

September 4, 2025

Vernon Rowen  
Executive Director  
Minnesota Prescription Drug Affordability Board  
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Dear Mr. Rowen:

The Partnership to Improve Patient Care (PIPC) is writing to share with the Minnesota 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 meeting, members heard from the Institute for Clinical and Economic Review (ICER), an entity that conducts value assessments of new health innovations using quality-adjusted life years (QALYs) and similar measures.<sup>1</sup> Knowing this perspective is being considered by the Board, it is important the Board also 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.

As the original author of the Americans with Disabilities Act (ADA), I feel strongly that QALYs and similar measures devaluing disabled lives have no place in our health care system. Over 100 organizations representing patients and people with disabilities agree.<sup>2</sup>

### **Federal Law Bars Use of QALYs and Similar Measures**

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>3</sup> The Partnership to Improve Patient Care (PIPC) joined 100 organizations and individuals on a letter supporting a rulemaking to bar the use of quality-adjusted life years and similar measures in decisions impacting access to care.<sup>4</sup> The final rule represents a critical step forward in protecting patients and people with disabilities against being devalued in health systems and sends a strong message that we need better solutions for U.S. decision-making that don't rely on the biased, outdated standards historically used by payers.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 QALYs and the equal value of life years gained (evLYG). The agency broadly interpreted what constitutes the

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

<sup>2</sup> <https://files.constantcontact.com/e7a90be4701/2e199106-a152-4598-838b-1b08dce510c2.pdf>

<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)

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.<sup>5</sup> The language of the new rule reflects the shared bipartisan perspectives that were communicated widely early in the COVID-19 pandemic, consistent with the first Trump administration taking action to enforce disability rights laws against state Crisis Standards of Care that would have put people with disabilities at the back of the line for care in a shortage.<sup>6,7</sup>

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 comments to HHS, studies have confirmed inherent bias against people with disabilities in the general public, finding much of the public perceives

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<sup>5</sup> 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.”

<sup>6</sup> “We’re concerned that crisis standards of care may start relying on value judgments as to the relative worth of one human being versus another, based on the presence or absence of disability,” said Roger Severino, the director of the Office for Civil Rights. “We’re concerned that stereotypes about what life is like living with a disability can be improperly used to exclude people from needed care.” See <https://www.npr.org/2020/03/28/823254597/hhs-warns-states-not-to-put-people-with-disabilities-at-the-back-of-the-line-for>

<sup>7</sup> “Traditionally, American health care policy and treatment approaches have largely been driven by the concepts of cost-effectiveness analysis (CEA) and quality-adjusted life year (QALY). But these approaches are inherently discriminatory. They devalue the life of people with disabilities and older adults.” See <https://www.warren.senate.gov/imo/media/doc/2020.04.09%20Letter%20to%20HHS%20OCR%20re%20Rationing%20of%20Care.pdf>

that people with disabilities have a low quality of life.<sup>8</sup> Therefore, the potential for discrimination is significant when measures rely on public surveys, as do QALYs and the evLYG.

### **Tradeoffs Among Cost Effectiveness Measures**

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, notably people living with disabilities, and more value to treatments achieving the notion of maximum quality of life. The evLYG gives less value to treatments improving quality of life in extended life years and uses the QALY's values for treatments in when treatments do not extend life years regardless of benefits to quality of life.<sup>9</sup> 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 be accountable for its work.

### **Bias Inherent Among Entities Supporting Use of QALYs and Similar Measures Undermines Trust and Credibility of PDAB**

The PDAB should avoid reliance on entities that support use of 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 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.<sup>10</sup>

### **Meaningful Engagement of Patients and People with Disabilities is Critical**

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

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<sup>8</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>9</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>10</sup> [https://www.pipcpatients.org/uploads/1/2/9/0/12902828/icer\\_2023\\_framework\\_final\\_comment.pdf](https://www.pipcpatients.org/uploads/1/2/9/0/12902828/icer_2023_framework_final_comment.pdf)

experts in the patient and disability communities.<sup>11,12,13,14</sup> 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.<sup>15</sup> Despite these constructive efforts, other state PDABs have struggled and too often failed to meaningfully incorporate patient perspectives or respond to their questions and concerns. We are hopeful Minnesota's PDAB will do better.<sup>16</sup>

### **Reference to Maximum Fair Price is Not a Solution**

We are similarly concerned that the Minnesota PDAB is considering a policy alternative to automatically set Medicare's "maximum fair price" as the upper payment limit (UPL) for drugs purchased in Minnesota whose price has been negotiated at the federal level. By doing so, the legislation removes opportunities for public input on potential access issues, raising concerns that treatment options will be limited without guaranteed cost savings for beneficiaries. By referencing Medicare drug prices, the state risks referencing the use of discriminatory measures of cost effectiveness, quality-adjusted life years (QALYs) and similar measures, on which CMS has in the past collected information to establish these "maximum fair prices".<sup>17</sup>

Such a policy also raises significant concerns for the patient and disability communities that have long fought for a seat at the table in decisions related to health coverage and reimbursement policy and against health care discrimination. As a person with a disability myself and the original author and sponsor of the ADA, I share these concerns. The PDAB should have a process for considering how a reference to Medicare prices may impact patient access to care, particularly how it may lead to misuse of utilization management tools by payers.

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<sup>11</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>13</sup> <https://www.pcori.org/sites/default/files/PCORI-Engagement-in-Research-Foundational-Expectations-for-Partnerships.pdf>

<sup>14</sup> <https://thevalueinitiative.org/ivi-partners-with-academyhealth-to-address-economic-impacts-on-patients-and-caregivers/>

<sup>15</sup> <https://eachpic.org/wp-content/uploads/2025/08/FINAL-PIC-Patient-Experience-Survey-Prescription-Drug-Affordability-and-Unaffordability-1.pdf>

<sup>16</sup> PIPC literature review of engagement recommendations, [http://www.pipcpatients.org/uploads/1/2/9/0/12902828/pipc\\_recommendations\\_for\\_patient\\_engagement\\_final.pdf](http://www.pipcpatients.org/uploads/1/2/9/0/12902828/pipc_recommendations_for_patient_engagement_final.pdf)

<sup>17</sup> <https://aesara.com/wp-content/uploads/2025/05/10-Poster-Is-the-IRA-Drug-Price.pdf>

## Conclusion

Affordable access to health care is a significant priority. State policymakers must manage health costs in a manner centered on both affordability and access to meet the differing health care needs of people with disabilities and chronic conditions. In doing so, PIPC urges Minnesota to avoid policies that would potentially violate federal laws against devaluing people with disabilities and older adults, including new regulations governing Section 504 of the Rehabilitation Act, by relying on discriminatory metrics such as the QALY that have detrimental implications for access to needed care and treatment. The consequence of devaluing patients and people with disabilities is real, with implications for formulary placement, delayed or denied care, and increased out-of-pocket costs for patients choosing the care their doctors prescribe and that best meets their health needs even when it is not preferred by payers or health economists. We do not need more policies putting payers between decisions made by doctors and patients.

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

Sincerely,



Tony Coelho  
Chairman  
Partnership to Improve Patient Care

cc:

Board members and staff