PIPC Partnership to Improve Patient Care

February 6, 2025

Christina Shaklee
Health Policy Analyst Advanced
Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715

Dear Ms. Shaklee:

I am writing again to share the strong concerns from patients and people with disabilities about the methodology proposed by the Maryland Prescription Drug Affordability Board to set Upper Payment Limits (UPLs) for selected drugs. As an original author and sponsor of the Americans with Disabilities Act (ADA), it is a high priority to me and the disability community that discriminatory value assessments have no place in the U.S. health care system. Yet, the Board's proposed methodology for establishing UPLs explicitly calls for use of cost effectiveness analysis and international prices from countries known to use quality-adjusted life years (QALYs) and similar measures barred by federal law and regulations. The Board has failed to include any safeguards in the proposed rulemaking that would protect people with disabilities and serious chronic conditions from decisions made in reliance on discriminatory value assessments.

Additionally, the Board does not describe how comparative effectiveness research (CER) may be used in decisions related to therapeutic alternatives, where treatments often impact patients very differently. For example, when Congress created the Patient-Centered Outcomes Research Institute, CER was a defined term that acknowledged differential impacts among subpopulations and sought to protect against its use to define effectiveness as averages, with legal protections against its use as a sole source for coverage decisions. Patients and people with disabilities are not average. No such protections exist in the Maryland proposed rule.

PIPC and others have consistently argued against policies that drive discrimination and increased barriers to accessing personalized care prescribed by doctors in consultation with their patients. We urge the Board to focus its efforts on making health care more affordable for patients and people with disabilities, such as addressing the utilization management strategies imposed by payers to make care less accessible and affordable. We are hopeful for a response to our concerns, described at length in prior letters attached.

Sincerely,

Tony Coelho
Chairman
Partnership to Improve Patient Care

August 26, 2024

Mr. Van T. Mitchell
Chair
Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715

Dear Chair Mitchel and Board members:

As organizations representing patients and people with disabilities, we strongly urge the Maryland Prescription Drug Affordability Board (PDAB) to prioritize the perspectives of people whose care may be impacted by your decisions as it works to finalize a Plan of Action for Implementing the Process for Setting Upper Payment Limits. Therefore, we would like to provide the following recommendations:

- Develop a concrete plan to monitor and respond to potential increased use of utilization management strategies and adverse formulary placements for both selected drugs *and* their alternative treatments.
- Improve the Board's patient engagement practices and use of survey data.
- Avoid the use of discriminatory value assessments.
- Avoid reference to drug prices in other countries.

We are deeply concerned with recommendations from academia to states implementing PDABs that are not centered on helping patients gain affordable access to the drugs that patients and doctors determine to be the most effective treatment.[1,2] Patients and people with disabilities have consistently expressed opposition to policies advancing use of discriminatory value assessments, closed formularies, utilization management strategies in which a drug must fail before patients can access a drug that works, non-medical switching to "therapeutic alternatives" as determined by a payer based on cost considerations, and formulary exclusions. Ultimately, we urge the Board to advance policies that support high-quality shared decision-making between patients and providers, ensuring patients can access the care that will have the most optimal impact on their quality of life and health outcomes. Adopting the recommendations below will be a strong start to protecting people with disabilities and serious chronic conditions in Maryland.

Develop a concrete plan to monitor and respond to potential increased use of utilization management strategies and adverse formulary placements for both selected drugs *and* their alternative treatments.

[1] NASHP Toolkit to PDABs https://nashp.org/prescription-drug-affordability-board-toolkit/
[2] https://pdab.maryland.gov/documents/stakeholders/2023/havard_med_brigm_prst.pdf

We appreciate that the statute governing the Board's activities calls for cost reviews that determine whether a treatment "has led or will lead to affordability challenges for the State health care system or high out-of-pocket costs for patients." It is our hope that the Board is first and foremost seeking to protect patients and people with disabilities seeking to access the treatment that is recommended by their providers and most effective for the patient. By now, the Board is aware that affordability challenges are often associated with placement on formularies, utilization management strategies imposed by payers to restrict access to certain drugs, and outright denials that force patients to pay out-of-pocket for access to the drug on which they are most stable. It does patients and people with disabilities little good to lower the price of a drug if the outcome is to make it harder to access that drug or an alternative drug that may be more effective for the patient but is no longer on a preferred tier or is subject to a fail first policy.

