DIABETES PATIENT ADVOCACY COALITION

February 23, 2026

Maryland Prescription Drug Affordability Board Stakeholder Council
16900 Science Drive, Suite 112-114
Bowie, MD 20715

RE: PDASC February 23, 2026 Meeting - Cost review study process

Dear Members of the Maryland Prescription Drug Affordability Stakeholder Council,

Thank you for the opportunity to comment on the PDAB's cost review study process and policy review procedures.

DPAC strongly suggests requiring both a patient out-of-pocket impact analysis and an affirmative, written finding of patient benefit before adopting any UPL. A policy adopted in the name of affordability should demonstrate evidence of meaningful patient benefit, including reductions in out-of-pocket costs or improvements in access, rather than relying on assumptions that system-level savings will be passed on to patients. Without an explicit analysis of how a proposed UPL is expected to affect patient out-of-pocket costs and access under common benefit designs, UPLs risk delivering savings to payers or intermediaries while leaving patient costs unchanged or reducing access to medications through formulary tier shifts, prior authorization, or other utilization controls. An impact analysis should consider whether unaffordability is driven by pricing, benefit design, or both.

What patients pay at the pharmacy counter is driven by deductibles, coinsurance, formulary placement, and utilization management. Two drugs with identical net prices to a payer can result in dramatically different patient out-of-pocket costs depending on how they are covered. Without explicitly analyzing these factors, the Board risks misidentifying the source of patient harm and applying policy tools that focus on reducing system spending without improving patient affordability. Below is a real world scenario of what could happen with a UPL on a drug.

UPL Example:

- Manufacturer list price: $1,027
- GoodRx price: $349
- Direct to consumer price from manufacturer: $349

The state sets a UPL at $349 to cap the amount the state plan will pay but doesn't pass the savings to plan participants. (Few plans pass these savings onto participants though it is required in WV, IN, AK, NM and NC).

A plan participant in their deductible will pay the list price of $1,349 until their deductible is met. The patient is likely to access the drug direct from the manufacturer at $349; however, this cost will not go towards their deductible because they are purchasing it outside of their health plan. After their deductible is met due to other expenses, they may pay a fixed copay or a coshare percentage of the cost of the drug (typically 20-30%). If they are paying a coshare, the percentage is based on the list price of the drug which in this case would be $205-$308. In this very likely scenario, the drug is no more affordable than it was before the UPL was set.

Now let's look at it from a pharmacy perspective. The community pharmacy pays roughly list price ~$1,027. If the UPL impacts the amount the pharmacy is reimbursed, which is highly possible if not probable, then the pharmacy loses money on the drug and refuses to stock it or refuses to sell it to a participant of a Maryland health plan. This is happening in jurisdictions across the country.

To address the question of patient affordability, DPAC has suggested the language below to the PDAB:

COMAR 14.01.05.08 — Establishing and Monitoring a UPL

[ADD] New subsection A(5) and A(6):

(5) Patient Out-of-Pocket Impact Analysis.
Before adopting a proposed regulation setting a UPL amount, the Board shall publish an analysis estimating the expected impact of the UPL on patient out-of-pocket costs, including whether and how patient cost-sharing amounts and utilization management controls are expected to change under common benefit designs.

(6) Patient Benefit Finding.
The Board shall not adopt a proposed regulation setting a UPL unless it makes a written finding, based on the best available information, that implementation of the UPL is reasonably expected to produce meaningful patient benefit, including reductions in patient out-of-pocket costs or improvements in patient access, and will not be beneficial solely to payers, PBMs, or other intermediaries without patient benefit.

Together, these provisions would strengthen the Board's work by centering patient experience and outcomes. They would grounded the Board's processes in real-world patient impact and ensure that affordability reforms will lead to patients seeing the results at the pharmacy counter.

Sincerely,

George Huntley

George Huntley
Chief Executive Officer
Diabetes Patient Advocacy Coalition

MARYLAND TECH COUNCIL
ADVANCING LIFE SCIENCES AND TECHNOLOGY

February 13, 2026

Submitted via email: comments.pdab@maryland.gov

Re: Cost Review Study Process

Dear Members of the Prescription Drug Affordability Board,

On behalf of the Maryland Tech Council and our members, particularly those in the life sciences industry, we are pleased to submit the following comments for consideration at the February 2026 Informational Hearings on the Cost Review Study Process.

