PIPC Partnership to Improve Patient Care

February 4, 2025

Senator Pamela Beidle
Chair
3 East Miller Senate Office Building
Annapolis, Maryland 21401

Delegate Joseline A. Pena-Melnyk
Chair
240 Taylor House Office Building
Annapolis, Maryland 21401

Senator Antonio Hayes
Vice Chair
3 East Miller Senate Office Building
Annapolis, Maryland 21401

Delegate Bonnie Cullison
Vice Chair
241 Taylor House Office Building
Annapolis, Maryland 21401

Dear Chair Beidle, Chair Pena-Melnyk, Vice Chair Hayes, and Vice Chair Cullison:

I am writing on behalf of the Partnership to Improve Patient Care (PIPC). The attached correspondence with the Legislative Policy Committee and the Maryland Prescription Drug Affordability Board (PDAB) demonstrates our continued efforts to share concerns about the implications for discrimination related to the PDAB's work. As the original author and sponsor of the Americans with Disabilities Act (ADA), I am concerned that the legislature is seeking to expand the PDAB's scope of work and influence over decisions that will impact how patients and people with disabilities access care and treatment. As you debate SB357 and HB424, I hope you will consider the strong concerns you are hearing from the patient and disability communities.

Thank you for reviewing and considering the attached in your deliberations.

Sincerely,

Tony Coelho

Tony Coelho
Chairman
Partnership to Improve Patient Care

PIPC Partnership to Improve Patient Care

October 15, 2024

Senator Bill Ferguson
Department of Legislative Services
Annapolis, Maryland 21401

Delegate Adrienne A. Jones
Department of Legislative Services
Annapolis, Maryland 21401

Dear Senator Ferguson and Delegate Jones:

Since its founding, the Partnership to Improve Patient Care (PIPC) has been at the forefront of applying principles of patient-centeredness to the nation's health care system – from the generation of comparative clinical effectiveness research at the Patient-Centered Outcomes Research Institute (PCORI), to the translation of evidence into patient care in a manner that achieves value to the patient. Having driven the concepts of patient-centeredness and patient engagement in the conduct of research, PIPC looks forward to bringing the voices of patients and people with disabilities to the discussion of how to advance patient-centered principles throughout an evolving health care system.

I am writing to share PIPC's serious concerns about the Upper Payment Limit Plan submitted to Maryland's General Assembly Legislative Policy Committee by the Prescription Drug Affordability Board (PDAB) for its review and approval. We share the goals of health care affordability and want to be engaged partners with you in addressing the challenges facing patients. For too long, patients and people with disabilities have been subjected to adverse utilization management strategies that force use of a treatment that fails patients before gaining access to a treatment that works – or outright coverage denials of prescribed treatments. Their real-world experiences are critical to allow policymakers to understand what is driving affordability challenges and develop policy solutions addressing their economic burdens.[1]

Unfortunately, the Maryland PDAB process was less focused on the perspectives of patients and people with disabilities and more focused on payer perspectives. For example, recent written comments on the draft UPL Plan were ignored by the Board. 38 organizations sent a letter to the Maryland PDAB suggesting changes to its draft UPL Plan.[2] That letter was not immediately posted to the PDAB website, it was not listed among letters considered by the Board, and it was not discussed at the PDAB meeting during which the revised UPL Plan was

[1] PCORI advanced a patient-engaged process to determine economic burdens. See https://www.pcori.org/sites/default/files/PCORI-Patient-Centered-Economic-Outcomes-Landscape-090524.pdf
[2] See http://www.pipcpatients.org/uploads/1/2/9/0/12902828/maryland_pdab_comments_final.pdf

approved to be sent to the Legislative Policy Committee.[3] Unsurprisingly, the revised UPL Plan did not address any of the concerns expressed in that letter.