The Board has significant latitude to determine whether an Upper Payment Limit (UPL) is the policy solution for an affordability challenge. What many patients know to be true is getting the drug they need is often difficult and burdensome. Meaningful policies to genuinely help patients address their out-of-pocket costs must mitigate the use of discriminatory value assessments by payers to justify restricting access to care for people with disabilities and serious chronic conditions, as well as older adults. Addressing affordability starts with policies that support shared decision-making between patients and providers and ensure affordable coverage of the treatment plan that patients and providers determine to be most effective.

Therefore, we urge the Board to develop a concrete plan to monitor and respond to potential increased use of utilization management strategies and adverse formulary placements for both selected drugs *and* their alternative treatments, which could increase patient costs and impede physicians' judgment about the best care for individual patients. The draft plan states the Board will set UPLs in a way to minimize adverse outcomes and minimize the risk of unintended consequences, as well as monitor availability of prescription drugs subject to a UPL to protect against shortages. We hope the Board will go further to ensure patients and people with disabilities are not losing access due to coverage denials, step therapy, prior authorization, etc. We appreciate that the Board proposes to reconsider or suspend UPL's where they find selected drugs to be unavailable and propose the Board adopt the same policy to respond to payers that restrict access to selected drugs or other alternatives.

Improve the Board's patient engagement practices and use of survey data.

The Board states in its draft UPL plan that its process is transparent and offers multiple opportunities for public engagement and input. Yet, it is not clear to stakeholders how information submitted by patients is used by the Board to make decisions. We would urge the Board to review the work of experts in patient engagement such as the patient-Centered Outcomes Research Institute (PCORI), National Health Council, the University of Maryland, AcademyHealth and the Innovation and Value Initiative on how to best engage the patient community in its work. For meaningful engagement on the factors listed for consideration by

the Board – including therapeutic alternatives, patient access, comparative clinical effectiveness research, cost sharing, clinical information and disease burden – we recommend the Board:

- Develop a formalized process to ensure continuous, robust engagement of patients and people with disabilities at multiple levels.
- Use patient insights to clearly communicate how it intends to use the input it receives, and how that input is reflected in the final negotiated prices.
- Solicit input from diverse communities to ensure representation of the diversity of the patients and communities affected by the topic.
- Ensure that opportunities for patient engagement are accessible.
- To gauge both successes and challenges, establish a structured process for continuous review and assessment of its engagement strategy.
- Avoid one-size fits all value metrics.[3]

The Board has received substantial comments about the factors that drive affordability challenges for patients and people with disabilities, yet the Board continues to focus its work on establishing UPLs without addressing the economic burdens that patients too often face, whether it be transportation, caregiving, utilization management strategies blocking coverage of prescribed care, etc. Entities such as the Patient-Centered Outcomes Research Institute (PCORI) have invested significant resources in engaging patients to identify the full range of clinical and patient-centered outcomes, including the potential burdens and economic impacts of health care services[4,5]. Additionally, a patient-developed survey is now available to help the Board determine the many factors that can lead to affordability and access challenges for patients, led by the Patient Inclusion Council, also known as the PIC.[6] We urge the Board to use these resources to better understand the burdens facing patients and to develop patient-centered strategies for improving access to care.

Avoid the use of discriminatory value assessments.

The Board highlights in the draft that it may consider many different factors part of a cost review, including cost effectiveness analyses. Yet, 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 against the use of discriminatory value assessments also known as cost effectiveness analyses.[7] The U.S. Department of Health and Human Services' rule represents a critical step forward to protecting

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

[4] https://www.pcori.org/sites/default/files/PCORI-Out-of-Pocket-Cost-Taxonomy-Scoping-Review-Sept-2023.pdf

[5] https://www.pcori.org/sites/default/files/PCORI-Assigning-Costs-to-Healthcare-Utilization-Report-March-2023.pdf

[6] https://www.surveymonkey.com/r/PatientDrugAffordability

[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

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) that are most common methodologies for calculating cost effectiveness. The agency broadly interpreted what constitutes the discriminatory use of value assessment in its description of the rule, stating recipient obligations under the rule are broader than section 1182 of the Affordable Care Act. Section 1182 of the ACA bars Medicare's use of QALYs and similar measures that that discount the value of a life because of an individual's disability. Therefore, it is important for the Board to avoid the use of cost effectiveness analyses to make decisions that affect reimbursement and coverage of prescription drugs to remain aligned with federal law and regulations barring discrimination.

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 Board to avoid the use of cost effectiveness analyses that at worst violate federal nondiscrimination laws and regulations and at best 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.[8]

Avoid reference to drug prices in other countries.