As we have in prior communications to the PDAB, we begin by highlighting the strength of the life sciences ecosystem in the State of Maryland and its overall importance to the Maryland economy. Maryland's life sciences ecosystem includes 2,700 companies and 54,000 workers. These innovative companies and workers develop therapies, cures, and treatments that millions of patients depend on. According to the 2024 annual rankings from *Business Facilities*, Maryland ranks as the third-best State in the country for life sciences, behind only Massachusetts and California. Assets such as proximity to the National Institutes of Health ("NIH") and other federal Research and Development funding agencies, strong academic and medical institutions, and a highly skilled workforce all combine to make Maryland a competitive state for life sciences. These are some of the reasons Governor Moore has rightly highlighted life sciences as one of the three "lighthouse industries of the future" and stated that his Administration wants Maryland to be the capital of biotech.

Despite Maryland's life sciences advantages, recent actions by the Federal government have put the industry under unprecedented threat and strain. Cuts to NIH grant funding, delays, freezes, and terminations of other grant and research activities, along with other reductions, have put the Maryland life sciences ecosystem at significant risk. Maryland policymakers, therefore, must be intentional about supporting this industry and the economic, job, and tax benefits it provides. As the MTC has consistently stated, we must seek opportunities to build on the life sciences industry's strengths. All too often, however, the industry feels that decisions made at the State level create a higher tax burden, foster uncertainty, and create an overall environment that feels more hostile than welcoming.

Maryland's Prescription Drug Affordability Board (PDAB) cost review study process is increasingly interpreted by the life sciences sector as a signal that the state's policy environment may be moving away from being welcoming to investment. Although the PDAB was established with the goal of addressing affordability concerns, the mechanism it uses, retrospective cost reviews that can lead to payment limits, introduces a layer of regulatory uncertainty that is particularly sensitive for companies making long-term research and commercialization investments. Drug development timelines often span a decade or more and require substantial upfront capital; when the potential pricing environment is unclear or subject to state-level intervention after market entry, firms may perceive greater financial risk in launching new therapies.

The MTC has consistently expressed skepticism that Upper Payment Limits (UPLs) will be effective in reducing patients' out-of-pocket costs. While we recognize that UPLs are the only tool available to the PDAB by law, we encourage a faster, more thorough examination of non-UPL alternatives. For example, when PDAB staff provided a briefing to the Senate Finance Committee earlier this Session, they

stated that they were supportive of legislation to increase transparency about Pharmacy Benefit Managers (PBMs) and how they influence the prices of prescription drugs. At the September PDAB meeting, PDAB Board members requested additional plans for non-UPL options, including a real-time benefit tool for patients and prescribers, a patient navigator program, and delinking PBM compensation from rebates to offset wholesale acquisition cost increases. We have seen little movement on these options in the months since. We recommend greater emphasis on pursuing additional legislative requirements and authority, rather than continuing to pursue UPLs, which will do little to reduce the amount that Maryland patients pay for prescription drugs. With the 2026 Legislative Session more than one-third complete already, the time for additional legislative action on non-UPL solutions that could directly benefit patients is now.

As leaders in the State, we have a choice – we can either continue to embrace innovation and build an environment open to research and development, economic growth, and job creation, or we can take actions that drive investment to our competitors. The pursuit of unproven and potentially ineffective strategies such as UPLs is consistent with the latter. For these reasons, we continue urge the PDAB to reconsider using UPLs as a strategy to achieve our shared goal of making prescription drugs more affordable for Maryland patients. Thank you for the opportunity to comment and for considering our comments.

Sincerely,

Kelly Schulz
CEO, Maryland Technology Council

February 10, 2026

Informational Hearing Written Testimony Submitted in Lieu of Verbal Testimony

Submitted By: Terry Wilcox, Co-Founder and Chief Mission Officer, Patients Rising

Re: Cost Review Study Process (COMAR 14.01.04.01, et seq.) and Policy Review Procedures (COMAR 14.01.05.01, et seq.)

The Maryland Prescription Drug Affordability Board has requested public written comment, submitted in lieu of verbal testimony, on the Cost Review Study Process (COMAR 14.01.04.01, et seq.) and Policy Review Procedures (COMAR 14.01.05.01, et seq.). I submit this testimony on behalf of patients who are directly affected by the Board's actions and whose stability depends on continued access to medically necessary treatment.

After five years of operation[1], the Board must answer a central question:

Where is the patient in this process — structurally, analytically, and measurably?

I. Five Years of Operation Without Demonstrated Patient or System Savings

The Board has existed for approximately five years. During that time:

- Administrative infrastructure has expanded
- Regulatory authority has broadened
- Consultants and external experts have been engaged
- Rulemaking has advanced

Yet there is no publicly documented evidence demonstrating measurable reductions in patient out-of-pocket costs attributable to PDAB activity.[2] If the Board's mission is affordability, the metric must be patient-level savings and not administrative progress.

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[1] Maryland General Assembly, HB 768 (2019), establishing the Maryland Prescription Drug Affordability Board; see also Maryland PDAB website, https://pdab.maryland.gov

[2] Maryland Prescription Drug Affordability Board, Annual Reports (2019–2025), https://pdab.maryland.gov/Pages/reports.aspx.

