December 16, 2019

The Honorable Nancy Pelosi  The Honorable Kevin McCarthy
United States House of Representatives  United States House of Representatives
Washington, DC 20515  Washington, DC 20515

The Honorable Mitch McConnell  The Honorable Chuck Schumer
United States Senate  United States Senate
Washington, DC 20510  Washington, DC 20510

Dear Speaker Pelosi, Leader McCarthy, Leader McConnell, and Leader Schumer:

The National Health Council (NHC) appreciates this opportunity to provide feedback on Congressional efforts to address drug pricing including H.R. 3, the Lower Drug Costs Now Act, and S. 2543, the Prescription Drug Pricing Reduction Act (PDPRA).

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 140 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; representatives from the pharmaceutical, generic drug, health insurance, device, and biotechnology industries; and research, provider, and family caregiving organizations.

The NHC is committed to ensuring patients have access to affordable, high-value treatments. We share your concern that many Medicare, Medicaid, and commercial insurance beneficiaries struggle to afford their medications. We appreciate the attention Members of Congress on both sides of the aisle and in both chambers have dedicated to this topic. As stated in our Domains and Values, the NHC aims to help ensure meaningful, affordable access to care, and many of the proposals in H.R. 3 and S. 2543 align with that goal.

Part D Redesign and Out-of-Pocket Cap

The NHC strongly supports the inclusion of an out-of-pocket (OOP) cap for Medicare beneficiaries. Specifically, we support the $2,000 OOP cap for Part D in Title III of H.R. 3. We believe the current Medicare Part D benefit structure needs to be updated to protect the growing number of patients who pay high cost sharing for important treatments. This cap would offer considerable protection for patients who have high drug costs. This is particularly timely as the $1,250 increase in the catastrophic limit and the accompanying cost sharing will impact patients starting in January 2020. We note, however, the OOP cap would not go into effect until 2022, so provisions should be included to reduce the catastrophic limit to its current threshold.
We are also encouraged by inclusion of provisions in H.R. 3 and S. 2543 that would allow patients with high costs to spread out (or “smooth”) their payments over time. This, partnered with the OOP cap, would significantly relieve the burden of high drug costs for Medicare beneficiaries. The proposals vary, and we hope Congress will make this benefit available to as many patients as possible who face significant, front-loaded cost sharing, regardless of the number of prescription drugs needed. Currently, we believe the Senate version of the smoothing provision best meets the needs of more patients. Thus, we strongly support the Senate provision and thank both chambers for including these important provisions.

**Price Increases**

The NHC appreciates efforts to address rapidly increasing drug prices. In 2017, NHC developed recommendations to reduce health care costs. In these recommendations, we called for system-wide transparency, including requiring manufacturer justification of price increases. We also recommended transparency and pass through of manufacturer rebates, which is why we were pleased to see recent passage of legislation to require transparency of rebates. H.R. 3 and S. 1895 also require manufacturers to pay penalties if prices rise faster than inflation. The NHC agrees with the premise that the costs of medical products should not arbitrarily increase year-over-year and support the aim of these provisions. However, we also recognize this is a multi-faceted issue with perverse incentives created by the current rebating system. This should be considered when crafting policy to reduce price increases. Additionally, any savings realized by such policy should be passed directly to the patients most directly impacted.

**PCORI Reauthorization**

We support provisions of S. 1895 that would reauthorize the Patient-Centered Outcomes Research Institute (PCORI) for 10 years. We also appreciate efforts by House Committees to reauthorize PCORI earlier this year. Notably, we are supportive of language in S. 1895 that would encourage PCORI to consider a full range of outcomes, including economic impacts of disease and treatments such as out-of-pocket costs, productivity/absenteeism, travel, and impacts on families. While we continue to support the prohibition on PCORI conducting cost-effectiveness, we believe this language is a positive step toward development of needed evidence on the impact diseases and treatments have on patients and families. Given PCORI’s track record on partnering with patients in research, we feel they are an appropriate body to develop this evidence for patients, providers, payers, and employers. In addition, we urge you to include language to encourage PCORI to continue its work in engaging patients in the prioritization and conduct of funded studies.

**Ensuring Direct Patient Benefit and Managing Unintended Consequences**

While Medicare beneficiaries would benefit from the reduced premiums that the proposals may deliver, we are concerned that there is not a greater guarantee of direct patient benefit, including greater levels of access and reduced out-of-pocket costs for beneficiaries before the catastrophic limit. Thus, we recommend additional protections to achieve this goal. For example, should Congress decide a direct negotiation approach is the right one, it is imperative it require payers to cover the drugs selected for negotiation with minimal cost sharing and no or minimal utilization management rules. Additionally, insurers in both the Medicare program and commercial market that choose to use the negotiated price should accept this price rather than a higher list price, with rebates tied to those list prices and that are not passed on to patients.

The NHC also encourages Congress to reinvest any realized savings achieved to the benefit of patients, such as improvements to the low-income subsidy (LIS) program. All efforts should be made to invest in improving access to needed treatments and relieving cost burdens of Medicare beneficiaries, particularly those most in need of access to medications.
The proposals being discussed include both a significant redesign of the Part D program and major changes to how Medicare plans, and potentially commercial insurance plans, purchase drugs. These changes are likely to have unintended consequences that have the potential to affect access for patients. For example, the Congressional Budget Office and others have predicted there will be an impact on new drug development. Potential adverse impacts, such as decreased availability of certain drugs, can be better avoided if the bill specifies how HHS will evaluate and respond to these potential unintended impacts. We recommend requiring periodic reporting to Congress on the impact of proposals on medical product development and access to treatment.

Finally, the NHC has long stated that any effort designed to reduce health care costs must be predicated on value. Over the course of the last several years, we have seen a growing interest in and debate around defining value. However, many of those discussions have not adequately included patients, and value must be defined from the patient perspective. For example, the ceiling proposed for negotiations in H.R. 3 is based on an international index. Reliance on international prices requires using value assessments made in those countries based on cost data, events, circumstances, and populations that may not be relevant to American patients, and with no input from American patients. This approach does not take into account the outcomes American patients want, how they prioritize them, how they assess benefits and risks, and what they will/will not trade off, which can vary significantly by country according to socioeconomics, culture, norms, etc. Given that we are an organization dedicated to elevating the voice of the patient, we are concerned about any effort that does not consider U.S. patient views and circumstances.

In closing, the NHC thanks Congress for addressing these important issues. We welcome the opportunity to work with you to design a solution to high drug prices that works best for patients. If you or your staff would like to discuss these issues further, please contact Eric Gascho, our Vice President of Policy and Government Affairs, at (202) 973–0545 or egascho@nhcouncil.org. Thank you for the opportunity to provide feedback on this legislation.

Sincerely,

Marc Boutin, J.D.
Chief Executive Officer