The Board's draft plan also proposes use of an international reference upper payment limit using drug prices in other countries. Referencing other countries is similarly contrary to federal laws governing disability discrimination due to their reliance on discriminatory value assessments, including QALYs. The Board's proposed policy would import those discriminatory standards from other countries and lead directly to lack of access to needed treatments for many Americans.[9] While Germany is often raised, we encourage the Board to review the German system, including 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.[10] In Canada, the current coverage and reimbursement process for new drugs impedes access to care due to its reliance on QALY-based assessments conducted by the Canadian Agency for Drugs and Technologies in Health (CADTH).[11] In the United Kingdom, medicines exceeding the National Institute for Health and Care Excellence (NICE) cost-per-QALY threshold are not deemed cost effective, leading to a high rate of

[8] https://www.pipcpatients.org/uploads/1/2/9/0/12902828/pipc_value_critique_updated.pdf
[9] https://www.pipcpatients.org/uploads/1/2/9/0/12902828/pipc_stakeholder_comment_on_importing_qalys.pdf
[10] https://www.pipcpatients.org/uploads/1/2/9/0/12902828/germany_draft_2022_9-21_edited_clean.pdf
[11] Guidelines for the Economic Evaluation of Health Technologies: Canada. July 2017

rejections denying patients access to new medicines.[12] Ireland similarly denies patients care based on QALY thresholds.[13]

We encourage the Board to 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,[14] Most Favored Nation policy,[15] and federal legislation.[16] The NCD's recommendations against reliance on cost effectiveness are largely reflected in the new federal Section 504 regulations, providing increased clarity on the prohibited use of discriminatory value assessments.

Thank you for the opportunity to comment on the draft UPL plan. We look forward to revisions that prioritize policies centered on access to care for patients and people with disabilities. Please reach out to sara@pipcpatients.org with any questions.

Sincerely,

Alliance for Aging Research
Alliance for Patient Access
ALS Association
American Association of Kidney Patients (AAKP)
Asthma and Allergy Foundation of America
Biomarker Collaborative
Cancer*Care*
Caring Ambassadors Program
Coalition of State Rheumatology Organizations (CSRO)
Color of Gastrointestinal lllnesses
Cystic Fibrosis Research Institute
Derma Care Access Network
Diabetes Leadership Council
Diabetes Patient Advocacy Coalition
Disability Equity Collaborative
Epilepsy Foundation
Exon 20 Group
Familia Unida Living with MS
GO2 for Lung Cancer

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[12] Drummond, M. and Sorenson, C. Nasty or Nice? A Perspective on the Use of Health Technology Assessment in the United Kingdom. Value in
Health 2009; 12(S2).
[13] National Centre for Pharmacoenomics (NCPE). http://www.ncpe.ie/about/
[14] https://www.ncd.gov/2020/08/05/ncd-statement-on-harm-of-using-international-pricing-index-for-u-s-prescription-drug-pricing/
[15] https://www.ncd.gov/letters/2021-01-15-ncd-letter-to-cms-on-most-favored-nation-rule/
[16] https://www.ncd.gov/letters/2021-04-29-ncd-letter-to-house-committees-with-concerns-regarding-h-r-3/

Headache and Migraine Policy Forum
Health Hats
HealthHIV
HIV+Hepatitis Policy Institute
ICAN, International Cancer Advocacy Network
Infusion Access Foundation
Lupus and Allied Diseases Association, Inc.
MET Crusaders
MLD Foundation
Monica Weldon Consulting, LLC
National Infusion Center Association (NICA)
National Infusion Center Association (NICA)
Partnership to Fight Chronic Disease (PFCD)
Partnership to Improve Patient Care
Patients for Patient Safety - US
PD-L1 Amplifieds
The Bonnell Foundation: Living with cystic fibrosis
The Coelho Center for Disability Law, Policy and Innovation
The IMAGE Center for People with Disabilities

cc: Stakeholder Council

PIPC Partnership to Improve Patient Care

May 13, 2024

Mr. Andrew York
Executive Director
Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715

Dear Mr. York:

I am writing on behalf of the Partnership to Improve Patient Care (PIPC) to comment on the Maryland Prescription Drug Affordability Board's ongoing Cost Review Study process. 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.[1] We are writing to update the Board on recent federal policy developments that increase clarity on the state's obligations and limitations.

