

October 13, 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  
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350 Winter Street NE  
Salem, OR 97309-0405

Dear Chair Bailey and Mr. Magrish:

I am writing to again share the comments submitted by the Partnership to Improve Patient Care (PIPC) on May, 14, 2024 urging the Prescription Drug Affordability Board (PDAB) 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. Additionally, we wanted to share the following comments related to the discussion at the prior PDAB meeting on October 2, 2024.

OHSU presented to the PDAB options for consideration that demonstrate its lack of awareness of the existing law and policy that bars the use of QALYs and similar metrics. The presentation outlined potential approaches for setting upper payment limits that included reference pricing to existing benchmarks. Among those included reference to prices in other countries, Veterans Affairs, and Medicare. OHSU also proposed use of cost effectiveness analyses, which historically rely on QALYs and similar measures. Like the Program on Regulation, Therapeutics and Law (PORTAL), the Institute for Clinical and Economic Review (ICER) and the National Association of State Health Policy (NASHP), OHSU's presentation is aligned with their perspectives supporting the use of tactics that devalue people with disabilities and ignore the potential consequences for patient access to care. The PDAB has continuously heard from patients and people with disabilities about their concerns with the PDAB's reliance on entities that support or at a minimum are complicit in the use of QALYs and similar measures. In fact, I testified to the Oregon legislature before it passed a bill barring the use of a "quality of life in general measure" like the QALY or similar measures<sup>1</sup> and testified on multiple occasions to the Health Evidence Review Committee.<sup>2</sup> Yet, the PDAB continues to rely on advice from entities that historically support their use, thereby creating distrust from people with disabilities and serious chronic conditions.

In response to OHSU's suggested reference to foreign health systems, we would emphasize that referencing other countries is contrary to federal laws governing disability discrimination. PIPC

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<sup>1</sup> <http://www.pipcpatients.org/blog/pipc-chair-testifies-before-oregon-house-committee-on-sb-1508>

<sup>2</sup> <http://www.pipcpatients.org/blog/chairmans-corner-chairman-coelho-testifies-in-oregon-against-use-of-qalys>

and others have commented on proposed federal policies that would reference prices in other countries, raising concerns that such a policy would import discriminatory standards from other countries, and lead directly to lack of access to needed treatments for many Americans.<sup>3</sup> We encourage the Board to review PIPC’s paper on the German system in which we discussed its limited use of evidence, inappropriate comparators and endpoints, exclusion of health outcomes that are important to patients, and failure to capture heterogeneity of patient populations.<sup>4</sup> PIPC would encourage the PDAB to also reference the work of the National Council on Disability, an independent federal agency advising Congress and the administration on disability policy, which has consistently recommended against referencing foreign prices in comments related to a proposed international pricing index,<sup>5</sup> Most Favored Nation policy,<sup>6</sup> and federal legislation.<sup>7</sup> The NCD’s recommendations against reliance on cost effectiveness are largely reflected in the new federal regulations discussed below, providing increased clarity on the prohibited use of discriminatory value assessments.

Additionally, it is important to recognize that the Veterans Health Administration has a partnership with ICER, a relationship that we are unaware of having changed since the recent regulations that bar all recipients of federal financial assistance from using discriminatory value assessments. As background, on June 27, 2017, ICER announced an agreement to work with the Department of Veterans Affairs (VA) Pharmacy Benefits Management Services office (PBM) to support its use of ICER drug assessment reports. Under this agreement, ICER works with VA staff to integrate ICER’s academic reports into the VA formulary management process of evaluating the comparative effectiveness and value of drugs. ICER relies on QALYs and the similar measure evLYG to assess the value of medications, measures barred by statute from use in Medicare due to its implications for discrimination. ICER’s value determinations are based on population-level averages that do not reflect individual differences among veterans and the military.

