EACH PIC COALITION

September 23, 2026

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

RE: Comments on Proposed Regulation – Circumstances Under Which Use of a Drug May Create an Affordability Challenge

Dear Members and Staff of the Maryland Prescription Drug Affordability Board:

The Ensuring Access through Collaborative Health (EACH) and Patient Inclusion Council (PIC) is a two-part coalition that unites patient organizations and allied groups (EACH), as well as patients and caregivers (PIC), to advocate for drug affordability policies that benefit patients.

The undersigned organizations appreciate the opportunity to comment on the board's proposed regulation establishing the circumstances under which use of a drug may create an affordability challenge. We commend the board for continuing to refine its affordability framework and for seeking greater clarity around the factors that may warrant review and policy consideration.

As the board undertakes this effort, we encourage it to ensure that affordability determinations remain focused on patient affordability. While healthcare spending is an important consideration for policymakers, spending metrics alone do not demonstrate that patients are experiencing affordability challenges. Affordability reviews should therefore be grounded primarily in evidence that patients are struggling to afford treatment.

Spending Metrics Alone Do Not Demonstrate Patient Affordability Challenges

The proposed regulation allows a drug to be deemed an affordability challenge based on factors such as spending levels, spending growth, value assessments, and market competition concerns.

These metrics may provide insight into healthcare system spending, but they do not necessarily demonstrate that patients are experiencing affordability hardships. Spending measures do not reveal whether patients can afford their medications, whether they are delaying or abandoning treatment due to cost, or whether they face barriers that make treatment unaffordable.

The purpose of an affordability review should be to identify and address affordability challenges experienced by patients. A finding that spending is high does not demonstrate that patients are struggling to afford a medication.

Evidence of Patient Affordability Challenges Should Be Required Before a UPL May Be Considered

As drafted, the regulation permits affordability challenge determinations based entirely on system spending metrics without evidence that patients are experiencing affordability challenges.

The board's reviews of Ozempic and Trulicity illustrate this concern. In both cases, the affordability challenge determination was driven primarily by healthcare system spending metrics rather than evidence that patients were experiencing affordability hardships associated with those therapies.

At the same time, upper payment limits (UPLs) have the potential to affect the patients who rely on these medications. As a result, patients may ultimately bear the consequences of affordability determinations that were not based on evidence of patient affordability challenges in the first place.

For that reason, we encourage the board to require that at least one patient affordability criterion be satisfied before a drug may advance to consideration of a UPL or other affordability intervention. If a policy is being pursued in the name of improving affordability, there should first be evidence that patients are experiencing affordability challenges associated with that drug.

Establishing this safeguard would help ensure that affordability reviews remain focused on improving patient affordability rather than solely reducing healthcare system spending.

Understanding the Drivers of Patient Affordability Challenges

Patients repeatedly described affordability as a function of insurance design, cost-sharing obligations, financial assistance availability, and changing life circumstances rather than the cost of a medication alone. This highlights an important reality: understanding that a patient is experiencing an affordability challenge is only the first step. Policymakers must also understand what is causing that challenge if they hope to design policies that effectively address it.

We appreciate that the proposed regulation includes patient-focused affordability criteria. However, patient affordability challenges are often driven by factors that are not fully captured through spending, utilization, or out-of-pocket cost metrics alone. Patients may discontinue or avoid treatment for very different reasons, including coverage denials, prior authorization requirements, changing cost-sharing obligations, loss of financial assistance, or other insurance-related barriers.

A patient-centered affordability framework should therefore seek to understand not only whether patients are experiencing affordability challenges, but why those challenges occur. Without understanding the underlying drivers, policymakers risk designing solutions that address symptoms rather than causes and may ultimately fail to resolve the affordability barriers patients face.

Conclusion

We appreciate the board's efforts to improve and clarify its affordability framework. As this work continues, we encourage the board to ensure that patient affordability remains the central focus of affordability determinations and to require that at least one patient affordability criterion be satisfied before a drug may be deemed to create an affordability challenge.

Thank you for the opportunity to provide comments. We look forward to continuing to engage with the board on policies that meaningfully improve affordability for Maryland patients.

EACH/PIC COALITION

Sincerely,

EACH/PIC Coalition
AiArthritis
Autoimmune Association
Biomarker Collaborative
Caring Ambassadors
Coalition of State Rheumatology Organizations
Community Liver Alliance
Crohn's & Colitis Foundation
Exon 20 Group
HIV+Hepatitis Policy Institute
ICAN, International Cancer Advocacy Network
Infusion Access Foundation
Lupus and Allied Diseases Association, Inc.
Lupus Foundation of America
MET Crusaders
National Infusion Center Association
Neuropathy Action Foundation (NAF)
NRG1 Energizers
PDL1 Amplifieds
Rare Access Action Project (RAAP)
The AIP BIPOC Network
The Bonnell Foundation: Living with Cystic Fibrosis