

May 2, 2023

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

comments.pdab@maryland.gov

Dear Mr. York:

The Partnership to Improve Patient Care (PIPC) is pleased to provide comments on the draft proposed regulations issued by the Maryland Prescription Drug Affordability Board, specifically related to the concerns of patients and people with disabilities related to the Board's potential use of cost effectiveness analyses. These comments follow the letter sent to the Board on August 3, 2021, from 38 organizations urging it 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. As you know, the organizations offered to be resources to the Board as it strives to make balanced decisions and avoid unintended consequences for patient access to needed care.¹

We are concerned that the draft regulations ignore the letter referenced above, instead specifically calling for information on cost effectiveness "derived from health economics and outcomes research" which is known to rely on biased and discriminatory measures such as QALYs. By devaluing people with disabilities, whether in terms of their life extension or quality of life, cost effectiveness analyses relying on QALYs and similar measures have no place in our health care system.

Recently, 56 organizations sent a letter to the Centers for Medicare and Medicaid Services (CMS) related to their initial guidance for implementing the Medicare Drug Price Negotiation Program. Their comments centered on three pillars: 1) creating additional procedures to meaningfully engage with patients and ensure that the evidence CMS relies on is transparent; 2) establishing patient-centered standards and outcomes; and 3) more definitively rejecting the use of Quality-Adjusted Life Years (QALYs) and other discriminatory cost-effectiveness standards. Their recommendations to CMS may also be useful to the Maryland Prescription Drug Affordability Board in its efforts to develop evidentiary standards and engagement practices that ensure patient benefits are central to decision-making. The letter is also attached as an appendix.² I hope that the Board will take into consideration each of its recommendations.

¹ <https://valueourhealth.org/wp-content/uploads/2021/08/MD-Letter-Final.pdf>

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

We strongly support standards for the research used to make judgements about therapeutic impacts of drugs, assuring it is centered on value to patients and people with disabilities and inclusive of real-world evidence.³ The same sentiment applies here to the Board's work if it is to truly be centered on patients and people with disabilities. Its decision-making process should be publicly transparent and avoid discriminatory research using QALYs or similar methods steeped in stigma in favor of measures that encourage treatments valued by patients and people with disabilities. The Board should begin by recognizing the historic discrimination from use of biased cost effectiveness measures such as QALYs to make decisions related to health care, instead of focusing on outcomes that matter to patients and people with disabilities.⁴

Therefore, we urge the Board to abandon its proposal to rely on cost effectiveness measures that are known to disproportionately impact care access for subpopulations already experiencing substandard health care, especially for people that too often experience discrimination doubly by virtue of being Black, Indigenous, or people of color and having a disability or chronic condition.⁵ We urge the Board to incorporate the recommendation of the National Council on Disability, an independent federal agency, calling for a blanket prohibition on QALYs, whether used directly or by reference to a third party, as part of its Health Equity Framework.⁶

We were particularly disappointed that the draft proposed regulations did not outline a robust process for engaging patients and people with disabilities. As outlined in the letter to CMS referenced above, engagement should happen early and often, including roundtables with affected patients and people with disabilities related to the treatments being considered by the Board, and concerted efforts to engage with diverse communities, especially those not represented in the data. We urge the Board to reference the best practices of the Patient-Centered Outcomes Research Institute (PCORI) outlined in its Patient Engagement Rubric,⁷ Compensation Framework,⁸ recommendations for Budgeting for Engagement Activities,⁹ and its Equity and Inclusion Guiding Principles¹⁰ providing insights on bringing diverse voices to the table. Robust patient engagement goes beyond public comment periods at a Board meeting and will require much more effort to capture outcomes that are valued by people living with the condition.

³ <https://www.healthaffairs.org/content/forefront/medicare-drug-price-negotiations-avoid-metrics-steeped-stigma>

⁴ <https://www.ajmc.com/view/is-the-qaly-fit-for-purpose->

⁵ https://www.thevalueinitiative.org/wp-content/uploads/2022/10/IVI_Sick-Cells_Equity-in-Value_2022.pdf

⁶ https://www.ncd.gov/sites/default/files/NCD_Health_Equity_Framework.pdf (Recommendation #8 on page 10)

⁷ <https://www.pcori.org/sites/default/files/Engagement-Rubric.pdf>

⁸ <https://www.pcori.org/sites/default/files/PCORI-Compensation-Framework-for-Engaged-Research-Partners.pdf>

⁹ <https://www.pcori.org/sites/default/files/PCORI-Budgeting-for-Engagement-Activities.pdf>

¹⁰ <https://www.pcori.org/sites/default/files/Equity-and-Inclusion-Guiding-Engagement-Principles.pdf>



Thank you for your consideration. I hope that the Board will strike reference to cost effectiveness measures in its final regulations and pursue robust engagement strategies with patients and people with disabilities.

Sincerely,

A handwritten signature in black ink that reads "Tony Coelho". The signature is written in a cursive style with a large initial "T" and "C".

Tony Coelho, Chairman
Partnership to Improve Patient Care