

October 15, 2024

Ms. MaryAnne Lindeblad, BSN, MPH
Chair
Washington State Prescription Drug Affordability Board

HCA_WA_PDAB@hca.wa.gov

Dear Ms. Lindeblad:

The Partnership to Improve Patient Care (PIPC) is writing to share with the Washington Prescription Drug Affordability Board (PDAB) the concerns of patients and people with disabilities related to the PDAB's potential use of cost effectiveness analyses. At the PDAB's most recent September meeting, members heard from entities advocating for the use of health technology assessments, economic valuations or cost effectiveness analyses, and, specifically, quality-adjusted life years (QALYs) and similar measures.¹ Therefore, it is important to be aware of the existing law and regulations that bar the use of QALYs and similar measures in decisions impacting reimbursement and coverage, as well as the inherent tradeoffs among different value assessment methods. QALYs and similar measures have no place in our health care system.

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.² 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.³

The U.S. Department of Health and Human Services' final 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and sends a strong message that we need better solutions for U.S. decision-making that don't rely on the biased, outdated standards historically used by payers.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

¹ <https://www.hca.wa.gov/assets/program/pdab-portal-slides-september-18-2024.pdf>

² 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

³ https://www.pipcpatients.org/uploads/1/2/9/0/12902828/pipc_504_comment_final.pdf

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 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 by the agency as broader than the section 1182 statute.⁴

The final rule 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 PDAB 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.⁵ Therefore, the potential for discrimination is significant when value assessments rely on public surveys, for example.

We are also concerned about the tradeoffs inherent in alternative approaches to the QALY. Every cost effectiveness measure has tradeoffs between conditions advantaged and disadvantaged. QALYs give less value to life-extending treatments among patients whose baseline health-related quality of life is low, particularly people living with disabilities. More value to treatments achieving maximum quality of life. The equal value of life year gained (evLYG) gives less value to treatments improving quality of life in extended life years, and uses the QALY’s values for treatments in when it does not extend life years regardless of benefits to quality of life. Generalized Cost Effectiveness Analysis (GCEA) gives less value to treatments for common conditions to manage symptoms and more value to treatments for severe and

⁴ 89 FR 40066, “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 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.”

⁵ 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>.

disabling conditions.⁶ Therefore, we urge the PDAB to avoid use of one-size-fits-all value metrics, like the QALY or evLYG, as part of its decision-making. It will be critical for the PDAB to identify and be transparent about the types and sources of research, data, and assessments considered in its decision-making process to allow for accountability of its work.

In addition, the PDAB should ensure it is exercising adequate oversight over entities that are advising it in this process to ensure they also do not rely on data from studies relying on one-size fits all metrics, like the QALY or evLYG. We are very concerned that entities including the Program on Regulation, Therapeutics, and Law (PORTAL) and the Institute for Clinical and Economic Review (ICER) publicly view the QALY as the gold standard for measuring cost effectiveness, a fact that will undermine the trust of patients and people with disabilities if they continue to be consulted in the PDAB's work.⁷

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.^{8,9,10,11} For example, a coalition of patients came together to develop a new survey instrument to understand the affordability challenges facing patients that we urge the PDAB to reference in its work.¹² Across other states, PDABs have struggled and too often failed to meaningfully incorporate patient perspectives or respond to their questions and concerns. We are hopeful Washington State's PDAB will do better.¹³

I hope that this information is useful to the PDAB as it moves forward in its deliberations. Thank you for your consideration.

⁶ https://www.pipcpatients.org/uploads/1/2/9/0/12902828/pipc_value_critique_updated.pdf

⁷ https://www.pipcpatients.org/uploads/1/2/9/0/12902828/icer_2023_framework_final_comment.pdf

⁸ <https://nationalhealthcouncil.org/wp-content/uploads/2024/03/Amplifying-the-Patient-Voice-Roundtable-and-Recommendations-on-CMS-Patient-Engagement.pdf>

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

¹⁰ <https://www.pcori.org/sites/default/files/PCORI-Engagement-in-Research-Foundational-Expectations-for-Partnerships.pdf>

¹¹ <https://thevalueinitiative.org/ivi-partners-with-academyhealth-to-address-economic-impacts-on-patients-and-caregivers/>

¹² <https://eachpic.org/pic-launches-patient-created-survey-on-drug-affordability-and-access/>

¹³ PIPC literature review of engagement recommendations, http://www.pipcpatients.org/uploads/1/2/9/0/12902828/pipc_recommendations_for_patient_engagement_final.pdf

Sincerely,



Tony Coelho
Chairman
Partnership to Improve Patient Care

cc:

Board members and staff