On November 13, 2017, organizations representing veterans, military families, patients and people with disabilities expressed concern to the VA about their partnership with ICER, stating, “Prescription drug coverage determinations based on flawed analyses like those conducted by ICER are not the answer and can only serve to further limit access to care for veterans with disabilities and serious chronic conditions, thereby exacerbating the challenges that they and their caregivers often face.”<sup>8</sup> Advocates expressed concern that ICER’s assessments do not reflect the unique needs of veterans, thereby potentially exacerbating the existing access

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<sup>3</sup> [https://www.pipcpatients.org/uploads/1/2/9/0/12902828/pipc\\_stakeholder\\_comment\\_on\\_importing\\_qalys.pdf](https://www.pipcpatients.org/uploads/1/2/9/0/12902828/pipc_stakeholder_comment_on_importing_qalys.pdf)

<sup>4</sup> [https://www.pipcpatients.org/uploads/1/2/9/0/12902828/germany\\_draft\\_2022\\_9-21\\_edited\\_clean.pdf](https://www.pipcpatients.org/uploads/1/2/9/0/12902828/germany_draft_2022_9-21_edited_clean.pdf)

<sup>5</sup> <https://www.ncd.gov/2020/08/05/ncd-statement-on-harm-of-using-international-pricing-index-for-u-s-prescription-drug-pricing/>

<sup>6</sup> <https://www.ncd.gov/letters/2021-01-15-ncd-letter-to-cms-on-most-favored-nation-rule/>

<sup>7</sup> <https://www.ncd.gov/letters/2021-04-29-ncd-letter-to-house-committees-with-concerns-regarding-h-r-3/>

<sup>8</sup> See [http://www.pipcpatients.org/uploads/1/2/9/0/12902828/va\\_letter\\_final.pdf](http://www.pipcpatients.org/uploads/1/2/9/0/12902828/va_letter_final.pdf)

challenges that they and their caregivers often face. The VA formulary is already more limited than Medicare’s formulary. The VA National Formulary frequently does not cover medications that ICER decides to be of low to intermediate value or imposes utilization management strategies recommended by ICER that create barriers to coverage through lengthy appeals or step therapy.

With regard to the Medicare Drug Price Negotiation Program, it has not yet provided clarification on its use of elements of studies that include QALYs or how it will use similar measures. Additionally, the agency has not provided patients and people with disabilities insight on how its decisions are being made, including how patient input is used or how cost effectiveness analyses are used. We cannot support reliance on Medicare’s decisions related to the Medicare Drug Price Negotiation Program knowing that the implications for patient access to care are unknown, the agency lacks transparency as to the evidence base for its decisions, and its methods for patient engagement have not been rigorous or robust.<sup>9</sup>

Finally, it is important to note that cost effectiveness analyses always come with risky tradeoffs for patients and people with disabilities. It is now widely recognized that traditional methods and metrics of value assessment – even beyond the QALY – have significant shortcomings. Well-intentioned development of other measures and approaches that developers assert to be nondiscriminatory and more patient-centered come with tradeoffs, need for improvement, and inherent methodological flaws. We urge the PDAB to avoid the use of cost effectiveness analyses that violate federal nondiscrimination laws and regulations and/or force tradeoffs such as whether to value life extension or quality of life improvement. No patient is average, and no measure of value should assume so.<sup>10</sup>

We appreciate your consideration and urge the PDAB to also review our prior letter sharing details of the law and existing regulations governing its use of cost effectiveness analyses. We look forward to development of strategies for incorporating input from patients and people with disabilities in a meaningful way, including use of the new survey developed by the Patient Inclusion Council.<sup>11</sup>

Sincerely,



Tony Coelho  
Chairman, Partnership to Improve Patient Care

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<sup>9</sup> <http://www.pipcpatients.org/resources/cms-publishes-final-guidance-for-2026-2027-implementation-of-negotiation-program>

<sup>10</sup> [https://www.pipcpatients.org/uploads/1/2/9/0/12902828/pipc\\_value\\_critique\\_updated.pdf](https://www.pipcpatients.org/uploads/1/2/9/0/12902828/pipc_value_critique_updated.pdf)

<sup>11</sup> <https://eachpic.org/pic-launches-patient-created-survey-on-drug-affordability-and-access/>

May 14, 2024

Ms. Shelley Bailey, MBA  
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Board  
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Mr. Ralph Magrish,  
Executive Director  
Oregon Prescription Drug Affordability  
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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.<sup>1</sup> 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.<sup>2</sup> 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

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

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

federal financial assistance.<sup>3</sup> In response to the proposed rule last year, 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>4</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 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.<sup>5</sup> Therefore, the potential for discrimination is significant when value assessments rely on public surveys, for example.

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<sup>3</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>4</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)

<sup>5</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>.

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:

- 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.<sup>6,7,8,9</sup>
- 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.<sup>10,11</sup>
- 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

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<sup>6</sup> <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>

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

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

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

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