

November 13, 2020

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Patient-Centered Outcomes Research Institute

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Dear Dr. Cook

The National Health Council (NHC) appreciates the opportunity to provide comments on the Patient-Centered Outcomes Research Institute (PCORI) *Proposed Principles for the Consideration of the Full Range of Outcomes Data*.

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 is proud to have worked with Congress to include this provision in the reauthorization bill ensuring the full range of burdens and economic impacts on patients is considered in PCORI-funded research. The goal of this language is to ensure PCORI-funded researchers produce more holistic evidence relevant to patient decision-making. It will assist patients as they navigate their options and understand what treatment impacts might be beyond clinical outcomes. This is something our experience shows is critical to patients.

Overall, we are supportive of these proposed principles and believe they are an important step towards capturing a broader range of outcomes that are most important to patients. These principles make it clear that the patient perspective is an important part of the evidence considered in patient-centered outcomes research. This has always been a priority for PCORI, and

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these principles further codify their commitment to serving patients and the patient community. We look forward to working with PCORI and our membership to implement these principles when finalized, helping with the next steps of developing proposals sharing guidance and best practices, and developing methods to measuring non-clinical outcomes.

The following are our specific comments on the proposed principles.

The list of potential burdens and economic impacts is a useful resource, as it is important to specify potential impacts that may affect patients. However, we encourage PCORI to make it clear that the list is a framework, and there may be other, unforeseen burdens or economic impacts that should be considered but are not specifically included in the list. This flexibility will help encourage patient advocates and researchers to think more holistically about potential areas to consider. We encourage PCORI to prioritize existing patient-centered evidence that has already been collected, such as the rare disease burden [survey](#) conducted by the EveryLife Foundation, for further insight into potential burdens on patients and caregivers.

There are a few additional burdens and economic impacts we encourage PCORI to include in the final guidance, including:

- **Forgone wages for patients.** The list includes forgone wages for caregivers but not for patients. This could be a significant issue for many patients;
- **Paid support for patients.** For patients who lack sufficient caregiver support, there may be a need to pay for support personnel and/or caregiver respite; and
- **Toll on caregivers.** For some caregivers, there may be a physical or mental health impact from caregiving duties.

The NHC agrees that patients and other stakeholders “benefit from more robust evidence based on the clinical and economic impacts of health care treatments and services to inform their decisions.” To achieve this goal the next steps after these principles, including providing greater guidance and methodology reviews to facilitate consistency, will be critical.

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