

May 13, 2024

Mr. Andrew York  
Executive Director  
Maryland Prescription Drug Affordability Board  
16900 Science Drive, Suite 112-114  
Bowie, MD 20715

Dear Mr. York:

I am writing on behalf of the Partnership to Improve Patient Care (PIPC) to comment on the Maryland Prescription Drug Affordability Board's ongoing Cost Review Study process. Our comments follow letters sent to the Board 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.<sup>1</sup> We are writing to update the Board on recent federal policy developments that increase clarity on the state's obligations and limitations.

On May 9, 2024, the final new regulations governing Section 504 of the Rehabilitation Act were published, protecting the rights of people with disabilities in programs and activities receiving federal financial assistance.<sup>2</sup> In response to the proposed rule last year, the Partnership to Improve Patient Care (PIPC) joined 100 organizations and individuals on a letter supporting agency rulemaking to bar the use of quality-adjusted life years and similar measures in decisions impacting access to care.<sup>3</sup>

The U.S. Department of Health and Human Services' rule represents a critical step forward to protecting patients and people with disabilities and sends a strong message that we need better solutions for U.S. decision-making that don't rely on the biased, outdated standards historically used by payers. As described in the final rule, the new regulations would bar health care decisions made using measures that discount gains in life expectancy, which would include measures such as the quality-adjusted life year (QALYs) and the combined use of QALYs and equal value of life years gained (evLYG). The agency broadly interpreted what constitutes the discriminatory use of value assessment in its description of the rule, stating, "The Department interprets recipient obligations under the current language of § 84.57 to be broader than section 1182 of the Affordable Care Act, because it prohibits practices prohibited by section 1182 (where they are used to deny or afford an unequal opportunity to qualified individuals

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

<sup>2</sup> [https://www.govinfo.gov/content/pkg/FR-2024-05-09/pdf/2024-09237.pdf?utm\\_campaign=subscription+mailing+list&utm\\_medium=email&utm\\_source=federalregister.gov](https://www.govinfo.gov/content/pkg/FR-2024-05-09/pdf/2024-09237.pdf?utm_campaign=subscription+mailing+list&utm_medium=email&utm_source=federalregister.gov)

<sup>3</sup> [https://www.pipcpatients.org/uploads/1/2/9/0/12902828/pipc\\_504\\_comment\\_final.pdf](https://www.pipcpatients.org/uploads/1/2/9/0/12902828/pipc_504_comment_final.pdf)

with disabilities with respect to the eligibility or referral for, or provision or withdrawal of an aid, benefit, or service) and prohibits other instances of discriminatory value assessment.” As you may be aware, section 1182 of the ACA bars Medicare’s use of QALYs and similar measures that discount the value of a life because of an individual’s disability. PIPC was pleased that the final rules governing Section 504 would be interpreted as broader than the section 1182 statute.

The agency referenced both § 84.56 and § 84.57 as relevant to entities receiving federal financial assistance, which includes state Medicaid programs. For example, the agency stated, “Methods of utility weight generation are subject to section 504 when they are used in a way that discriminates. They are subject to § 84.57 and other provisions within the rule, such as § 84.56’s prohibition of discrimination based on biases or stereotypes about a patient’s disability, among others.” Therefore, it will be critical for compliance with these rules that the Board understand the methods for generating the utility weights in any clinical and cost effectiveness studies that it may be using to make decisions to ensure they do not devalue people with disabilities. As PIPC and others noted in its comments to HHS, studies have confirmed inherent bias against people with disabilities in the general public, finding much of the public perceives that people with disabilities have a low quality of life.<sup>4</sup> Therefore, the potential for discrimination is significant when value assessments rely on public surveys, for example.

Alternatively, we would encourage the Board to engage directly with patients and people with disabilities to learn about their real-world experiences, consistent with recommendations from experts in the patient and disability communities.<sup>5,6,7,8</sup> We are also concerned about the transparency of the decision-making process by the Board and hope that the evidentiary basis for its decisions will be made public in a manner that is accessible and clear.

Thank you for your consideration of our comments.

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<sup>4</sup> Ne’eman Et. Al, “Identifying and Exploring Bias in Public Opinion on Scarce Resource Allocation During the COVID-19 Pandemic,” October 2022, <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2022.00504>.

<sup>5</sup> <https://nationalhealthcouncil.org/wp-content/uploads/2024/03/Amplifying-the-Patient-Voice-Roundtable-and-Recommendations-on-CMS-Patient-Engagement.pdf>

<sup>6</sup>

<https://www.pharmacy.umaryland.edu/media/SOP/wwwpharmacyumarylandedu/programs/PATIENTS/pdf/Patient-driven-recommendations-for-the-Medicare-Drug-Price-Negotiation-Program.pdf>

<sup>7</sup> <https://www.pcori.org/sites/default/files/PCORI-Engagement-in-Research-Foundational-Expectations-for-Partnerships.pdf>

<sup>8</sup> <https://thevalueinitiative.org/ivi-partners-with-academyhealth-to-address-economic-impacts-on-patients-and-caregivers/>

Sincerely,



Tony Coelho  
Chairman  
Partnership to Improve Patient Care