

February 6, 2025

Honorable Luke E. Torian
Chair, House Appropriations Committee
General Assembly Building, Room 1223
201 North 9th Street
Richmond, VA 23219

Honorable Rodney T. Willett
Chair, Subcommittee on Health and Human
Resources
General Assembly Building, Room 1012
201 North 9th Street
Richmond, VA 23219

Dear Chair Torian and Chair Willett:

The Partnership to Improve Patient Care (PIPC) is writing to share the concerns of patients and people with disabilities related to efforts in Virginia to establish a Prescription Drug Affordability Board (PDAB). We oppose HB 483 and SB 271 which would allow for reference to value assessments of new health innovations using quality-adjusted life years (QALYs) and similar measures.¹ Over 100 organizations representing patients and people with disabilities agree.²

HB 483 Fails to Meaningfully Bar the Use of QALYs and Similar Measures

The Virginia bill include the same provision which was originally in legislation that passed in the State of Washington and later Oregon. This provision was communicated to patients and people with disabilities during legislative consideration in those states as a ban on the use of QALYs and similar metrics,³ but, in practice, it has failed to be interpreted as one. This provision was originally crafted by the Institute for Clinical and Economic Review (ICER), an entity that conducts value assessments that rely on QALYs and the similar measure called the equal value of life year gained (evLYG), which similarly devalues disabled lives in its failure to accurately value quality of life and quality of life improvement. ICER calls QALYs the “gold standard” despite federal law barring their use.⁴ Several entities, with support from Arnold Ventures - including ICER- continue pushing for infusion of QALY-based cost effectiveness measures to inform Medicare and Medicaid coverage and payment decisions,⁵ in direct conflict with the

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

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

³ See <https://icer.org/our-approach/methods-process/cost-effectiveness-the-qaly-and-the-evlyg/>

⁴ “States that explore prescription drug affordability review authority through Medicaid DUR boards or PDABs should consider safeguard language such as that developed by ICER and used by Washington state that sets standards for the use of the quality-adjusted life year (QALY) or other measures of health improvement in cost-effectiveness analysis to address concerns regarding discrimination against individuals living with chronic disabilities.” See https://icer.org/wp-content/uploads/2023/03/ICER_CA_CER_White_Paper_031623_1.pdf

⁵ Authors supported by Arnold Ventures stated, “Congress should explicitly authorize, if not require, CMS to consider cost-effectiveness...” see <https://www.healthaffairs.org/content/forefront/addressing-costs-through-pricing-and-coverage-policy>

recommendations of the National Council on Disability, an independent federal agency advising Congress and the administration on disability policy. Regardless of the political party in charge, NCD's position has always been that policymakers should avoid referencing QALYs, whether directly or indirectly from entities like ICER or from referencing other prices that were also established using QALYs.⁶

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.⁷ The Partnership to Improve Patient Care (PIPC) and the 100 organizations and individuals that were supportive of rulemaking to bar the use of quality-adjusted life years and similar measures in decisions impacting access to care⁸ were pleased to see the final rule, which 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 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.⁹ 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

⁶ National Council on Disability. (November 16, 2019). Quality-Adjusted Life Years and the Devaluation of Life with Disability. <https://www.ncd.gov/report/quality-adjusted-life-years-and-the-devaluation-of-life-with-a-disability/>

⁷ 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
⁸ https://www.pipcpatients.org/uploads/1/2/9/0/12902828/pipc_504_comment_final.pdf

⁹ 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."

against state Crisis Standards of Care that would have put people with disabilities at the back of the line for care in a shortage.^{10,11}

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 that people with disabilities have a low quality of life.¹² 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.¹³ Therefore, Virginia should avoid use of one-size-fits-all value metrics, like the QALY or evLYG, as part of its decision-making.

¹⁰ “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>

¹¹ “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>

¹² 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>.

¹³ https://www.pipcpatients.org/uploads/1/2/9/0/12902828/pipc_value_critique_updated.pdf

Reference to Maximum Fair Price is Not a Solution

We are similarly concerned that the legislation advances a policy alternative to set Medicare’s “maximum fair price” as the upper payment limit (UPL) for drugs purchased in Virginia 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”.¹⁴

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.

Meaningful Engagement of Patients and People with Disabilities is Critical

Alternatively, we encourage Virginia 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.¹⁵ For example, a coalition of patients came together to develop a new survey instrument to understand the affordability challenges facing patients and how to address them.¹⁶ Despite these constructive efforts, other state PDABs have struggled and too often failed to meaningfully incorporate patient and disability perspectives, respond to their questions and concerns or establish safeguards against unintended consequences for patient care.¹⁷

Conclusion

As recently written in Health Affairs by two leaders in the disability community, the Honorable Tony Coelho and the Honorable Cathy McMorris Rodgers, “While PDABs exist to reduce system costs, they’re doing so at the expense of patients and people with disabilities.” Others have made similar statements.¹⁸ We can all agree that affordable access to health care is a significant priority. Therefore, 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

¹⁴ <https://aesara.com/wp-content/uploads/2025/05/10-Poster-Is-the-IRA-Drug-Price.pdf>

¹⁵ <https://www.pipcpatients.org/resources/recommendations-for-enhancing-patient-engagement-strategies>

¹⁶ <https://eachpic.org/patient-experience-revisited-what-patients-say-about-prescription-drug-affordability-and-policies-to-resolve-patient-hardships/>

¹⁷ <https://www.healthaffairs.org/sponsored-content/national-minority-quality-forum/state-prescription-drug-affordability-boards-when-cost-takes-precedence-over-patient-health>

¹⁸ “PDABs claim to promote affordability, but they can reduce access to medicines without guaranteeing real savings for patients.” See <https://www.healthaffairs.org/sponsored-content/national-minority-quality-forum/prescription-drug-affordability-boards-a-flawed-approach-to-equity-and-access>

chronic conditions. In doing so, PIPC urges Virginia 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. Thank you for your consideration.

Sincerely,

Thayer Roberts

Deputy Director
Partnership to Improve Patient Care

CC: Governor Abigail Spanberger