July 19, 2022

Sandra R. Hernández, MD
President & Chief Executive Officer
California Health Care Foundation
1438 Webster Street #400
Oakland, CA 94612

Dear Dr. Hernández:

We are writing to applaud the California Health Care Foundation's (CHCF) focus on fair access to health care, and to raise concerns about the equity implications of the Foundation's recent announcement to fund the Institute for Clinical and Economic Review (ICER). As we understand, the Foundation was established in 1996 with the support of Blue Cross Blue Shield of California and Anthem to lay the foundation for improving access to coverage and care and advance people-centered care. Similarly, ICER is an organization that prides itself on being a "drug pricing watchdog" whose reports are largely used by insurers and payers to drive coverage and benefit design decisions. ICER has often used discriminatory and flawed comparative effectiveness metrics such as the QALY to assess the value of medicines. While the goal is to lower health care costs, health policy decisions based on QALYs would harm patients and people with disabilities, especially those with low incomes and whose needs are not well served by the status quo. We urge the Foundation to ensure that ICER does not use discriminatory, biased value assessments or comparative effectiveness metrics as they complete CHCF-funded work. We will be monitoring the grant deliverable closely.

On March 3, 2022, ICER announced it had received a new grant from CHCF to "develop 1) two annual unsupported price increase reports specific to California, and 2) a policymaker guide outlining how to use comparative effectiveness research to ensure that patients have fair access to fairly priced drugs." Additionally, the grant funds ICER value assessments evaluated by the California Technology Assessment Forum. We are very concerned that ICER's announcement stated that the Foundation has "allowed ICER to lead a national discussion about how to align the prices in our health care system with the benefits patients receive from various treatments, therapies, and interventions." We could not agree more with the Foundation's mission to advance meaningful, measurable improvements in the health care delivery system, yet there are no restrictions to assure the quality of the value assessment tools developed by ICER as part of the CHCF-funded work.

If biased against people with disabilities and chronic diseases, comparative effectiveness tools can have a long-reaching negative impact on equity and access. We have strong concerns that policymakers regularly reference discriminatory health-benefit price benchmarks and other metrics such as "life years" when crafting policies to address health care costs or ration care in a shortage, in stark contrast to the Foundation's health equity goals. We do not want this CHCF work stream to expand policymaker reliance on flawed methods and metrics. For example, early in the pandemic, organizations representing people with disabilities fought to amend

California's Crisis Standards of Care to address its discriminatory implications, including its reliance on a discriminatory focus on "life years" to prioritize who would have access to critical life-saving care.[1] Also, it is well understood that inherent bias of traditional value assessments is exacerbated by the lack of representation of subpopulations in the data that is used to develop them, entrenching health inequity when used to drive policy.[2]

The United States has a thirty-year, bipartisan track record of opposing the use of the quality-adjusted life year (QALY) and similar discriminatory metrics and establishing appropriate legal safeguards to mitigate their use. Section 504 of the Rehabilitation Act ensures that people with disabilities will not be "excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination," under any program offered by any Executive Agency, including Medicare.[3] Title II of the Americans with Disabilities Act (ADA) extended this protection to programs and services offered by state and local governments.[4] Based on the ADA's passage in 1990, in 1992 the George H.W. Bush Administration established that it would be a violation of the ADA for state Medicaid programs to rely on cost-effectiveness standards, as this could lead to discrimination against people with disabilities.[5]

The Affordable Care Act (ACA) directly states that the Secretary of Health and Human Services (HHS) has no authority to deny coverage of items or services "solely on the basis of comparative effectiveness research" nor to use such research in a manner that would attribute a lower value to extending the lives of older adults, people with disabilities or people with a terminal illness.[6] Additionally, the ACA specifically prohibits QALYs and similar metrics from being used by HHS as a threshold to establish what type of health care is cost effective or recommended, as well as prohibiting their use as a threshold in Medicare to determine what is covered, reimbursed or incentivized.[7] Most recently, HHS reiterated in a final rule that it is a violation of section 504 of the Rehabilitation Act, the ADA, the Age Discrimination Act, and section 1557 of the ACA for state Medicaid agencies to use measures that would unlawfully discriminate on the basis of disability or age when designing or participating in value-based payment (VBP) arrangements.[8]

