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February 19, 2019

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 2020 CMS-9926-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 2020" (the NBPP).

Founded in 1920, the NHC is the only organization that brings together all segments of the health community to provide a united voice for the more than 160 million people with chronic diseases and disabilities and their family caregivers. Made up of more than 125 diverse national health-related organizations and businesses, the NHC's core membership includes the nation's leading patient advocacy organizations, which control its governance and policy-making process. Other members include professional and membership associations; nonprofit organizations with an interest in health; and representatives from the pharmaceutical, generic drug, health insurance, device, and biotechnology industries.

Consistent with our commitment to ensuring that individuals with chronic conditions have access to affordable, high-value health care, the NHC's advocacy efforts related to the Patient Protection and Affordable Care Act (PPACA) have focused on five key goals: non-discrimination, transparency, uniformity, continuity of care, and oversight. The NHC also recognizes that the long-term viability of the exchanges is dependent on stability of the PPACA marketplace.

We direct our comments to the NBPP provisions that are likely to either advance or impede our goal of ensuring that all Americans, particularly

those with chronic diseases and disabilities, have access to the health care they need at a cost they can afford. Specifically, the NHC:

- Supports CMS' decision to continue to permit silver loading for 2020;
- Urges CMS to withdraw its proposed changes to the calculation of the PPACA's 'Premium Adjustment Factor;'
- Supports increased use of generic medications but recommends protections for complex patients for whom generic substitution may not be medically appropriate;
- Opposes "therapeutic substitutions" for non-medical reasons;
- Appreciates CMS' targeted approach to limiting the use of manufacturer coupons and recommends specific patient safeguards if this proposal moves forward;
- Supports CMS' efforts to increase access to medication-assisted treatment for opioid use disorder; and
- Urges CMS to ensure that requirements for Navigators and web brokers include protections for individuals with disabilities, and that federal oversight is sufficient to ensure Navigator and web broker compliance.

The NHC supports CMS' decision to continue to permit silver loading for 2020.

The NHC appreciates that CMS' NBPP for 2020 does not disrupt market stability by banning "silver loading." As the Agency noted in preamble to the NBPP:

> On January 20, 2017, the President issued an Executive Order which stated that, to the maximum extent permitted by law, the Secretary of HHS and heads of all other executive departments and agencies . . . should exercise all authority and discretion available to them to waive, defer, grant exemptions from, or delay the implementation of any provision or requirement of the PPACA that would impose a fiscal burden on any state or a cost, fee, tax, penalty, or regulatory burden on individuals, families, health care providers, health insurers, patients, recipients of health care services, purchasers of health insurance, or makers of medical devices, products, or medications.[1]

Banning silver loading without ensuring that issuers are reimbursed for the cost-sharing reduction (CSR) subsidies would impose a fiscal burden on both individuals and insurers in conflict with the Executive Order, disrupt the health insurance market, and significantly increase premiums for consumers seeking any level of coverage under the PPACA. CMS' decision to continue permitting plans to offset their CSR expense through silver loading through the 2020 plan year, while not a perfect solution, will ensure that patients, particularly those with chronic diseases and disabilities, are empowered to choose the plan that best suits their needs.[2]

[1] https://www.regulations.gov/document?D=CMS-2018-0075-0001

[2] These expectations are consistent with the experience in the five states that chose to broad load their CSRs on all qualified health plan premiums in 2018: these states lost more enrollment, on average, relative to other states that allowed or required silver loading. In states that use HealthCare.gov, those with broad loading had no county with a gold plan that was less expensive than the silver benchmark plan. In contrast, states that used silver loading had more than 500 counties with at least one gold plan that was less expensive than the silver benchmark plan (meaning consumers had lower-price options for more generous gold plans).

The NHC urges CMS to approach this issue in future years with the same focus on market stability and patient access that have driven the 2020 NBPP proposal. A future ban on silver loading would result in up to seven million non-subsidized enrollees paying more for no additional benefit. In addition, up to 1.8 million subsidized enrollees would lose access to lower-premium bronze and gold plans that they were able to enroll in during 2018.[3] In August, 2017, the Congressional Budget Office (CBO) estimated that not funding the CSRs would increase the federal deficit by $6 billion in 2018, $21 billion in 2020, and $26 billion in 2026 – a cumulative deficit increase of $194 billion during the period 2017 to 2026.[4] We urge CMS to prioritize direct funding of the CSRs within its set of initiatives to reduce health care costs while improving access to affordable care. In the event that Congress does not act on this issue, the NHC urges CMS to avoid banning silver-loading unless the Agency implements a more permanent regulatory mechanism to effectuate continued funding of the CSRs.

