



November 4, 2022

Honorable Rob Bonta
Attorney General
State of California
1515 Clay St., 20th Floor
Oakland, CA, 94612

Dear Attorney General Bonta:

We are writing to applaud your efforts to address racial and ethnic bias in commercial health care algorithms.¹ We fully support your efforts to advance a more inclusive and equitable health care system by identifying and addressing the historic and systemic biases inherent in how decision-makers value and deliver health care. Therefore, we urge you to investigate the biased and discriminatory methods inherent in value assessments driving coverage decisions and benefit design, and to work toward identifying higher standards for the evidence used to make decisions.

We are especially concerned that the California Health Care Foundation (CHCF) recently provided a grant to the Institute for Clinical and Economic Review (ICER), an entity whose clinical and cost effectiveness studies are known to rely on data that fails to represent racial and ethnic communities impacted by structural racism. Among its methods, ICER is known for conducting cost effectiveness analyses of medical treatments using metrics that discriminate against people with disabilities, the quality-adjusted life year (QALY) and the equal value of life year gained (evLYG). As you know, people experiencing structural racism are also disproportionately represented among people with disabilities. Therefore, we have serious concerns that increased reliance on ICER studies will further bias decisions related to coverage and access in California's health care system and urge you to investigate their use.

¹ <https://oag.ca.gov/news/press-releases/attorney-general-bonta-launches-inquiry-racial-and-ethnic-bias-healthcare>

As background, we have long-held strong concerns that payers and 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 state’s health equity goals. 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 care.² As you may know from news stories, Michael Hickson, a Black, disabled, married father of 5 children, died in a Texas hospital from COVID-19 after life-saving treatment was withheld due to assumptions that his quality of life was not worth saving.³ The work you are doing to address the clinical algorithms that promote this stigma against caring for people of color with disabilities is crucial.

ICER Relies on Discriminatory Methods

ICER’s cost-effectiveness analyses rely on the use of discriminatory QALYs and similar one-size-fits-all summary metrics. These metrics have long been prohibited from use in public health care programs because they discriminate against patients and people with disabilities and chronic illnesses by placing a lower value on their lives and treating them as averages rather than individuals. Despite the widely acknowledged ethical problems related to using QALYs in health care decision-making, this metric continues to underpin ICER’s value assessments, with ICER calling QALYs the “gold standard.”⁴ We urge California to end use of QALY-based value assessments.

The United States has a thirty-year, bipartisan track record of opposing the use of the 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.⁵ Title II of the Americans with Disabilities Act (ADA) extended this protection to programs and services offered by state and local governments.⁶ Based on the ADA’s passage in 1990, in 1992 the Secretary of the U.S. Department of Health and Human Services (HHS) 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.⁷

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

² <https://dredf.org/letter-opposing-californias-health-care-rationing-guidelines/>

³ <https://www.npr.org/2020/07/31/896882268/one-mans-covid-19-death-raises-the-worst-fears-of-many-people-with-disabilities>

⁴ <https://icer.org/news-insights/press-releases/icer-describes-qaly/>

⁵ 29 USC Sec 794, 2017.

⁶ 42 USC Sec 12131, 2017.

⁷ Sullivan, Louis. (September 1, 1992). Oregon Health Plan is Unfair to the Disabled. *The New York Times*.

civil rights and disability policy.⁸ The Council has recommended a ban on the use of QALYs across federal programs as part of its Health Equity Framework.⁹ We share the Council’s concerns that health equity is not achieved by relying on metrics that discriminate and fail to recognize how treatment impact differs among subpopulations. Such policies only entrench barriers to care imposed by payers.

