November 19, 2024

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

TO: Members of the Maryland Prescription Drug Affordability Board

As a physician who has spent decades caring for patients whose families struggled to access and afford their needed medicines, I urge you to reconsider approving the draft regulations. I have specific concerns regarding the new regulation on hearing procedures and the new chapter on policy review, final action, and upper payment limits. I am deeply concerned that the proposed implementation of UPLs could inadvertently prevent input from diverse stakeholders and restrict access to necessary medications for patients, especially those with rare or complex conditions.

First, provisions in the draft regulations around hearing procedures suggest a process where stakeholder participation could be limited or selectively considered, reducing transparency and inclusivity in UPL development. For example, the proposed language allows the Board to limit "repetitious testimony," granting subjective discretion to the Board Chair or staff designee to decide what constitutes repetition. This could restrict stakeholders' ability to fully present their viewpoints during hearings. In addition, the draft regulations list tools such as public hearings and stakeholder council input, but it gives the Board and staff significant control over which inputs to include, potentially excluding certain stakeholder feedback without a transparent process.

Marylanders and Maryland lawmakers deserve recommendations informed by comprehensive and extensive stakeholder feedback. Physicians and patients are concerned that the current approach risks overlooking individual patient needs and could disadvantage certain populations.

As a board-certified pediatrician and rheumatologist, I have dedicated my career to serving children and youth with chronic or disabling conditions. Many of my young patients, including those with juvenile idiopathic arthritis or lupus, depend on specialized, innovative and, unfortunately, expensive therapies. The draft outlines extensive information gathering about costs, utilization, and spending by “eligible governmental entities” but lacks comparable measures directly addressing patient affordability or health outcomes.

Among the many complexities not yet considered in creating a UPL is the role of national and out-of-state group purchasing organizations and the unique cost structures for infusible or other administered medicines. Medications can only remain accessible if providers can afford to purchase and administer them; restrictive UPL policies may jeopardize these critical care sites, resulting in decreased access to care. The Coalition of State Rheumatology Organizations, National Infusion Center Association and others have highlighted these challenges, underscoring the fact that these are not isolated state-level concerns. Ensuring that medications remain locally available and affordable is critical to prevent patient care disruptions and unintended outcomes.

I urge the Board to review and provide recommendations that include the roles of **all** players in the system, since payors and pharmacy benefit managers (PBMs) and others are involved in setting both the list prices and patient costs. Without examining the entire drug supply and distribution chain, we cannot

achieve the goal of improving access to affordable, life-saving drugs. Effective solutions must focus on what patients actually pay, not inflated list prices.

Physicians and patients remain committed to working with you to ensure affordable medications for all Marylanders, but to accomplish this goal will require a more thorough, comprehensive, and extensive consideration.

Thank you for your attention to this critical issue.

Sincerely,

Harry L. Gewanter, MD, FAAP, MACR
President, Virginia Society of Rheumatology
Board Member, Let My Doctors Decide Action Network