PIPC Partnership to Improve Patient Care

August 17, 2026

The Honorable Ron Wyden
Ranking Member
Committee on Finance
United States Senate
Washington, DC 20510

Submitted electronically to drugs@finance.senate.gov

RE: Response to the Senate Finance Committee Minority Staff Request for Information, "Commonsense Policy Options to Lower Drug Prices for Patients" (June 16, 2026)

Dear Ranking Member Wyden and Members of the Committee:

We appreciate the opportunity to provide comments in response to the Senate Finance Committee minority staff's request for information (RFI), *Commonsense Policy Options to Lower Drug Prices for Patients*.

We represent patients, people with disabilities, caregivers, clinicians, and other healthcare stakeholders dedicated to ensuring that healthcare decisions — including those that determine access to and affordability of prescription drugs — are centered on patients and people with disabilities and grounded in evidence that reflects their needs and experiences. We support the development and use of evidence centered on patients and people with disabilities to drive informed healthcare decisions and oppose reliance on quality-adjusted life years (QALYs) and similar measures of cost-effectiveness that devalue individuals with disabilities, serious illness, or advanced age.[1]

We share the Committee's goal of making prescription drugs more affordable. We also believe that lower costs must be accomplished in tandem with ensuring patients are able to access the treatments prescribed by their physicians and tailored to their individual needs. Policies intended to reduce costs should improve affordability, ensure access, strengthen informed decision-making, preserve longstanding disability protections, and minimize patient out-of-pocket costs. With those principles in mind, we offer the following comments on the proposals outlined in Section I of the RFI.

We oppose any reliance on foreign reference pricing and, by extension, value metrics used by other countries such as the QALY, in U.S. pricing or coverage policy.

We oppose incorporating international reference prices into the Medicare Drug Price Negotiation Program's ceiling or process — whether as a new factor considered in negotiation, a new prong in the ceiling price calculation, or a discount tied to a percentage of an international benchmark.

[1] https://www.pipcpatients.org/uploads/1/2/9/0/12902828/pipc_ipay_2028_comment_letter.pdf

QALYs are not a hypothetical concern. In countries that rely on QALYs and similar discriminatory metrics, patients with disabilities and complex conditions are routinely not able to access the medications that would best control their conditions and that are recommended by their physicians.[2] The National Council on Disability (NCD) has been quite clear that coverage denials and access restrictions are commonplace for people with disabilities in countries that rely on the QALY and that this should be anticipated here if the U.S. moved to such a system.[3]

PIPC recently published a paper examining how Health Technology Assessment (HTA) processes in the UK diverge from the U.S.' patient-centered principles,[4] including key shortcomings such as:

- Failure to meaningfully capture the full range of outcomes (health and quality of life) that matter to patients and caregivers;
- Imposition of evidence standards that disadvantage patients with serious diseases and conditions;
- Lack of transparency and flexibility in HTA processes; and
- Failure of patient input to meaningfully shape decision outcomes.

Together, these features often result in long delays in access to new tests and treatments for UK patients and reduced flexibility for physicians to tailor care to the needs of different patients. The concept of a QALY originated in the UK where it became a single national standard by which the government makes decisions about healthcare resource distribution, or care rationing. While many wealthier countries in Europe and elsewhere have embraced the QALY as part of their national health systems in order to ration healthcare resources, the U.S. has consistently enacted laws and regulations to prevent replicating their use to drive reimbursement and coverage decisions, instead working to strengthen the role of patients and people with disabilities in research and treatment decision-making. As U.S. policymakers consider approaches modeled on countries like the UK, understanding how these underlying systems shape access and decision-making is critical to ensuring that efforts to lower costs do not come at the expense of patient-centered care.[5]

More than 100 patient, disability, aging, and caregiver organizations have formally opposed international reference pricing models on these grounds, warning that both models would import the values and standards of countries that routinely deprioritize patients with serious diseases and disabling conditions.[6]

Congress has historically shared these concerns. In the Affordable Care Act (ACA), Congress prohibited Medicare from using QALYs and similar measures of cost effectiveness that devalue the lives of older, disabled, or seriously ill patients — protections carried forward and reinforced in the Inflation Reduction Act (IRA) itself.[7] In fact, the United States has a thirty-year, bipartisan