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.[2] In response to the proposed rule last year, the Partnership to Improve Patient Care (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.[3]

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

[1] https://valueourhealth.org/wp-content/uploads/2021/08/MD-Letter-Final.pdf
[2] 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
[3] https://www.pipcpatients.org/uploads/1/2/9/0/12902828/pipc_504_comment_final.pdf

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 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 as broader than the section 1182 statute.

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.[4] Therefore, the potential for discrimination is significant when value assessments rely on public surveys, for example.

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 experts in the patient and disability communities.[5,6,7,8] We are also concerned about the transparency of the decision-making process by the Board and 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.

[4] 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.
[5] https://nationalhealthcouncil.org/wp-content/uploads/2024/03/Amplifying-the-Patient-Voice-Roundtable-and-Recommendations-on-CMS-Patient-Engagement.pdf
[6] https://www.pharmacy.umaryland.edu/media/SOP/wwwpharmacyumarylandedu/programs/PATIENTS/pdf/Patient-driven-recommendations-for-the-Medicare-Drug-Price-Negotiation-Program.pdf
[7] https://www.pcori.org/sites/default/files/PCORI-Engagement-in-Research-Foundational-Expectations-for-Partnerships.pdf
[8] https://thevalueinitiative.org/ivi-partners-with-academyhealth-to-address-economic-impacts-on-patients-and-caregivers/

Sincerely,

Tony Coelho
Chairman
Partnership to Improve Patient Care

PIPC Partnership to Improve Patient Care

May 2, 2023

Andrew York
Executive Director
Maryland Prescription Drug Affordability Board 4160 Patterson Avenue
Baltimore, MD 21215

comments.pdab@maryland.gov

Dear Mr. York:

The Partnership to Improve Patient Care (PIPC) is pleased to provide comments on the draft proposed regulations issued by the Maryland Prescription Drug Affordability Board, specifically related to the concerns of patients and people with disabilities related to the Board's potential use of cost effectiveness analyses. These comments follow the letter sent to the Board on August 3, 2021, from 38 organizations 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 you know, the organizations offered to be resources to the Board as it strives to make balanced decisions and avoid unintended consequences for patient access to needed care.[1]

We are concerned that the draft regulations ignore the letter referenced above, instead specifically calling for information on cost effectiveness "derived from health economics and outcomes research" which is known to rely on biased and discriminatory measures such as QALYs. By devaluing people with disabilities, whether in terms of their life extension or quality of life, cost effectiveness analyses relying on QALYs and similar measures have no place in our health care system.

Recently, 56 organizations sent a letter to the Centers for Medicare and Medicaid Services (CMS) related to their initial guidance for implementing the Medicare Drug Price Negotiation Program. Their comments centered on three pillars: 1) creating additional procedures to meaningfully engage with patients and ensure that the evidence CMS relies on is transparent; 2) establishing patient-centered standards and outcomes; and 3) more definitively rejecting the use of Quality-Adjusted Life Years (QALYs) and other discriminatory cost-effectiveness standards. Their recommendations to CMS may also be useful to the Maryland Prescription Drug Affordability Board in its efforts to develop evidentiary standards and engagement practices that ensure patient benefits are central to decision-making. The letter is also attached as an appendix.[2] I hope that the Board will take into consideration each of its recommendations.

[1] https://valueourhealth.org/wp-content/uploads/2021/08/MD-Letter-Final.pdf
[2] http://www.pipcpatients.org/uploads/1/2/9/0/12902828/joint_comment_to_cms_on_negotiation.pdf

We strongly support standards for the research used to make judgements about therapeutic impacts of drugs, assuring it is centered on value to patients and people with disabilities and inclusive of real-world evidence.[3] The same sentiment applies here to the Board's work if it is to truly be centered on patients and people with disabilities. Its decision-making process should be publicly transparent and avoid discriminatory research using QALYs or similar methods steeped in stigma in favor of measures that encourage treatments valued by patients and people with disabilities. The Board should begin by recognizing the historic discrimination from use of biased cost effectiveness measures such as QALYs to make decisions related to health care, instead of focusing on outcomes that matter to patients and people with disabilities.[4]

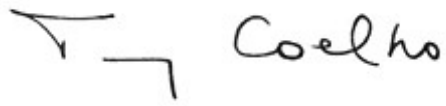
Therefore, we urge the Board to abandon its proposal to rely on cost effectiveness measures that are known to disproportionately impact care access for subpopulations already experiencing substandard health care, especially for people that too often experience discrimination doubly by virtue of being Black, Indigenous, or people of color and having a disability or chronic condition.[5] We urge the Board to incorporate the recommendation of the National Council on Disability, an independent federal agency, calling for a blanket prohibition on QALYs, whether used directly or by reference to a third party, as part of its Health Equity Framework.[6]

