November 8, 2024

Maryland Prescription Drug Affordability Board
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Bowie, MD 20715
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Via Electronic Correspondence

RE: COMAR 14.01.01.05 (Policy Review, Final Action, and Upper Payment Limits) and COMAR 14.01.01.06 (Hearing Procedures)

Dear Maryland Prescription Drug Affordability Board,

Aimed Alliance is a not-for-profit health policy organization that seeks to protect and enhance the rights of healthcare consumers and providers. We are writing to provide written comments on the Maryland Prescription Drug Affordability Board's draft regulations, COMAR 14.01.01.05 (Policy Review, Final Action, and Upper Payment Limits) and COMAR 14.01.01.06 (Hearing Procedures). In reviewing the regulations, we urge the Board to:

1. **Adopt a patient-center approach in the policy review process;**
2. **Consider a copay accumulator ban in the policy review process;**
3. **Avoid the use of discriminatory cost-effectiveness measures in setting UPLs;**
4. **Adopt a UPL monitoring approach where the Board assumes responsibility, not patients; and**
5. **Remove the authority for the chair or staff designee to limit repetitious testimony from speakers**

I. Adopt a Patient-Centered Approach in the Policy Review Process

The policy review process requires the Board to identify the drivers and market conditions causing affordability challenges and determine which policies may effectively address them. While we appreciate the Board's consideration of alternative, non-UPL policies and its focus on ensuring solutions address affordability drivers, we continue to urge the Board to ensure it adopts a patient-centered approach in its review to ensure that any recommended policies are fully evaluated for their impact on patient affordability of and access to medications.

As the primary beneficiaries of medications, patients offer invaluable insights into challenges that contribute to affordability issues. Their firsthand experiences with disease management, access barriers, treatment preferences, and other factors directly related to medication use provide crucial perspective for understanding the drivers and solutions to high drug costs.[1] By engaging patients, providers, and caregivers, the Board can gain valuable insights essential for conducting a patient-centered policy review that allows for a comprehensive understanding of the most effective policies to address challenges related to prescription drug affordability.

[1] Alex Krist, et al., *Engaging patients in decision-making and behavior change to promote prevention*, 240 STUDENT HEALTH TECHNOLOGY INFORMATION 284-302 (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6996004/.

Additionally, in reviewing UPLs as a potential policy recommendation, we strongly urge the Board to proactively identify and assess the access barriers that UPLs could potentially create for patients. While UPL policies intend to reduce costs, they may unintentionally limit patient access to the medications they need, particularly if the UPL results in restrictions on coverage, treatment options, or availability.[2] These unintended consequences must be carefully considered to ensure that any policy aimed at reducing costs does not come at the expense of patient access to essential care.

Furthermore, if the Board decides to recommend the implementation of a UPL, it is crucial that the Board not only assess potential cost savings for payors but also consider how these savings will be passed down to patients. For UPL policies to improve affordability, the benefits must be directed toward reducing out-of-pocket costs for patients. This requires a clear mechanism to ensure that cost savings translate into tangible savings for those who rely on these medications and are directly impacted by high prescription drug costs. Only by fully integrating the patient perspective into its policy analysis can the Board develop policies that truly address the unaffordability of prescription drug while safeguarding access to necessary treatments.

II. Consider Copay Accumulator Ban in the Policy Review Process

In considering policy options, we urge the Board to recommend that Maryland implement a copay accumulator ban. Many patients rely on financial assistance from pharmaceutical manufacturers or other third parties to afford their copays and meet their health plan's cost-sharing obligations for prescription medications. Typically, this third financial assistance is applied toward the patient's deductible and out-of-pocket maximum—unless the health plan has implemented a copay accumulator program.

Under these programs, any third-party assistance is excluded from counting toward the deductible or out-of-pocket maximum, causing patients to face unexpected, additional costs to meet their yearly cost-sharing obligation. This abrupt financial burden can cause significant anxiety and stress and may even force patients to switch medications or discontinue treatment due to unaffordable out-of-pocket expenses once their financial assistance runs out. Consequently, patients may experience worsening of their condition, relapse, and other adverse health outcomes, increasing their overall healthcare needs and costs.

Furthermore, if a patient changes health plans mid-year after exhausting copay assistance under their previous plan, they are unable to access similar assistance through their new plan for the rest of the year. While copay accumulator programs may yield short-term savings for insurers, they ultimately result in higher costs and harm patient well-being over time. Importantly, while health plans may allege that copay accumulators are necessary to mitigate costs, a study by The AIDS Institute found that there was no statistically significant difference in premiums between states that have implemented copay accumulator bans and states that permit the use of copay accumulators. As such, this assistance should be passed directly to consumers to lower their health care costs.