The HHS Office for Civil Rights recently issued a proposed rule that specifically calls for comments on the “impermissible discrimination in the application of value assessment methodologies used to set valuations for health care goods and services.” The agency recognized the influence of value assessment methodologies on coverage decisions and health benefit design and how “methods for calculating value that penalize individuals or groups of individuals on the basis of race, color, national origin, sex, age, or disability (*e.g.*, by placing a lower value on life-extension for a group of individuals based on a protected basis or via inappropriate adjustment of clinical end points on the basis of a protected basis under Section 1557)” may violate Section 1557.¹⁰

In response, patients and people with disabilities urged the HHS Office for Civil Rights to issue a rulemaking that codifies a bar on the use of methods for calculating value that penalize individuals or groups of individuals on the basis of race, color, national origin, sex, age, or disability as part of utilization management, formulary design, price negotiations, alternative payment models and other incentive-based programs impacting access to care and affordability of care. In their letter, advocates expressed concern that studies comparing the value of health care treatments and services using historic methods have strong potential to devalue outcomes that matter to people needing care, a challenge exacerbated for people excluded from the data and biasing conclusions about health care value.¹¹ The result is health inequity.

ICER Fails to Meaningfully Engage Expert Stakeholders

ICER chooses to leave patients, caregivers and clinicians who have firsthand experience with the condition under review out of the voting process. Their failure to include experts who can provide relevant and meaningful insight about the impact of specific conditions demonstrates how little ICER respects the value of patient and clinician voices. Instead, ICER resists giving stakeholders who have firsthand experience with the topic being discussed, either as a patient, caregiver, or clinician, an equal voice and vote in all assessments.

⁸ 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.

⁹ https://www.ncd.gov/sites/default/files/NCD_Health_Equity_Framework.pdf

¹⁰ 87 FR 47824

¹¹ http://www.pipcpatients.org/uploads/1/2/9/0/12902828/pipc_1557_comments.pdf

ICER Fails to Rely on Inclusive Evidence

Throughout its work, ICER fails to evaluate the impact of treatments on subpopulations, does not empower patients to meaningfully participate in their processes, and excludes much of the data collected and shared by patients, instead basing its reports largely on randomized controlled trial (RCT) data that fails to be inclusive. All of these factors lead to biased research that does not reflect effectiveness and value of treatments for racial and ethnic communities not represented in research literature.

For example, ICER fails to rely on survey data or other patient data providing a more accurate account of patient experiences in its base case analyses of treatment value. Patients and people with disabilities expend significant resources to engage with ICER in its value assessment process, only to find much of their input is referenced in contextual considerations and not the cost effectiveness analysis that largely influences payer decisions.

Over-reliance on RCTs is also a key critique of the ICER Unsupported Price Increase (UPI) report. ICER consistently argues that certain real-world evidence does not meet their “high quality” standards. This outdated and restrictive view of real-world data means many important benefits of a medicine observed in real patient populations could be completely disregarded. Additionally, as RCTs often do not reflect the true diversity of patient populations, ICER’s reports may also fail to capture important added value to underrepresented populations. Under its current methods, ICER solely determines the studies that will be used in its analyses. Only information provided by manufacturers would be considered to justify an exception to ICER’s usual methods, and only ICER would determine how to use that additional information in its report’s conclusions that would trigger state action.¹²

ICER Fails to Consider Outcomes that Matter to Patients and People with Disabilities

Rather than prioritizing outcomes that matter to patients and people with disabilities, ICER values treatments strictly from the health system and insurer perspectives. This can lead to situations where it is more “valuable” not to provide care for some patients because to do so would not be “cost-effective.” Placing payers’ perspectives over patients’ needs is wrong. California should demand that the clinical algorithms for making decisions incorporate a range of patient-relevant outcomes in any determinations of value for treatments recognize how value may vary among diverse patients and people with disabilities and/or chronic and rare diseases.

For example, the health utility weights for ICER’s algorithm are derived from broad survey data known to ignore quality of life improvements important to people living with the condition. A very recent survey on disability bias among the public demonstrates that even higher education is associated with disability bias, the same people likely to be valuing treatments and creating clinical algorithms for care.¹³ Also, ICER’s models for measuring both cost and clinical

¹² https://icer.org/wp-content/uploads/2022/04/ICER_UPI_2022_National_Protocol_041422.pdf

¹³ <https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2022.00504>

effectiveness tend to rely on flawed data that largely represents a white, male population.¹⁴ Given the biased and exclusive data that feeds these metrics, treatments that are particularly effective for excluded populations, such as people in underserved communities and communities impacted by structural racism, can be especially vulnerable to being devalued.