The NHC urges CMS to withdraw its proposed changes to the calculation of the PPACA's 'Premium Adjustment Factor.'

CMS proposes changes to calculation of the premium adjustment factor used to determine the annual adjustment in the amount subsidized marketplace enrollees contribute to plan premiums, the cap on annual out-of-pocket spending, the amount insurers pay via the health insurance tax, and the fine for employers who fail to offer affordable coverage to their employees. The NHC is concerned about the potential impact of this provision of the NBPP on individuals with chronic diseases and disabilities, due to a worsening of the PPACA risk pool as well as an expected out-of-pocket cost increase of $400 per year**.** HHS estimates that the proposed change in formula will result in net premium increases of over $180 million per year and a decline of approximately 100,000 marketplace enrollees in 2020.[5] We urge CMS to withdraw this proposal or counterbalance it with enhanced protections for individuals with chronic diseases and disabilities.

The NHC supports increased use of generic medications but recommends protections for complex patients for whom generic substitution may not be medically appropriate.

The NHC recognizes that one of the biggest barriers to health care access is the rising cost of care, especially for the more than 160 million Americans with chronic diseases and disabilities who require prescription drugs to manage their conditions. We have consistently supported efforts to increase development of, and access to generic medications, when available and medically appropriate, as an important step toward ensuring that individuals with chronic conditions have affordable access to needed medications. In its NBPP, CMS has proposed several strategies to reduce reliance on higher-cost brand medications in favor of lower-cost alternatives.

CMS proposes to allow issuer formulary changes during the plan year when a generic equivalent to a prescription drug becomes available. Under this provision of the NBPP, an issuer could, with 60 days prior written notice, remove the brand drug from its formulary or subject it to a different

[3] Calculated from 2018 Marketplace Open Enrollment Period Public Use Files
[4] Congressional Budget Office, The Effects of Terminating Payments for Cost-Sharing Reductions, https://www.cbo.gov/system/files/115th-congress-2017-2018/reports/53009-costsharingreductions.pdf
[5] Id.

cost-sharing tier. The NHC fully supports incentive frameworks to encourage appropriate use of generic prescription drugs, as long as there are sufficient protections to ensure that patients have affordable access to branded medications when substitution is not medically appropriate. While two formulations may be considered bioequivalent at a population level, individual variability on dose, age, comorbidities, use of other medications, and disease status are generally not factored into bioequivalence studies.[6] Differences in inactive ingredients and formulation quality can also affect clinical efficacy and lead to adverse events in some patients.[7] This is more likely to occur for some disease states than others. For example, switching between brand and various generic versions of anti-epileptic drugs can cause changes in the amount of active ingredient reaching the brain, which can precipitate break-through seizures or increase side effects.

The NHC supports the aim of this provision but urges CMS to include sufficient patient protections to ensure timely and affordable access to prescription drugs not covered on the formulary. We appreciate that CMS recognizes that patients and providers require advance notice of formulary changes so that the exceptions process can be conducted without interrupting treatment. However, we are concerned the proposal to permit issuers to exclude non-formulary drugs from a plan's essential health benefits (EHB) would have a disproportionate negative impact on more complex patients in certain therapeutic classes for whom generic substitution may not be medically appropriate. These patients could be subjected to annual or lifetime dollar limits on the branded treatments upon which they rely. Similarly, excluding these products as falling outside a plan's EHB would put patients in a situation where their substantial prescription drug expenditures would not count toward their annual cap on out-of-pocket spending. Similarly, placing these products on a higher cost-sharing tier will subject patients to higher out-of-pocket expenses.

Various states have implemented sets of checks and balances on pharmacies, often limiting or prohibiting generic substitution when a patient and their clinician determine that a specific branded prescription drug is the most appropriate treatment. We urge CMS to consider these factors and design patient safeguards if it moves forward with this provision. Specifically, we urge the Agency to:

- Avoid disruption of state laws and regulations;
- Ensure that patients have access to expedited appeals and exceptions processes;
- Include the patient's out-of-pocket costs associated with "excluded" drugs in calculating progress toward the annual out-of-pocket maximum;
- Avoid implementing the proposal as a requirement for issuers so that plans have the flexibility to determine whether or not they will implement the provision and what types of drugs it would be applied to; and
- Require that issuers implementing this provision also maintain emergency-fill policies so that treatment regimens are not delayed or interrupted.

