

October 30, 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:

We are writing as patients, people with disabilities, caregivers and their representative organizations to express our deep concerns about the Prescription Drug Affordability Board's (PDAB) work and its alignment with state and federal law. While we are relieved to hear that the PDAB is considering recommendations to the legislature to better support engagement of patients and people with disabilities, we remain concerned about the implications for access and affordability, such as the potential for dispensing fees to be passed on to patients. Our concerns are amplified by the Board's conversation around the potential use of cost effectiveness analyses, contrary to the state and federal laws that bar use of discriminatory value assessments in reimbursement and coverage decisions.

During the October 16, 2024 meeting of the PDAB, a Board member asked whether the use of value assessments would be permissible. The response was a resounding yes, with the caveat that the quality-adjusted life year (QALY) could not be considered. Specifically, the work of the Institute for Clinical and Economic Review (ICER) was mentioned, and the use of the equal value of life year gained (evLYG) measure of cost effectiveness. It was stated that ICER and evLYGs were permitted for use in the PDAB's decisions.

Since creation of the PDAB, patients and people with disabilities have shared their opposition to the Board's use of biased and discriminatory value assessments, including QALYs and evLYGs. When the PDAB was created, it was communicated to patient and disability advocates that the language in the statute would prevent the Board from considering these types of measures that devalue people with disabilities, including patients with serious chronic conditions. At the time, it was not transparent that the language in the statute was developed by ICER and therefore intended to have a loophole for consideration of the evLYG. We do not interpret the language as allowing for use of ICER's evLYG measure, which is developed using the same inputs as the QALY. We have shared with the Board our concerns about the involvement of PORTAL Research and OHSU, entities strongly aligned with ICER with the same funders as ICER. As you can imagine, the recent Board conversation only serves to entrench our distrust of a process that views entities supporting the use of QALYs and similar measures as its trusted advisors.

Not only are QALYs and similar measures barred from use by federal law, but they are also barred by state law. Federal regulations governing Section 504 of the Rehabilitation Act bar health care decisions made using measures that discount gains in life expectancy under § 84.57, as well as

methods of utility weight generation used in a way that discriminates under § 84.56's prohibition of discrimination based on biases or stereotypes about a patient's disability. In fact, HHS interpreted § 84.57 to be broader than section 1182 of the Affordable Care Act which bars the use of QALYs and similar measures in Medicare coverage and reimbursement decisions.

Also, the state legislature passed SB 1508 barring consideration of a quality of life in general measure, either directly or by considering a source that relies on a quality of life in general measure, in decisions related to the provision of and payments for health services. This language supplements the language in the PDAB law, providing a broader scope for the ban on use of discriminatory value assessments, closing any loopholes that be perceived in the PDAB law barring use of QALYs and similar measures. For example, SB 1508 clearly encompasses the evLYG which devalues disabled lives the same as the QALY in expected life years and uses the same health utilities that rely on biases and stereotypes from public surveys. It is contrary to state law to reference evLYG, QALY or related ICER studies.

Simply put, there is no one-size-fits-all measure of cost effectiveness that should be used as a benchmark for value. It is important for the PDAB to understand the alternative measures that it may be considering, including their limitations and tradeoffs. Their use and potential for use should be disclosed to the public and allow for patients and people with disabilities to share perspectives on the quality of the measure and its impact on health equity.

It has been a source of great frustration for patients and people with disabilities that ICER views the QALY as the gold standard for valuing health care. The fact that the PDAB views ICER and entities that are aligned with ICER's methodologies as credible sources will taint the work of the PDAB and our ability to trust its stated intentions to help patients. It will be essential for the PDAB to disclose the evidence on which it is relying so that it may be held accountable to the law's restrictions on use of QALYs and similar measures, as well as to the expectation that it is relying on high quality evidence.

Thank you for your consideration. We look forward to the PDAB clarifying if and how it will use cost effectiveness analyses or value assessments, how it will ensure any policy recommendations put forward to the legislature do not increase cost for patients, as well as how it will value input from patients and people with disabilities.

Sincerely,

ADAP Advocacy
Aimed Alliance
Answer2Cancer Inc.
Biomarker Collaborative
Cancer Support Community
Caring Ambassadors Program
Center for Autism and Related Disorders
Community Access National Network
Community Liver Alliance
Depression and Bipolar Support Alliance (DBSA)
Disability Rights California
Disability Rights Oregon

Epilepsy Foundation America
Exon 20 Group
HIV + Hepatitis Policy Institute
ICAN, International Cancer Advocacy Network
Lupus and Allied Diseases Association, Inc.
MET Crusaders
National Infusion Center Association (NICA)
Pacific Northwest Bleeding Disorders
Partnership to Improve Patient Care
PDL1 Amplifieds
PlusInc
The Bonnell Foundation
The Coelho Center for Disability Law, Policy and Innovation
The Hepatitis C Mentor and Support Group, Inc.
United Mitochondrial Disease Foundation

Individuals in Support
Paul Terdal
Health Hats
jacki gethner

cc: Governor Kotek
Members of the Oregon Legislature
TK Keen, DCBS