ICER Assessments are Premature

ICER's rush to deliver payers and policymakers value assessments immediately upon FDA approval has led to hasty reviews based on early assumptions, oversimplified models, and incomplete data. By prioritizing speed over quality, ICER provides payers and policymakers with flawed information based on limited evidence, which leads to decisions that are similarly flawed. ICER assessments are not subject to peer review and therefore are not subject to standards for consistency and accuracy in their methodology. ICER should not prioritize swift service to its payer customers over scientific rigor. California should not allow for value assessments to be incorporated into clinical algorithms driving care until the assessments are able to determine the 'impact on net health benefit' with 'high certainty.'

ICER Lacks Transparency to Patients and People with Disabilities

ICER's assessment process is a black box to patients and people with disabilities and chronic diseases; they are left in the dark on the assumptions used and important limitations that may have impacted the results. It is imperative that all stakeholders have access to the models used so they can assess their validity and understand the implications of alternative methodologies. ICER's Unsupported Price Increase report suffers from many of the same weaknesses as its value assessments, including lack of transparency, disregard for outcomes that matter to patients and their families, cherry-picked data, and fundamental issues with the underlying information. Instead, California should rely on models that are open-source, transparent, and available to all patients and researchers to fully understand and replicate findings.

Provide Oversight of ICER's Methods for Valuing Treatments

California is home to the California Technology Assessment Forum (CTAF), a health care appraisal committee that operates as part of ICER.¹⁵ ICER prides itself on being a "drug pricing watchdog" whose reports are largely used by insurers and payers to drive coverage and benefit design decisions.¹⁶ Their primary goal is to lower the cost of health care for insurers and pharmacy benefit managers, yet decisions based on ICER's assessments can harm access to affordable care for patients and people with disabilities, especially those with low incomes and whose needs are not met by the status quo.

Payers frequently turn to ICER's research to justify restrictive coverage decisions, with some entities incorporating ICER's determinations into their algorithms for developing formularies. A 2018 Xcenda survey found that 78% of payers use ICER's research as part of their decision-

¹⁴ <https://www.nmqf.org/nmqf-media/traditional-value-assessment-methods>

¹⁵ <https://icer.org/who-we-are/people/independent-appraisal-committees/ctaf/>

¹⁶ <https://icer.org>

making process.¹⁷ For example, in 2018, CVS Caremark announced a plan to use ICER's determinations of cost effectiveness to create a benefit package limited to drugs under \$100,000 per QALY, with certain exceptions. CVS marketed this QALY-based benchmark plan for covered drugs in a benefit package for their employer clients. Patients and people with disabilities, particularly people that rely on these drugs to survive, responded directly to the company urging its reconsideration.¹⁸ While CVS Caremark agreed to stop marketing the employer benefit package that explicitly tied coverage to QALYs, we remain concerned that pharmacy benefit managers and other payers still reference ICER's studies behind closed doors to make decisions. Therefore, we urge expanding this investigation to better understand the influence of ICER's reports, as well as value assessments conducted by other entities, on coverage and utilization management decisions that create discriminatory barriers to care for communities of color, people with disabilities and older adults.

We have serious concerns about the CHCF's recent announcement to fund ICER for use in California's health system, especially considering efforts to advance health equity. CHCF was established in 1996 with the support of Blue Cross Blue Shield of California and Anthem, claiming to lay the foundation for improving access to coverage and care and advance people-centered care.¹⁹ We urged CHCF to ensure that ICER does not use biased data to inform value assessments or use discriminatory metrics to determine clinical and cost effectiveness as they complete the CHCF-funded work.²⁰ We will be monitoring the grant deliverable closely and urge you to do the same to ensure that health policy in California is not influenced by any ICER studies relying on flawed data that fails to represent Californians.