We were particularly disappointed that the draft proposed regulations did not outline a robust process for engaging patients and people with disabilities. As outlined in the letter to CMS referenced above, engagement should happen early and often, including roundtables with affected patients and people with disabilities related to the treatments being considered by the Board, and concerted efforts to engage with diverse communities, especially those not represented in the data. We urge the Board to reference the best practices of the Patient-Centered Outcomes Research Institute (PCORI) outlined in its Patient Engagement Rubric,[7] Compensation Framework,[8] recommendations for Budgeting for Engagement Activities,[9] and its Equity and Inclusion Guiding Principles[10] providing insights on bringing diverse voices to the table. Robust patient engagement goes beyond public comment periods at a Board meeting and will require much more effort to capture outcomes that are valued by people living with the condition.

[3] https://www.healthaffairs.org/content/forefront/medicare-drug-price-negotiations-avoid-metrics-steeped-stigma
[4] https://www.ajmc.com/view/is-the-qaly-fit-for-purpose-
[5] https://www.thevalueinitiative.org/wp-content/uploads/2022/10/IVI_Sick-Cells_Equity-in-Value_2022.pdf
[6] https://www.ncd.gov/sites/default/files/NCD_Health_Equity_Framework.pdf (Recommendation #8 on page 10)
[7] https://www.pcori.org/sites/default/files/Engagement-Rubric.pdf
[8] https://www.pcori.org/sites/default/files/PCORI-Compensation-Framework-for-Engaged-Research-Partners.pdf
[9] https://www.pcori.org/sites/default/files/PCORI-Budgeting-for-Engagement-Activities.pdf
[10] https://www.pcori.org/sites/default/files/Equity-and-Inclusion-Guiding-Engagement-Principles.pdf

Thank you for your consideration. I hope that the Board will strike reference to cost effectiveness measures in its final regulations and pursue robust engagement strategies with patients and people with disabilities.

Sincerely,



Tony Coelho, Chairman
Partnership to Improve Patient Care

August 3, 2021

Andrew York
Executive Director
Maryland Prescription Drug Affordability Board
4160 Patterson Avenue
Baltimore, MD 21215

Dear Mr. York:

We understand that the rising cost of healthcare is a concerning issue that requires real solutions. As organizations representing patients and people with disabilities, the affordability of health care is a significant priority, and we look forward to working with state policymakers to manage health costs in a manner centered on meeting the health care needs of people with disabilities and chronic conditions. In doing so, we urge the state 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.

We are aware that the Maryland Prescription Drug Affordability Board (PDAB) is tasked with addressing high-cost prescription drug products and engaging diverse stakeholders in that process. As created by statute, the Board consists of five members who possess expertise in the fields of either health care economics or clinical medicine, thereby missing the critical voices of patients and people with disabilities. Therefore, it is essential that people with disabilities and chronic conditions, those who would be most impacted by these policies, are able to have a robust voice in this discussion. The undersigned organizations representing patients and people with disabilities would like to be resources to the PDAB as it strives to make balanced decisions and avoid unintended consequences for patient access to needed care.[1]

We are writing to share information with the Board about QALYs. As you may be aware, other states that have recently enacted similar legislation to create a Prescription Drug Affordability Board have included a bar on the use of metrics that discriminate such as QALYs.[2] As the Maryland PDAB initiates its work, we are hopeful that the entity will similarly take a stand against incorporating the use of QALYs in its deliberations. Recently, the Institute for Clinical and Economic Review (ICER), an entity that relies on QALYs in its value assessment studies and calls QALYs the "gold standard",[3] presented to the PDAB on how its work could be leveraged by the PDAB.[4]

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[1] https://ncd.gov/newsroom/2021/NFO-state-use-qaly-based-cost-effectiveness-reports
[2] Colorado Senate Bill 21-175, 10-16-1407(4)(a) and Oregon Senate Bill 844 A
[3] https://icer.org/news-insights/press-releases/icer-describes-qaly/
[4] https://pdab.maryland.gov/2021_board_meeting.html

