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December 4, 2020

The Honorable Alex Azar
Secretary

U.S. Department of Health and Human Services
200 Independence Ave SW
Washington, DC 20201

RE: HHS-OS-2020-0012: Securing Updated and Necessary Statutory Evaluations Timely

Dear Secretary Azar:

The National Health Council (NHC) appreciates the opportunity to provide comments on the Department of Health and Human Services' (HHS) proposed rule on creating a system of regular review of regulations.

Created by and for patient organizations 100 years ago, the 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 shares HHS' desire to ensure that regulations are regularly reviewed and remain necessary and effective. In particular, we continually advocate that new regulatory initiatives include oversight and analysis mechanisms so that policymakers and the stakeholder community understand how regulations impact people with chronic conditions. Specifically, we urge HHS agencies to consistently engage with patients and patient organizations to develop systems to review regulations' impacts on patient care. **However, we ask the Department to withdraw this proposed rule as it will not meet our joint goal.**

We have significant concerns about the proposed rule's provision to automatically sunset unreviewed rules. The sunset provision could result in the loss of important protections and services for patients; predictability for researchers, medical product sponsors, and Medicaid Directors; and a vast array of other important regulations, depending on the views of future administrations. Most importantly, this automatic sunset provision could allow any future administration to make policy or political decisions to undo regulations without any opportunity for the public to provide their perspective and feedback through a typical notice and comment process. In particular, the rule's impact on programs that affect millions of Americans, including those in underserved and underrepresented populations, could be extremely detrimental. Finally, the sunset provision would not necessarily be effective in driving reviews of regulations. A mechanism for such review already exists. In August of 2011, the Department issued a final Retrospective Review Plan and has issued 10 updates on the plan since then. The proposed rule does not reference the existing plan and any concerns with its implementation.

In addition, the standard that triggers the need for review in the proposed rule is not focused on patient impact. The proposed rule states that review would be triggered if a rule "currently has a significant economic impact upon a substantial number of small entities." If any review is triggered, it needs include considerations of how patients and other stakeholders are impacted, which may or may not have an economic impact. In order to craft an appropriate trigger, the patient community would need to weigh in on patient-identified needs and impacts of specific regulations.

Conclusion

We appreciate the opportunity to provide input on this important issue. Please do not hesitate to contact Eric Gascho, 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,



Eleanor Perfetto, PhD, MS
Interim Chief Executive Officer and
Executive Vice President, Strategic Initiatives