According to ICER's announcement on March 3, 2022, CHCF granted funds to ICER 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's value assessments evaluated by the CTAF. 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." Yet, CHCF omits grant restrictions to assure that the quality of the value assessment tools and policy guides developed by ICER as part of the CHCF-funded work are consistent with the state's health equity goals.²¹ ICER's role should be monitored and limited, not expanded to influence policy.

Investment in Alternative Strategies to Value and Deliver Health Care Improves Health Equity

By contrast, there are many other entities developing and testing alternative 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 Patient-Centered Outcomes Research Institute has published Equity and Inclusion Guiding Engagement Principles that

¹⁷ <https://www.xcenda.com/insights/htaq-winter-2020-icer-payer-decision-making>

¹⁸ http://www.pipcpatients.org/uploads/1/2/9/0/12902828/cvs_letter.pdf

¹⁹ <https://www.chcf.org>

²⁰ <https://www.cfri.org/wp-content/uploads/2022/07/Co-Signed-Letter-to-CHCF-Re-ICER-Grant.pdf>

²¹ <https://icer.org/news-insights/press-releases/chcf-grant-2022/>

provide a model for establishing processes that will facilitate increased and more meaningful participation from subpopulations that have historically been devalued or harmed by research and value assessment, thereby building trust by explicitly recognizing the past harm and committing to work collaboratively to assure future research is centered on improving health equity. 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.²² 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.²³ 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.²⁴

Conclusion

Therefore, we urge investigation of the quality of research and value assessments used by payers to make decisions impacting access to care and their implications for entrenching historic biases into our health care system, starting with ICER and the CTAF. We hope that your office will be able to provide an understanding of how ICER's research impacts equity and access, especially for communities of color that are disproportionately represented among patients with chronic conditions and people with disabilities explicitly devalued by their value metrics or omitted from the data informing their work.

California has an opportunity to lead by discontinuing use of clinical and cost effectiveness studies that exacerbate health inequity, instead setting a higher standard for the methods, metrics and data that inform health care decisions. Your efforts to address biased commercial health care algorithms could hold decision-makers accountable when relying on research and value assessments that fail to account for the diversity of Californians or that devalue a person's right to health care based on race, ethnicity, age or disability status.

Sincerely,

A handwritten signature in purple ink, appearing to read 'Siri Vaeth', with a stylized flourish at the end.

Siri Vaeth, MSW
Executive Director
Cystic Fibrosis Research Institute (CFRI)

²² <https://www.thevalueinitiative.org/health-equity-initiative/>

²³ <https://ptehealth.org/vision>

²⁴ <https://pubmed.ncbi.nlm.nih.gov/34458963/>

Adrienne Shapiro
Founder
Axis Advocacy

Liz Helms
President and CEO
California Chronic Care Coalition

Rhonda Connolly
Board Member
Children's PKU Network/ NPKUA

Taelor Shweiki
Patient Advocate
Cutaneous Lymphoma Foundation

Tomisa Starr
Member
Jacob's Hugs

Thayer Roberts
Deputy Director
Partnership to Improve Patient Care

Kari Luther Rosbeck
President and CEO
TSC Alliance

Gunnar Esiason
EVP, Strategy & Advocacy
Boomer Esiason Foundation

Julie Kornack
Chief Strategy Officer
Center for Autism and Related Disorders

Katherine Perez
Director
The Coelho Center for Disability Law, Policy
and Innovation

Irma Resendez
CEO – Founder
Familia Unida Living With MS

James D. Lee
Public Policy Chair
Neuropathy Action Foundation

Christine Von Raesfeld
Founder
People with Empathy

Rosie Bartel
Patient Partner

Cc: Deputy Attorney General Anna Rich at Anna.Rich@doj.ca.gov