Moreover, regulations were finalized in May, 2024 under Section 504 of the Rehabilitation Act barring disability discrimination that included provisions barring the use of discriminatory value assessments in decisions impacting access to care, including reimbursement and coverage.[4] PIPC and its partners have reiterated to the Maryland PDAB several times that federal law bars the use of cost effectiveness measures such as quality-adjusted life years (QALYs) and similar measures that devalue disabled lives.[5,6,7] That includes reference to international prices in countries that use such measures and do not prioritize care for people with disabilities and serious chronic conditions. Yet, the Maryland PDAB is relying on entities such as the Program on Regulation, Therapeutics and Law (PORTAL) and the Institute for Clinical and Economic Review (ICER) that favor use of discriminatory value assessments to inform its work.[8,9] Their advice is not centered on achieving access to affordable care for patients and people with disabilities yet seems to be taken most seriously. We are concerned about Board members' ties to entities that view the QALY and similar measures as the gold standard for assessing value in healthcare.[10] Those concerns were amplified by the PDAB's failure to provide answers to credible questions from the disability community as to how UPLs may impact the use of payer tools to restrict formularies and increase out-of-pocket costs for patients, whether for the drug under review or other drugs in its class.

Also, the Maryland PDAB process has not prioritized accessibility. Comment deadlines and meeting dates and times often change, leaving patients and people with disabilities unable to participate. Comments submitted by the public are difficult to find on the website and are not posted in a timely manner. Accessing the recorded PDAB meetings for older meetings is challenging and are difficult to navigate on the Maryland PDAB website. Public participation has clearly not been a priority for the PDAB, much less participation from the disability community or patients personally affected by decisions related to drugs under review. Recent federal regulations issued by the U.S. Department of Justice covering Title II of the ADA require the accessibility of web content and mobile applications (apps) for people with disabilities. To be compliant, state and local governments must make their websites and mobile applications

[3] See https://pdab.maryland.gov/Pages/2024-Board-Meeting.aspx
[4] 45 CFR § 84.56 and § 84.57
[5] See http://www.pipcpatients.org/uploads/1/2/9/0/12902828/pipc_maryland_pdab_2024.pdf
[6] See https://www.pipcpatients.org/uploads/1/2/9/0/12902828/pipc_maryland_pdab_050223.pdf
[7] See https://valueourhealth.org/wp-content/uploads/2021/08/MD-Letter-Final.pdf
[8] PORTAL Presentation to PDAB, https://pdab.maryland.gov/documents/meetings/2023/havard_med_sch_prst.pdf
[9] ICER Presentation to PDAB, https://pdab.maryland.gov/documents/presentations/Leveraging_ICER_Rpt_for_Prescription_Drug_Affordability.pdf
[10] Dr. Gerard Anderson has reported grants from Arnold Ventures, which is a primary funder of the Institute for Clinical and Economic Review and supporter of their QALY-based methodology, as well as funder of PORTAL Research and NASHP.

accessible. Beyond what is legally required, we had hoped that the PDAB would proactively want to make the process accessible for patients and people with disabilities and prioritize responding to their concerns and incorporating their input.

As the original author and sponsor of the Americans with Disabilities Act and a person with epilepsy, I have spent my adult life fighting for disability rights and against these types of policies that devalue us. I have had personal experience with non-medical switching imposed by my insurer, with adverse outcomes that were entirely unavoidable. As an older adult now, I am do not subscribe to the idea that my life is worth less, as most measures of cost effectiveness would have you believe. With recent federal regulations to more clearly guide us, the disability community is now fighting for enforcement of U.S. laws that protect patients and people with disabilities.

The Legislative Policy Committee should not approve a UPL Plan that does not protect against disability discrimination and adverse utilization management strategies by payers. The goal of the PDAB should be to improve patient access to the care they and their doctors determine to be most effective. By pausing this process, the Legislative Policy Committee could take the time to understand the implications of the PDAB's UPL Plan and engage with patients and people with disabilities on solutions that are meaningful for advancing affordable access to care and in compliance with disability rights laws.

Thank you for your consideration.

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
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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