[2] https://www.pipcpatients.org/international.html
[3] National Council on Disability. Quality-Adjusted Life Years and the Devaluation of Life with Disability. November 16, 2019. https://ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf
[4] https://www.pipcpatients.org/uploads/1/2/9/0/12902828/uk_health_care_system_-_pipc_white_paper__4_.pdf
[5] https://www.pipcpatients.org/uploads/1/2/9/0/12902828/uk_health_care_system_-_pipc_white_paper__4_.pdf
[6] https://www.pipcpatients.org/resources/pipc-100-orgs-submit-comments-to-cms-innovation-center-on-globeguard-models
[7] 42 U.S.C. § 1320e; Seo, Thorpe, and Mattingly, supra note 10.

track record of opposing the use of the QALY or similar discriminatory metrics and establishing appropriate legal safeguards to mitigate their use. Among these safeguards, in 2010, the ACA directly stated that the Secretary of Health and Human Services (HHS) has no authority to deny coverage of items or services "solely on the basis of comparative effectiveness research" nor to use such research in a manner that would attribute a lower value to extending the lives of older adults, people with disabilities or people with a terminal illness.[8]

Additionally, the ACA specifically prohibits QALYs and similar metrics from being used by HHS as a threshold to establish what type of healthcare is cost effective or recommended, as well as prohibiting their use as a threshold in Medicare to determine what is covered, reimbursed or incentivized.[9] In Medicaid, based on passage of the Americans with Disabilities Act (ADA) in 1990, the administration established in 1992 that it would be a violation of the ADA for state Medicaid programs to base coverage decisions on cost effectiveness measures that give a lower value to people with disabilities.[10]

Regulations advanced in the Biden administration doubled down on the U.S. posture opposing reference to QALYs in healthcare decision-making. When Congress passed Section 504 of the Rehabilitation Act in 1973, the law was intended to ensure that people with disabilities will not be "excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination," under any program offered by any Executive Agency, including Medicare.[11] Title II of the ADA extended this protection to programs and services offered by state and local governments.[12] In 2024, the Biden administration updated the final regulations governing Section 504 to explicitly bar use of "any measure, assessment, or tool that discounts the value of life extension on the basis of disability 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 any aid, benefit, or service, including the terms or conditions under which they are made available."[13]

We also appreciated the agency's clarification that "discounting the value of quality of life on the basis of disability for purposes of denying or limiting medical treatment to a qualified individual with a disability would likely violate § 84.56." The agency also 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." Taken together, HHS interpreted the obligations of entities receiving federal financial assistance to be broader than the ACA's QALY ban because it prohibits unequal access and prohibits discriminatory value assessment. This language implies that the final rule holistically is intended to be interpreted in a manner that is consistent with, and broader than, the law barring the use of QALYs and similar measures in Medicare.[14] Any drug pricing policy would not only need to

[8] 42 USC Sec 1320e, 2017. Accessed November 30, 2020.
[9] 42 USC Sec 1320e, 2017. Accessed November 30, 2020.
[10] Sullivan, Louis. (September 1, 1992). Oregon Health Plan is Unfair to the Disabled. *The New York Times*.
[11] 29 USC Sec 794, 2017. Accessed November 30, 2020.
[12] 42 USC Sec 12131, 2017. Accessed November 30, 2020.
[13] 89 FR 40066, § 84.57
[14] https://www.pipcpatients.org/resources/hhs-finalizes-the-regulations-on-section-504-of-the-rehab-act-clarifying-rules-for-nondiscrimination

avoid direct reference to QALYs but also indirect reference implicated by incorporating prices derived from QALYs and/or similar measures from another country or third party health technology assessment.

The aim of these statutory and regulatory protections is not to encourage workarounds, but to ensure that measures used in federal programs do not disadvantage individuals based on age, disability, or health status. As once discussed on the Senate floor, the spirit of these provisions was to protect vulnerable populations from policies that "set national practice standards or coverage restrictions" and to ensure that research used in such decisions is grounded in meaningful clinical outcomes.[15] This robust record shows that policymakers on both sides of the aisle fully understand the discriminatory implications of the QALY, yet, the RFI's list of potential comparator countries— Canada, Denmark, France, Germany, Italy, Japan, Switzerland, and the U.K. — all rely on formal health technology assessments that use the QALY as a central or supporting metric.[16] An independent analysis found that 18 of 19 countries referenced in the Trump administration's recent international reference pricing proposals use QALYs. [17] Referencing those countries' prices in the Medicare Drug Price Negotiation Program would import the discriminatory consequences of QALY-based value assessments.

