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Via Electronic Correspondence

RE: COMAR 14.01.01 (General Provisions) and COMAR 14.01.05 (Policy Review, Final Action, Upper Payment Limits)

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 comment on the Maryland Prescription Drug Affordability Board's draft regulations, COMAR 14.01.01 (General Provisions) and COMAR 14.01.05 (Policy Review, Final Action, Upper Payment Limits). In reviewing the regulations, Aimed Alliance urges the Board to:

(1) Consider out-of-pocket costs for patients;
(2) Adopt a UPL monitoring approach where the Board assumes responsibility, not patients;
(3) Remove the authority for the chair or staff designee to limit repetitious testimony from speakers; and
(4) Prohibit the use of QALYs in PDAB assessments.

I. Consider Out-of-Pocket Costs for Patients

The purpose of the PDAB "is to protect *State residents,* State and local governments, commercial health plans, health care providers, pharmacies licensed in the State, and other stakeholders within the health care system from the high costs of prescription drug products" (emphasis added). [1] However, when outlining the methodology for establishing an upper payment limit (UPL), the draft rules only consider total out-of-pocket costs for state health plans, county, bicounty, and municipal health plans, and Medicaid. They do not consider the direct patient costs. As such, Aimed Alliance urges the Board to incorporate patient out-of-pocket costs, including copayments, deductibles, and other associated costs, when determining a UPL. This would ensure a more patient-centered approach that fully considers the UPL's impact on patient affordability. This more comprehensive assessment would also provide a clearer picture of the economic burden patients face and help the Board fulfill its mission of protecting State residents from the high costs of prescription drugs.

[1] Md. Code, Health-Gen. § 21-2C-02.

II. 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 a UPL is monitored. If the Board does move forward with imposing a UPL, we believe it is essential for the responsibility of any 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.

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

The proposed rules authorize the Chair or staff designee to limit repetitious testimony. However, it is essential to respect the time and commitment of individuals, especially patients, 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. Therefore, 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 informal hearings.

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 may overlook critical insights that could 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 a positive environment that encourages stakeholder engagement and ensure that policy decisions are based on a comprehensive understanding of the issues.

IV. Prohibit the Use of QALYs in PDAB Assessments

Under the proposed rules, the Board may use a "cost-effectiveness analysis" when setting the UPL for a prescription drug. This entails modelling how much health benefit is gained per dollar of additional spending when using a drug product compared to an alternative. These frameworks, however, can limit patient access to care by assigning a fixed value to a medication, without considering individual needs or circumstances. For example, quality adjusted life years (QALYs) aim to quantify the health benefits of medical interventions or healthcare programs that are often used in decision-making to ration healthcare resources. The use of QALY measures raises significant ethical concerns, as these measures effectively place a monetary value of human life based solely on a diagnosis, suggesting that individuals with chronic, debilitating, and rare conditions are less valuable than those with common conditions. These types of approaches treat

individuals' lives and health as a commodity and ignores patients' and practitioners' individualized perception of the value of a specific treatment. Aimed Alliance reiterates its longstanding position against using QALYs to evaluate any treatment and urges the Board to prohibit the use of QALYs throughout the UPL-setting process and in any cost effectiveness analysis.

V. Conclusion

In conclusion, we urge the Board to revise its rules to prioritize patients by (1) considering the total out-of-pocket costs for patients; (2) adopting a UPL monitoring approach where the Board assumes responsibility, not patients; (3) removing the authority for the chair or staff designee to limit repetitious testimony from speakers; and (4) prohibiting the use of QALYs in PDAB assessments.

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,

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Staff Attorney
Aimed Alliance