June 30, 2023

Steven D. Pearson, MD, MSc
President
Institute for Clinical and Economic Review (ICER)
14 Beacon Street, Suite 800
Boston, MA 02108

Re: 2023 Value Assessment Framework: Proposed Changes

Dear Dr. Pearson,

The National Health Council (NHC) is pleased to provide the following comments in response to the 2023 Value Assessment Framework Proposed Changes. The ICER’s Value Assessment Framework can have significant effects on NHC-member patient advocacy groups and their constituent populations, many of whom have been through past ICER reviews. The NHC is appreciative that ICER has updated its framework and released the changes for public comment.

Created by and for patient organizations more than 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 150 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 drug, and payer organizations.

Clinical Trial Diversity

Under proposed changes in Sub-Section 2.1, Clinical Trial Diversity, the NHC suggests expanding the criteria described in Table 2.2. Under race and ethnicity, we suggest including American Indian/Alaskan Native (AI/AN) Indigenous representative groups. Under the sex category, we suggest including non-binary classification, and in relation to the age category, we recommend stratifying across age groups rather than exclusively aggregate data in clinical trial participants over the age of 65. Particularly, the age category would amplify the intent of ICER to focus on diversity as varied age group participation may yield differential outcomes measures. AI/AN representative groups classification is imperative particularly due to reduced sample size reporting and future investment for targeted clinical trial recruitment.

Expanded sex classification is congruent to the broader understanding of LGBTQ+ clinical trial representative participants. No mention was provided in the proposed changes nor the white paper on Advancing Health Technology Assessment Methods.
that Support Health Equity of clinical trial participants with differential abilities. ICER should consider adding this category for classification purposes and expansion of diversity metrics.

Lastly, we suggest outlining how the proposed changes to this framework on clinical trial diversity complements the US Food and Drug Administration’s (FDA’s) ongoing work on creating advisory councils and other initiatives that account for patient centricity and transparency. Also, the FDA guidance “Collection of Race and Ethnicity Data in Clinical Trials (October 2016)” and, “Diversity Plans to Improve Enrollment of Participants From Underrepresented Racial and Ethnic Populations in Clinical Trials.” have robust suggestions on increasing diversity in clinical trials for sponsors and drug developers. It is unclear how ICER’s Clinical Trial Sample Diversity Ratings would build upon these guidances. As an organization with a diverse membership of multiple patient advocacy organizations and biotech and pharmaceutical companies, we believe these new changes could lead to confusion and duplicative efforts.

Subpopulation Analyses
Under the proposed changes 2.2.1, subpopulation analyses, the NHC suggests that ICER rely primarily on interviews with patients, caregivers, and recommendations from patient advocacy groups. Targeted literature reviews and advice from clinical experts are helpful but may impose preconceived interpretations that are not in line with current patient experiences. Non-patient provided information should be considered secondary, after first-hand patient input is given.

Patient Engagement Program
The NHC applauds ICER’s efforts to update its patient engagement program. Patient engagement is not only important to capturing the true value of treatments, but it is also essential to fully understanding the impacts, costs and benefits, and outcomes that are important to patients and family caregivers. The suggested accessibility and inclusive design of public meetings is an impactful step that ICER can take to increase participation of those with chronic diseases and disabilities in ICER meetings.

The NHC is appreciative of the addition of honoraria for patient and caregiver participants in ICER’s patient engagement work. Compensation is an important driver of diverse patient participation, especially as many patients who are hourly wage earners, do not have paid leave, or have elder or childcare-giving responsibilities. In 2020, the NHC published its Fair-Market Value Calculator and Compensation Toolkit on compensation for patient, caregiver, and patient advocacy group engagement that includes a calculator for “an estimated, reasonable, and fair hourly compensation range.” The NHC encourages ICER to use this toolkit, including the calculator, as a reference when determining a fair-market value compensation range for patient engagement activities.

The NHC is excited about the creation of a new Patient Council to reflect ICER’s commitment to diverse and inclusive patient participation in the value assessment space. The NHC suggests that ICER publishes how it recruited and chose the patient advisors, as well as list any relevant affiliations the patients have. The NHC further suggests that the Council’s authority and oversight be transparently shared with the patient community – including how suggestions by the Council have been incorporated into practice. Good practice guidelines for patient engagement (including engagement with a Patient Council) can be found in the NHC’s Rubric to Capture the Patient Voice.2

**Conclusion**
We deeply appreciate ICER’s commitment to value assessment. We hope that our suggestions are taken into consideration as you continue enhancing a framework that reflects patient engagement and centricity.

Please do not hesitate to contact Omar A. Escontrías, DrPH, MPH, Senior Vice President, Equity, Research & Programs, if you or your staff would like to discuss these issues in greater detail. He is reachable via e-mail at oescontrias@nhcouncil.org.

Sincerely,

Randall L. Rutta, MA
Chief Executive Officer

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