

May 14, 2024

Ms. Shelley Bailey, MBA
Chair
Oregon Prescription Drug Affordability
Board
Department of Consumer and Business
Services
350 Winter Street NE
Salem, OR 97309-0405

Mr. Ralph Magrish,
Executive Director
Oregon Prescription Drug Affordability
Board
Department of Consumer and Business
Services
350 Winter Street NE
Salem, OR 97309-0405

Dear Chair Bailey and Mr. Magrish:

I am writing on behalf of the Partnership to Improve Patient Care (PIPC) to comment on the Oregon Prescription Drug Affordability Board's ongoing affordability review activities. 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, as well as encouraging the Board to include patients and people with disabilities throughout its decision-making process.¹ I am writing to update the Board on recent federal policy developments that increase clarity on the state's obligations and limitations related to its use of discriminatory value assessments and to request robust engagement of patients and people with disabilities.

The State of Oregon has a long history related to the use of QALYs in developing its prioritized list of services under Medicaid. Over the last few years, PIPC was engaged in advocacy with the Health Evidence Review Commission (HERC) to shift away from the use of quality-adjusted life years (QALYs) and similar measures that discriminate. Recently, the legislature passed Senate Bill 1508 barring the use of generalized quality of life measures by statute.² We have been very concerned that the legislative provisions governing the use of QALYs and similar measures in legislation creating the Prescription Drug Affordability Board may be interpreted narrowly. Entities supporting the use of QALYs as the gold standard for value assessment, such as the Program on Regulation, Therapeutics and Law (PORTAL) and the Institute for Clinical and Economic Review (ICER), may be playing a role in the Board's decisions.

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.³ In response to the proposed rule last year, PIPC joined 100

¹ <https://caringambassadors.org/pnw-advocates-confab/>

² <https://www.drOregon.org/releases/landmark-legislative-healthcare-wins-for-people-with-disabilities>

³ 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

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.⁴

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 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 the final rules governing Section 504 would be interpreted as broader than section 1182.

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

In summary, the new rules clarify that recipients of federal financial assistance, including Medicaid programs, may not rely on measures like QALYs.

Alternatively, PIPC recommends:

⁴ https://www.pipcpatients.org/uploads/1/2/9/0/12902828/pipc_504_comment_final.pdf

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>.

- The Board should 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.^{6,7,8,9}
- The Board should collaborate directly with the patient and disability communities to solicit information. To date, we have seen very little participation from patients in the Board’s meetings and listening sessions. We are also concerned that the Board did not develop its survey for patients in collaboration with patients. We have learned from other states how survey data may be misleading or fail to solicit the kind of information that is most useful to Board decisions.^{10,11}
- The Board should respond to new federal regulations by making its process and decisions transparent related to its use of value assessments. We 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.

Sincerely,



Tony Coelho
Chairman
Partnership to Improve Patient Care

⁶ <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>

⁸ <https://www.pcori.org/sites/default/files/PCORI-Engagement-in-Research-Foundational-Expectations-for-Partnerships.pdf>

⁹ <https://thevalueinitiative.org/ivi-partners-with-academyhealth-to-address-economic-impacts-on-patients-and-caregivers/>

¹⁰ <https://drive.google.com/file/d/1oYGIPVVLrXL7ZXeu-eZ2vLZEunPhzN3u/view>

¹¹ <https://drive.google.com/file/d/1hF5-4Lxf5IHNNHMunRVm-fBaDt6QF-M3/view>