We urge the Committee not to pursue international reference pricing as a mechanism to expand the Medicare Drug Price Negotiation Program or as a pathway to lower prices in the commercial market. We would welcome working with the Committee on approaches to lower out-of-pocket costs for patients that do not rely on importing foreign cost-effectiveness judgments into the American healthcare system that are known to delay and deny access to care in countries that embrace care rationing.

The Inflation Reduction Act's Medicare Drug Price Negotiation Program is not centered on the needs of patients and people with disabilities.

We support efforts to improve prescription drug affordability while ensuring Medicare decisions remain transparent, patient-centered, and grounded in evidence that reflects patients' needs and experiences. Yet, we are concerned that the Medicare Drug Price Negotiation Program is not aligned with advancing affordable access to individualized care. Many of the structural flaws raised by patients and people with disabilities since the program's implementation have not been addressed.[18]

Though Medicare is barred from using QALYs and similar measures to make coverage and reimbursement decisions, the Centers for Medicare and Medicaid Services (CMS) has cited several National Institute for Health and Care Excellence (NICE) and Institute for Clinical and Economic Review (ICER) studies as part of its explanations of Maximum Fair Prices (MFPs) under the Medicare Drug Price Negotiation Program in both Initial Payment Applicability Year (IPAY)

[15] Colloquy by Senators Baucus, Enzi, Conrad, Hatch, Carper and Menendez. "Comparative Effectiveness Research Funds." Congressional Record 155:24 (February 6, 2009) p. S. 1796.
[16] Jason Shafrin, Richard Xie, and Louis P. Garrison Jr., "How Foreign Reference Pricing Embeds Valuations And Risks Undermining Global Innovation," Health Affairs Forefront, June 24, 2026, https://www.healthaffairs.org/content/forefront/import-price-import-threshold-foreign-reference-pricing-embeds-valuations-and-risks.
[17] https://www.pipcpatients.org/news/the-data-mine-new-analysis-by-highlights-why-the-us-could-back-into-use-of-qalys-by-referencing-other-countries.
[18] https://www.pipcpatients.org/uploads/1/2/9/0/12902828/joint_comment_to_cms_on_negotiation.pdf

2026 and 2027. Both NICE and ICER rely heavily on the QALY and similar measures to do their work based on budgetary considerations rather than supporting coverage and reimbursement decisions that match patient needs. Also, the explanations for development of MFPs omitted high-quality patient experience data, including some developed in partnership with CMS's colleagues at the Food and Drug Administration (FDA). In at least one example, the "Voice of the Patient" report that exists for the negotiated drug was clearly not cited by CMS and for other drugs the citations to the FDA website did not clearly indicate that the associated "Voice of the Patient" reports were part of the cited evidence informing its decision-making process.

Experience with implementation of the Medicare Drug Price Negotiation program to date reinforces our concerns about the program undermining patient-centered care. The process still lacks adequate patient engagement, evidentiary transparency, and enforceable QALY safeguards. We do not support extending the program's existing shortcomings to a larger share of the Medicare population. Instead, we encourage the Committee to use its oversight authority to urge stronger patient engagement, evidentiary disclosure, and QALY safeguards.

We support ongoing evaluation of the impact of maximum fair prices and policies to address unintended consequences quickly.

Ongoing, robust engagement from patients and providers will be needed even after implementation of MFPs to mitigate or address any barriers to patient access for needed treatments that result from the program. We urge the Committee to take the time to evaluate the impact of the program, including engagement of patients, people with disabilities and caregivers to understand their real-world experiences accessing selected drugs and the "alternatives" that may or may not be preferred on a formulary. In this modern age, more is understood about the differential impact of any given treatment on different patients, i.e. heterogeneity of treatment impact. The goal should be paving the way for patients to receive the treatment best for them.