[6] Tayrouz Y, Ding R, Burhenne J, Riedel K-D, Weiss J. Pharmacokinetic and pharmaceutic interaction between digoxin and Cremophor RH40. Clin Pharmacol Ther. 2003;73:397–405.
[7] Wandel C, Kim RB, Stein CM. 'Inactive' excipients such as Cremophor can affect in vivo drug disposition. Clin Pharm Ther. 2003;73:394–6.

The NHC opposes "therapeutic substitutions" for non-medical reasons, as it could undermine provider-patient treatment decisions and compromise care for individuals with chronic conditions.

CMS seeks stakeholder comment on whether issuers should be permitted to implement both generic substitution and "therapeutic substitution," which consists of substituting chemically different compounds within the same class for one another. CMS stated that "[t]herapeutic substitution may help decrease drug costs if it can be implemented in a way that does not negatively affect quality and access to care."

In a 2011 publication evaluating best practices in implementing generic and therapeutic equivalence, European experts recognized this difficult balance, opining that while both strategies might offer opportunities for cost savings "when switches of medication are driven purely on economic grounds, there may be potential conflicts between the needs of the health care provider and those of individual patients, and this may impact patients' safety and treatment outcomes."[8] The patient-level factors discussed above in connection with generic substitution can have an even greater impact, on a much larger group of patients, when considering therapeutic substitution across classes.

Rather than allow therapeutic substitutions, we urge CMS to rely instead on initiatives similar to that proposed for Medicare Part D, i.e., increasing the information patients and providers receive on the costs of prescribed drugs and alternative treatments.

The NHC appreciates CMS' targeted approach to limiting the use of manufacturer coupons and recommends specific patient safeguards if this proposal moves forward.

CMS has proposed to exclude any form of direct manufacturer cost-sharing support from calculations toward applicable annual limitations on out-of-pocket costs when it is offered in connection with a specific prescription brand drug that has a generic equivalent. Because the proposed rule is silent on other uses of manufacturer coupons, we interpret this policy shift to not apply to them. In our comments to the HHS Blueprint, the NHC addressed potential initiatives to curb use of manufacturer coupons and other forms of assistance. We urged the Administration to "consider nuanced and incremental approaches to eliminate inappropriate use of copay discount cards as opposed to broad policies that impact all uses." We appreciate that this policy is more nuanced than other proposed approaches that more broadly impact use of cost-sharing assistance.

As we stated in previous comments, the current system subjects patients to high out-of-pocket costs, particularly for drugs used to treat complex and chronic conditions. Patients rely on copay coupons, discount cards, charitable assistance, and other assistance to afford the medicines they need to improve or maintain their health. While there is criticism that copay discount cards and other assistance drive utilization of higher cost drugs when a generic is available, the data are mixed. It is likely that some copay discount cards are inappropriately implemented, while others are not. There is, therefore, justification for differentiating between manufacturer support that enables access versus incentives that could encourage inappropriate use of higher-cost branded

[8] Generic and therapeutic substitution: a viewpoint on achieving best practice in Europe, 2011. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3243005/

medications when medically-appropriate generic products are available. We appreciate that CMS sought to incorporate that distinction into its NBPP proposal but reiterate our concern that individual patient response to some generics may differ from branded products. There may also be instances in which generic products are not on a plan's formulary or may not offer significant savings. Therefore, we urge additional patient safeguards to further help distinguish between appropriate and inappropriate use of assistance.

Specifically, the NHC urges CMS to:

- Refrain from expanding this proposal to charitable assistance;
- Limit its scrutiny of manufacturer assistance to instances 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.

The NHC supports CMS' efforts to increase access to medication-assisted treatment (MAT) for opioid use disorder (OUD).

The NHC appreciates CMS' efforts to ensure that individuals suffering from OUD have access to evidence-based MAT to increase their chance for recovery. In its NBPP, CMS encourages health plans to provide comprehensive coverage of MAT, even if the applicable EHB-benchmark plan does not require the inclusion of all MAT on the plan's formulary.