In the United States, ICER is well known for its reliance on QALYs to develop its value assessments, calling QALYs "the gold standard."[9] QALY-based assessments assign a financial value to health improvements provided by a treatment that do not account for outcomes that matter to people living with the relevant health condition and that attribute a lower value to life lived with a disability. When applied to health care decision-making, the results can mean that people with disabilities and chronic illnesses, including older adults, are deemed not worth

---

[1] https://dredf.org/letter-opposing-californias-health-care-rationing-guidelines/
[2] https://www.nmqf.org/nmqf-media/traditional-value-assessment-methods
[3] 29 USC Sec 794, 2017.
[4] 42 USC Sec 12131, 2017.
[5] Sullivan, Louis. (September 1, 1992). Oregon Health Plan is Unfair to the Disabled. *The New York Times*.
[6] 2 USC Sec 1320e, 2017.
[7] 42 USC Sec 1320e, 2017.
[8] https://www.federalregister.gov/d/2020-12970
[9] https://icer.org/news-insights/press-releases/icer-describes-qaly/

the cost to treat.[10] We encourage you to review the report from the National Council on Disability, an independent federal agency, recommending that policymakers avoid referencing or importing the QALY from other countries, clarifying that its use in public programs would be contrary to United States civil rights and disability policy.[11] The Council has recommended a ban on the use of QALYs across federal programs as part of its Health Equity Framework.[12] We share their concerns that health equity is not achieved by relying on metrics that discriminate and fail to recognize how treatment impact differs among subpopulations. The outcome of such a policy only serves to entrench barriers to care imposed by payers.

By contrast, there are many other entities developing and testing methodologies for assessing the clinical and cost effectiveness of treatments with a strong focus on identifying methods to address health equity concerns. For example, the Innovation and Value Initiative has launched a Health Equity Initiative aimed at determining how patient engagement and innovation of methods can move us closer to achieving health equity.[13] The Preparedness and Treatment Equity Coalition was created to study and identify health system reforms and metrics to reduce health disparities, and advance policies and practices to help address urgent care gaps in underserved communities.[14] There has been a tremendous amount of investment from health care stakeholders and academia to improve methodologies for valuing health care to address this health equity challenge.[15]

Therefore, we are disappointed that entities embracing QALYs and similar average metrics receive funds to continue advancing value assessments that work against health equity goals. We hope that the Foundation will take steps to assure Californians that the work it is funding will not be used against patients and people with disabilities to drive health policy.

Please know that we appreciate the Foundation's efforts to address important issues such as workforce challenges. We hope that this information is useful to the Foundation and its future work and look forward to hearing from you about it. Should you have any questions or wish to discuss this, please feel free to email Siri Vaeth at svaeth@cfri.org, or any of the signers listed below.

Sincerely,

Siri Vaeth
Executive Director, Cystic Fibrosis Research Institute

---

[10] https://dredf.org/2021/09/23/pharmaceutical-analyses-based-on-the-qaly-violate-disability-nondiscrimination-law/

[11] National Council on Disability. (November 16, 2019). Quality-Adjusted Life Years and the Devaluation of Life with Disability. https://ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf.

[12] https://www.ncd.gov/sites/default/files/NCD_Health_Equity_Framework.pdf

[13] https://www.thevalueinitiative.org/health-equity-initiative/

[14] https://ptechealth.org/vision

[15] https://pubmed.ncbi.nlm.nih.gov/34458963/

Adrienne Shapiro
Cofounder and Science Administrator
Axis Advocacy
adrienne@axisadvocacy.org

Carole Florman
Policy Fellow
CancerCare
cflorman@cancercare.org

Julie Kornack
Chief Strategy Officer
Center for Autism and Related Disorders
j.kornack@centerforautism.com

Katherine Perez
Executive Director
Coelho Center for Disability Law, Policy and Innovation
katherine.perez@lls.edu

Eric M. Harris
Director of Public Policy
Disability Rights California
eric.harris@disabilityrightsca.org

Silvia Yee
Senior Staff Attorney
Disability Rights Education and Defense Fund
syee@dredf.org

Irma Resendez
President and Founder
Familia Unida Living with MS
iresendez@familia-unida.org

Marc Yale
Advocacy and Research Coordinator
International Pemphigus and Pemphigoid Foundation
marc@pemphigus.org

Scott Suckow
Executive Director
Liver Coalition of San Diego
scott@livercoalition.org

Sara Traigle van Geertruyden
Executive Director
Partnership to Improve Patient Care
sara@pipcpatients.org

Kari Rosbeck
President and CEO
TSC Alliance
krosbeck@tscalliance.org