Before expanding toward Upper Payment Limits under COMAR 14.01.05.01, the Board should provide:

- Documented evidence of reduced patient out-of-pocket costs
- Identification of affected patient populations
- Clear baseline comparisons

Without patient-evidence data, expansion of authority is premature.

II. Upper Payment Limits Are Not Proven to Reduce Patient Costs

COMAR 14.01.05.01 authorizes the Board to establish Upper Payment Limits (UPLs).[3] However, the regulations do not require proof that a UPL will reduce patient out-of-pocket spending.

A state-imposed reimbursement cap does not automatically:

- Reduce deductibles
- Lower coinsurance
- Prevent formulary exclusions
- Eliminate prior authorization

The Board regulates payment benchmarks. It does not regulate insurer benefit design. If payors respond to compressed reimbursement by tightening utilization management, patients will face greater barriers, not fewer.[4] Affordability cannot be assumed. It must be demonstrated.

III. The Board Has Acknowledged Implementation and Market Risks

In its September 29, 2025 public meeting, Board leadership and members expressed concern regarding the Board's progress, available data, and the operational complexity of Upper Payment Limits. The Chair noted concerns about the Board's return on investment and lack of tangible outcomes. Staff acknowledged that available data to assess savings impacts remains limited. Members also expressed reservations about moving forward absent scoring or clearer evidence of savings.[5]

These statements, made in the Board's own deliberations, underscore the need for caution before expanding implementation authority.

- Operational enforcement challenges
- Legal complexities

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[3] COMAR 14.01.05.01.
[4] Kaiser Family Foundation, "How Health Plan Cost-Sharing Affects Consumers," https://www.kff.org/private-insurance/issue-brief/how-health-plan-cost-sharing-affects-consumers/; see also Kaiser Family Foundation, "Prior Authorization in Medicare Advantage Plans," https://www.kff.org/medicare/issue-brief/prior-authorization-in-medicare-advantage-plans/.
[5] Maryland Prescription Drug Affordability Board Public Meeting, September 29, 2025, available at: https://www.youtube.com/watch?v=X8RW4rH8zeU (see approximately 1:55:03–1:55:50; 2:20:00–2:20:48; 1:25:49–1:26:07; 1:33:09–1:33:15).

- Market response uncertainty
- Administrative burden

These concerns are not speculative criticisms. They are issues raised within the Board's deliberations. Proceeding toward UPL implementation without resolving these acknowledged risks exposes patients to unintended consequences.

IV. The Cost Review Study Process Lacks Structural Patient Integration

COMAR 14.01.04.01, et seq. outlines detailed procedures for cost review, including financial data analysis and manufacturer submissions.

What it does not require is:

- A mandatory patient impact assessment
- Access certification prior to any payment cap
- Modeling of non-medical switching consequences
- Evaluation of downstream utilization management expansion
- Analysis of provider stocking risk

Patients may provide testimony. That is not the same as embedding patient impact into the analytical framework. Public comment is not structural protection.

V. Upper Payment Limits Risk Access Instability

Maryland is one state within a national pharmaceutical market.

Significant divergence in reimbursement benchmarks can predictably lead to:[6]

- Altered distribution strategies
- Reduced provider willingness to stock affected therapies
- Narrowed formularies
- Increased prior authorization and step therapy

Patients living with cancer, autoimmune conditions, rare disease, and other life-sustaining treatment needs cannot absorb policy instability. Affordability cannot come at the cost of availability.

[6] National Conference of State Legislatures, "State Prescription Drug Affordability Boards," https://www.ncsl.org/health/state-prescription-drug-affordability-boards; Avalere Health, "State Prescription Drug Affordability Boards Consider Cost Containment Measures," https://avalere.com/insights/state-prescription-drug-affordability-boards-consider-cost-containment-measures.

VI. Recommendation

Before implementing Upper Payment Limits under COMAR 14.01.05.01, the Board should:

1. Publish documented evidence of patient-level savings achieved to date;
2. Adopt mandatory patient impact assessments prior to any UPL determination;
3. Establish enforceable safeguards preventing increased utilization management;
4. Certify that access will not be reduced as a result of Board action;
5. Demonstrate legal and operational feasibility without cost-shifting to other parts of the system.

Absent these safeguards, the Cost Review Study Process functions primarily as a fiscal mechanism — not a patient protection policy.

Patients are not economic variables in a reimbursement model. After five years of operation, the Board should demonstrate results before expanding power. Upper Payment Limits are not a patient-centered reform unless and until the Board proves they improve patient affordability without compromising access.

Respectfully submitted,

Terry Wilcox
Co-Founder & Chief Mission Officer, Patients Rising