As background. referencing discriminatory metrics such as QALYs can potentially violate existing civil and disability rights laws. QALY-based assessments assign a financial value to health improvements provided by a treatment that do not account for outcomes that matter to people living with the relevant health condition and that attribute a lower value to life lived with a disability. When applied to health care decision-making, the results can mean that people with disabilities and chronic illnesses, including older adults, are deemed not worth the cost to treat. We encourage you to review the report from the National Council on Disability, an independent federal agency, recommending that policymakers avoid referencing the QALY, clarifying that its use in public programs would be contrary to United States civil rights and disability policy.[5] Most recently, the National Council on Disability initiated work to review "State's use of QALY-Based Cost-Effectiveness Reports to Inform Medicaid Coverage for Prescription Drugs" which is anticipated to provide information on how QALYs are being used and their implications for restricting access to care.[6]

The United States has a thirty-year, bipartisan track record of opposing the use of the QALY and similar discriminatory metrics and establishing appropriate legal safeguards to mitigate their use. Section 504 of the Rehabilitation Act ensures 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.[7] Title II of the Americans with Disabilities Act (ADA) extended this protection to programs and services offered by state and local governments.[8] Based on the ADA's passage in 1990, in 1992 HHS rejected a state waiver application because its reliance on QALYs and cost effectiveness standards would have violated the ADA and lead to discrimination against people with disabilities in determining the state's prioritized list of services.[9]

In 2010, the Affordable Care Act (ACA) 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.[10] Additionally, the ACA specifically prohibits QALYs and similar metrics from being used by HHS as a threshold to establish what type of health care is cost effective or recommended, as well as prohibiting their use as a threshold in Medicare to determine what is covered, reimbursed or

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[5] National Council on Disability. (November 16, 2019). Quality-Adjusted Life Years and the Devaluation of Life with Disability. https://ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf.
[6] https://ncd.gov/newsroom/2021/NFO-state-use-qaly-based-cost-effectiveness-reports
[7] 29 USC Sec 794, 2017. Accessed November 30, 2020.
[8] 42 USC Sec 12131, 2017. Accessed November 30, 2020.
[9] Sullivan, Louis. (September 1, 1992). Oregon Health Plan is Unfair to the Disabled. The New York Times.
[10] 42 USC Sec 1320e, 2017. Accessed November 30, 2020.

incentivized.[11] Most recently, HHS reiterated in a final rule that it is a violation of section 504 of the Rehabilitation Act, the ADA, the Age Discrimination Act, and section 1557 of the ACA for state Medicaid agencies to use measures that would unlawfully discriminate on the basis of disability or age when designing or participating in VBP arrangements.[12]

We hope that you will engage patients and people with disabilities in your current process and bear in mind these legal protections under health and civil rights laws as you work on policies to reduce the cost of care for beneficiaries. We appreciate the important work you are doing and stand ready to work with you on appropriate policies that do not discriminate or limit access to needed care and treatment. We would be happy to speak with the members of the Maryland PDAB about our concerns and the experiences of patients and people with disabilities. Please reach out to Sara van Geertruyden at sara@pipcpatients.org if you would like to discuss in more depth.

Sincerely,

Allergy & Asthma Network

Alliance for Aging Research

Alliance for Patient Access

ALS Association

American Association on Health & Disability

American Autoimmune Related Diseases Association

Autistic Self Advocacy Network

Axis Advocacy

Boomer Esiason Foundation

Cancer*Care*

Center for Autism and Related Disorders

Color of Crohn's and Chronic Illness

Cystic Fibrosis Research Institute

Davis Phinney Foundation

[11] 42 USC Sec 1320e, 2017. Accessed November 30, 2020.
[12] https://www.federalregister.gov/d/2020-12970

Diabetes Leadership Council

Diabetes Patient Advocacy Coalition

Epilepsy Foundation Maryland

Global Liver Institute

GO2 Foundation for Lung Cancer

Health Hats

ICAN, International Cancer Advocacy Network

International Foundation for Autoimmune & Autoinflammatory Arthritis (AiArthritis)

Lupus and Allied Diseases Association, Inc.

Lupus Foundation of America

Maryland Center for Developmental Disabilities at Kennedy Krieger Institute

Men's Health Network

MLD Foundation

Not Dead Yet

Partnership to Improve Patient Care

Rare New England

SYNGAP1 Foundation

The Bonnell Foundation: Living with cystic fibrosis

The Coelho Center for Disability Law, Policy and Innovation

TSC Alliance

United Spinal Association

VHL Alliance

Whistleblowers of America

ZERO - The End of Prostate Cancer