least one non-VBID plan at the silver-metal level and create other oversight mechanisms to ensure that VBID QHP entry does not disproportionately increase premiums or overall cost sharing for enrollees in non-VBID plans;

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[2] https://nationalhealthcouncil.org/wp-content/uploads/2019/12/NHC_Health_Care_Costs_Initiative_2019.pdf

[3] HHS Notice of Benefit and Payment Parameters for 2021; Notice Requirement for Non-Federal Governmental Plans, 85 FR 7088 at 7137.

- Require that VBID QHPs select the outcome measures being used to reflect high-value care based on the outcomes important to patients; and,
- Give VBID plans flexibility to include services such as transportation, social and psychological services, and bi-directional integrated behavioral care services.

Conclusion

The NHC believes that the important modifications outlined above are crucial in ensuring the proposed 2021 NBPP reduces costs for exchange enrollees without compromising provision of high-value care.

Please do not hesitate to contact Eric Gascho, our Vice President of Policy and Government Affairs, if you or your staff would like to discuss these issues in greater detail. He is reachable by phone at 202-973-0545 or via e-mail at egascho@nhcouncil.org.

Sincerely,

Marc Boutin, JD
Chief Executive Officer
National Health Council