According to the American Society for Addiction Medicine:

> Relative to treatment without medication, office-based opioid treatment with buprenorphine improves six-month treatment engagement, significantly reduces cravings, illicit opioid use and mortality, and improves psychosocial outcomes. Importantly, agonist therapy has been shown to decrease mortality by approximately 50% among persons with opioid-use disorder.[9]

The NHC believes that excluding a treatment option that is associated with a 50 percent decrease in mortality is an example of a discriminatory benefit design. We agree that plans excluding MAT for opioid use treatment, but covering it for other medically necessary purposes, (e.g., analgesia) should be required to justify the basis for the exclusion and explain how the benefit design is not discriminatory under the PPACA's non-discrimination rules. We urge CMS to

[9] American Society of Addiction Medicine, Public Policy Statement, Regulation of Office-Based Treatment, https://www.asam.org/advocacy/find-a-policy-statement/view-policy-statement/public-policy-statements/2018/01/18/regulation-of-office-based-opioid-treatment (accessed February 12, 2019).

consider going further in implement a broader, more robust mechanism to ensure that issuers are actively working toward, not against, the public policy imperative of curbing the opioid use epidemic. Specifically, we ask that CMS:

- Encourage or require states to update their benchmark plan to include all formulations of MAT; and
- Inform issuers that a benefit design excluding MAT for opioid use disorder will be presumed to be discriminatory.

The NHC urges CMS to ensure that requirements for Navigators and web brokers include protections for individuals with disabilities, and that federal oversight is sufficient to ensure Navigator and web broker compliance.

The NHC supports initiatives that increase the quality and quantity of information available to individuals as they determine which health insurance plan best suits their needs. We have supported the PPACA's Navigator Program as an important resource for Americans seeking to make informed decisions about which health insurance plans best fit their needs. The NHC has opposed the series of funding cuts that have likely deterred organizations from continuing to serve as Navigator entities, resulting in even more limited access for consumers needing in-person assistance to choose a plan and complete enrollment.

We note that CMS' proposed regulatory changes are intended to provide Navigators with more flexibility through a streamlined set of training requirements. The NHC is concerned that by replacing the 20 existing, specific training topics with broad categories CMS may give Navigator entities the impression that they are no longer required to train Navigators to assist individuals with disabilities. We urge CMS to clarify that Navigators must be equipped to ensure that individuals with disabilities retain meaningful access to their services. This means that training must continue to include considerations associated with vulnerable populations, including individuals with disabilities, in accordance with the Americans with Disabilities Act and section 504 of the Rehabilitation Act.

Similarly, the NHC understands that CMS seeks to expand the sources of PPACA information and enrollment assistance by encouraging use of HHS-certified web brokers. As CMS acknowledges, web brokers are likely incentivized by issuers, often on a differential, plan-specific basis. We agree that web brokers should be prohibited from displaying recommendations for plans based on the compensation they receive from insurers, and share CMS' concern that these entities could structure their platforms toward implicit recommendations by choosing how to display plan alternatives.

The NHC urges CMS to reduce the risk that implicit web-broker recommendations would steer enrollees toward or away from specific plan offerings. We ask that CMS bolster its certification mechanism with clear web broker requirements, and Agency oversight to ensure compliance. For example, a web broker is less able to influence the plans displayed if it enables searches based on premium, medical deductible, prescription drug formulary structure (including any coinsurance for a specialty tier), and actuarial value. Similarly, web brokers should be required to provide all plan information for all plans so that enrollees can make meaningful comparisons and determine which plan best suits their needs.

The NHC is also concerned that web brokers may service non-PPACA-compliant plans and display those offerings alongside PPACA options. The expansion of available options, including short-term, limited-duration (STLD) plans, could inject confusion about the scope and breadth of coverage these plans offer. We are concerned that brokers may be incentivized to sell these plans, and consumers will not have the information about what STLD plans do and do not cover, or a clear understanding of the differences between marketplace coverage and STLD plans. We urge CMS to require that web brokers maintain transparency and make a clear distinction between marketplace plans and alternative coverage. Without these safeguards, enrollees will not have clear information to choose the plan that best meets their needs, putting them at significant risk of being underinsured.

Conclusion

The NHC believes that the important modifications outlined above are crucial in ensuring the proposed 2020 NBPP could reduce costs for exchange enrollees without compromising care. The NHC firmly believes that the market will best address enrollee needs through broad patient protections, flexibility to accommodate the needs of more complex patients, and increased information for patients on the cost of their care and availability of lower-cost alternatives. As CMS finalizes the 2020 Notice of Benefit and Payment Parameters, the NHC strongly encourages the Agency to include or strengthen these elements.

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