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[2] Avalere, *Upper Payment Limits on Drugs Could Alter Patient Access*, https://avalere.com/insights/upper-payment-limits-on-drugs-could-alter-patient-access.

To mitigate these issues, 20 states, as well as the District of Columbia and Puerto Rico, have enacted bipartisan laws requiring health plans and pharmacy benefit managers to apply copay assistance toward individuals' deductibles and annual cost-sharing requirements. Therefore, as Maryland evaluates policy options, we strongly encourage the Board to consider a copay accumulator ban as an effective solution to improve affordability and supporting patients across the state.

III. Avoid the Use of Discriminatory Cost-effectiveness Measures in Setting UPLs

Under the proposed rules, UPLs may be set "using a cost-effectiveness analysis to model how much additional health outcome is gained per dollar of additional spending when using a drug product compared to an alternative." Cost-effectiveness frameworks can restrict patient access to care by assigning a fixed value to medications, failing to account for individual circumstances or needs. For example, quality-adjusted life years (QALYs) are a cost-effective measurement that combines a person's quality of life with their life expectancy to assess the value of health care interventions.[3]

The use of certain cost-effective measures, like QALYs, to assess the value of any prescription drug treatment raises significant ethical issues because they assign a monetary value to human life based solely on diagnosis, implying that individuals with chronic or rare conditions are less valuable than those with more common conditions. This approach effectively discriminates against individuals with chronic or rare diseases in favor of those with more common or less costly conditions. We strongly urge that the Board abstain from using discriminatory cost-effectiveness frameworks, such as QALYs, when setting UPLs, as they could unintentionally exacerbate disparities and limit access to care for vulnerable patient populations.

IV. Adopt a UPL Monitoring Approach Where the Board Assumes Responsibility, Not Patients

We appreciate the Board's commitment to ensuring that any potential imposition of UPL is effectively monitored. If the Board does move forward with imposing a UPL, we believe it is essential for the responsibility of ongoing monitoring to rest with the PDAB itself. Patients already face substantial burdens in managing their health, personal lives, and careers, and it is unrealistic to expect them to proactively follow complex regulatory changes or the intricacies of UPL implementation. To facilitate effective monitoring, we suggest that the Board actively engage trusted stakeholders within relevant disease communities. These stakeholders can provide critical feedback and share experiences regarding access, out-of-pocket costs, and overall impact of UPLs on patients. By regularly consulting these community leaders, the Board will be better equipped to respond to patient concerns and ensure that any unintended consequences of UPL policies are promptly addressed.

V. Remove the Authority for the Chair or Staff Designee to Limit Repetitious Testimony from Speakers

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[3] Gabriel Andrade, *Ethical Shortcomings of QALY: Discrimination Against Minorities in Public Health*, CAMBRIDGE QUARTERLY OF HEALTHCARE ETHICS, 1-8 (Jan. 15, 2024).

Lastly, we urge the Board to remove the language providing the chair or staff designee the authority to limit repetitious testimony from speakers in the procedures for conducting an informal hearing. It is essential to respect the time and commitment of individuals who volunteer to speak at these hearings. When stakeholders sign up to participate, they invest their time and perspectives, and their contributions should be heard with respect. Limiting repeated testimony may inadvertently silence important concerns of patients and caregivers.

Moreover, when a particular issue or concern is repeatedly raised by multiple individuals, it may signal a broader and potentially significant issue that warrants additional attention and discussion. Dismissing or limiting these repeated comments can overlook critical insights that may shape more informed and effective decisions. Thus, we urge the Board to remove the language providing the authority for the chair or staff designee to limit repetitious testimony to foster stronger stakeholder engagement and ensure that policy decisions are based on a comprehensive understanding of the issues.

VI. Conclusion

In conclusion, we urge the Board to revise its rules to prioritize patients by: (1) prioritizing a patient-centered approach throughout the policy review process; (2) considering a copay accumulator ban in the policy review process; (3) refraining from using discriminatory cost-effectiveness measures when setting UPLs; (4) adopting a UPL monitoring approach that places the responsibility on the Board rather than patients; and (5) removing the authority for the chair or staff designee to limit repetitious testimony.

We appreciate the opportunity to provide written comments. If you have any questions or would like to further discuss our concerns. Please contact us at policy@aimedalliance.org.

Sincerely,

Olivia Backhaus
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Aimed Alliance