Unfortunately, there is significant reporting and concern about egregious prior authorization and other utilization management policies that undermine personalized medicine and individualized treatment. Understanding unintended consequences related to the implementation of MFPs will allow policymakers to respond in real time and support continuous learning and improved policy making. For example, while the IRA requires selected Part D drugs to be included on formularies, CMS did not establish uniform tier placement or utilization management requirements for selected drugs in 2026, meaning formulary coverage does not translate into unrestricted access at the point of care as demonstrated by initial rejection rates.[19] A survey of plans showed that most will add utilization management tools such as step therapy to prefer competitor products with rebates over negotiated drugs and limit the number of therapeutic options in negotiated product classes, achieving the opposite of expanded patient choice to receive individualized care.[20]

[19] https://www.iqvia.com/locations/united-states/blogs/2026/07/rejection-rates-unchanged-by-mfp-drug-coverage-requirement
[20] https://www.magnoliamarketaccess.com/wp-content/uploads/UM_Blog-Post_2025.10.06-v2.pdf

Therefore, we encourage taking the time necessary to revisit the processes for implementation of the program and address any shortcomings going forward as policymakers learn more about program's impact on patients and people with disabilities.

Conclusion

We appreciate the opportunity to share our perspective on these proposals, and we share the Committee's commitment to lowering the price patients pay for prescription drugs. We urge the Committee, however, to pursue that goal in ways that strengthen, rather than bypass, existing patient protections. That means addressing the patient engagement, evidentiary transparency, and QALY safeguard gaps in the current Medicare Drug Price Negotiation and rejecting international reference pricing as a mechanism for negotiation. We urge a focus on policies that prevent payers from rejecting access to treatments that work best for individual patients and people with disabilities. No patient is average.

We stand ready to work with the Committee in developing thoughtful policies that are aligned with informed decision-making and personalized medicine. Thank you again for the opportunity to comment, and please do not hesitate to contact us with any questions at sara@pipcpatients.org.

Sincerely,

Ability Resources
ACCSES
ADA Watch/Coalition for Disability Rights & Justice
AiArthritis
Akari Foundation
Alliance for Aging Research
Alliance for Patient Access
ALS Association
American Academy of Nursing
American Association of Kidney Patients
American Association of People with Disabilities
American Association on Health and Disability
American Behcet's Disease Association
Association on Aging in New York
Autism Insurance for Oregon
Autistic Women & Nonbinary Network
Avery's Hope
Blue Ridge Independent Living Center
Bonnie M Ryan, Attorney
Cancer Support Community
Cancer*Care*
Caregiver Action Network
Lakeshore Foundation
Lane Independent Living Alliance
Living Beyond Breast Cancer
Living Hope Wheelchair Association
Lupus and Allied Diseases Association, Inc.
Lupus Colorado
MLD Foundation
Multiple Sclerosis Foundation
National Disability Rights Network (NDRN)
National Down Syndrome Society
National Mental Health Consumers' Self-Help Clearinghouse
National Minority Quality Forum
National Organization of Nurses with Disabilities
Neuropathy Action Foundation
Nevada Chronic Care Collaborative
Northern Regional Center for Independent Living
Not Dead Yet
Partnership to Improve Patient Care
Patients' Rights Action Fund
RASopathies Network

PIPC Partnership to Improve Patient Care

Chronic Care Policy Alliance
Color of Gastrointestinal Illnesses (COGI)
Cure LGMD2i Foundation
Cystic Fibrosis Research Institute
Davis Phinney Foundation
Depression and Bipolar Support Alliance
Diabetes Leadership Council
Diabetes Patient Advocacy Coalition
Disabilities Resource Center of Siouxland
Disability Policy Consortium
disAbility Resource Center
Disability Rights Education and Defense Fund
Eastern Shore Center for Independent Living
Epilepsy Alliance America
Epilepsy Foundation New England
Epilepsy Foundation of America
Exceptional Child Center
Free ME from Lung Cancer
Genetic Alliance
Global Colon Cancer Association
GO2 for Lung Cancer
Health Hats
HealthHIV
Healthy Men Inc.
Huntington's Disease Society of America
Hypertrophic Cardiomyopathy Association
ICAN, International Cancer Advocacy Network
Infusion Access Foundation
International Pemphigus and Pemphigoid Foundation
San Juan Center for Independence
Seniors Speak Out
TASH
The Bonnell Foundation: Living with cystic fibrosis
The Coelho Center for Disability Law, Policy, and Innovation
The Global Foundation for Peroxisomal Disorders
The Speak Foundation
The Statewide Independent Living Council of Illinois
U.S. Pain Foundation
United Liver
United Spinal Association
US Hereditary Angioedema Association
WeMatter Disability Organization
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