August 3, 2021

Andrew York
Executive Director
Maryland Prescription Drug Affordability Board
4160 Patterson Avenue
Baltimore, MD 21215

Dear Mr. York:

We understand that the rising cost of healthcare is a concerning issue that requires real solutions. As organizations representing patients and people with disabilities, the affordability of health care is a significant priority, and we look forward to working with state policymakers to manage health costs in a manner centered on meeting the health care needs of people with disabilities and chronic conditions. In doing so, we urge the state to avoid policies that would potentially discriminate by relying on discriminatory metrics such as the Quality-Adjusted Life Year (QALY) that have detrimental implications for access to needed care and treatment.

We are aware that the Maryland Prescription Drug Affordability Board (PDAB) is tasked with addressing high-cost prescription drug products and engaging diverse stakeholders in that process. As created by statute, the Board consists of five members who possess expertise in the fields of either health care economics or clinical medicine, thereby missing the critical voices of patients and people with disabilities. Therefore, it is essential that people with disabilities and chronic conditions, those who would be most impacted by these policies, are able to have a robust voice in this discussion. The undersigned organizations representing patients and people with disabilities would like to be resources to the PDAB as it strives to make balanced decisions and avoid unintended consequences for patient access to needed care.[1]

We are writing to share information with the Board about QALYs. As you may be aware, other states that have recently enacted similar legislation to create a Prescription Drug Affordability Board have included a bar on the use of metrics that discriminate such as QALYs.[2] As the Maryland PDAB initiates its work, we are hopeful that the entity will similarly take a stand against incorporating the use of QALYs in its deliberations. Recently, the Institute for Clinical and Economic Review (ICER), an entity that relies on QALYs in its value assessment studies and calls QALYs the "gold standard",[3] presented to the PDAB on how its work could be leveraged by the PDAB.[4]

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[1] https://ncd.gov/newsroom/2021/NFO-state-use-qaly-based-cost-effectiveness-reports
[2] Colorado Senate Bill 21-175, 10-16-1407(4)(a) and Oregon Senate Bill 844 A
[3] https://icer.org/news-insights/press-releases/icer-describes-qaly/
[4] https://pdab.maryland.gov/2021_board_meeting.html

As background. referencing discriminatory metrics such as QALYs can potentially violate existing civil and disability rights laws. 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 the cost to treat. We encourage you to review the report from the National Council on Disability, an independent federal agency, recommending that policymakers avoid referencing the QALY, clarifying that its use in public programs would be contrary to United States civil rights and disability policy.[5] Most recently, the National Council on Disability initiated work to review "State's use of QALY-Based Cost-Effectiveness Reports to Inform Medicaid Coverage for Prescription Drugs" which is anticipated to provide information on how QALYs are being used and their implications for restricting access to care.[6]

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.[7] Title II of the Americans with Disabilities Act (ADA) extended this protection to programs and services offered by state and local governments.[8] Based on the ADA's passage in 1990, in 1992 HHS rejected a state waiver application because its reliance on QALYs and cost effectiveness standards would have violated the ADA and lead to discrimination against people with disabilities in determining the state's prioritized list of services.[9]

In 2010, the Affordable Care Act (ACA) stated 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.[10] 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

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[5] 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.

[6] https://ncd.gov/newsroom/2021/NFO-state-use-qaly-based-cost-effectiveness-reports

[7] 29 USC Sec 794, 2017. Accessed November 30, 2020.

[8] 42 USC Sec 12131, 2017. Accessed November 30, 2020.

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

[10] 42 USC Sec 1320e, 2017. Accessed November 30, 2020.

incentivized.[11] 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 VBP arrangements.[12]

We hope that you will engage patients and people with disabilities in your current process and bear in mind these legal protections under health and civil rights laws as you work on policies to reduce the cost of care for beneficiaries. We appreciate the important work you are doing and stand ready to work with you on appropriate policies that do not discriminate or limit access to needed care and treatment. We would be happy to speak with the members of the Maryland PDAB about our concerns and the experiences of patients and people with disabilities. Please reach out to Sara van Geertruyden at sara@pipcpatients.org if you would like to discuss in more depth.

Sincerely,

Allergy & Asthma Network

Alliance for Aging Research

Alliance for Patient Access

ALS Association

American Association on Health & Disability

American Autoimmune Related Diseases Association

Autistic Self Advocacy Network

Axis Advocacy

Boomer Esiason Foundation

Cancer*Care*

Center for Autism and Related Disorders

Color of Crohn’s and Chronic Illness

Cystic Fibrosis Research Institute

Davis Phinney Foundation

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[11] 42 USC Sec 1320e, 2017. Accessed November 30, 2020.

[12] https://www.federalregister.gov/d/2020-12970

Diabetes Leadership Council

Diabetes Patient Advocacy Coalition

Epilepsy Foundation Maryland

Global Liver Institute

GO2 Foundation for Lung Cancer

Health Hats

ICAN, International Cancer Advocacy Network

International Foundation for Autoimmune & Autoinflammatory Arthritis (AiArthritis)

Lupus and Allied Diseases Association, Inc.

Lupus Foundation of America

Maryland Center for Developmental Disabilities at Kennedy Krieger Institute

Men's Health Network

MLD Foundation

Not Dead Yet

Partnership to Improve Patient Care

Rare New England

SYNGAP1 Foundation

The Bonnell Foundation: Living with cystic fibrosis

The Coelho Center for Disability Law, Policy and Innovation

TSC Alliance

United Spinal Association

VHL Alliance

Whistleblowers of America

ZERO - The End of Prostate Cancer