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National Groups:

Hepatitis Education, Advocacy & Leadership (HEAL) Group

Industry Advisory Group (IAG)

National ADAP Working Group (NAWG)

February 4, 2025

VIA Electronic Mail

Maryland Legislature House of Delegates Health and Government Operations Committee

RE: HB 424 Expanding Authority of the Prescription Drug Affordability Board; <u>OPPOSE</u>.

Honorable Chairperson Delegate Pena-Melnyk, Vice Chair Delegate Cullison, and Members of the Maryland House of Delegates Health and Government Operations Committee,

The Community Access National Network (CANN) is a 501(c)(3) national nonprofit organization focusing on public policy issues relating to HIV/AIDS and viral hepatitis. CANN's mission is to define, promote, and improve access to healthcare services and support for people living with HIV/AIDS and/or viral hepatitis through advocacy, education, and networking.

Maryland Legislators Have Already Voiced Critical Concerns

Several Maryland legislators have raised questions and concerns regarding the effects of Board decisions. During a recent Maryland Finance Committee meeting, Senator Lam raised a question of patient protection. He asked if the Board had stipulations in place to ensure that drugs selected for a UPL would be guaranteed to be covered on the formularies affected plans for state employees. This is a pertinent question because to avoid the loss of revenue from a UPL, a plan could simply decide not to include the drug on the formulary in favor of a different drug that was more profitable. Presently, no such stipulations are in place, and Director York stated separate policies would need to be drafted.

Senator Lam also inquired about ensuring that proposed savings from a UPL are passed through directly to patients and consumers instead of being reaped by payors or PBMs. Director York explained that state and local government plans often have nominal patient costs. The question of pass-through savings only applies to the commercial market. Thus, the possibility of saving patients' money directly in the current state doesn't effectively exist currently. There would only be a potential cost saving for the state. Extending authority to the entire state is unwise given the current lack of understanding of the full effects on the state when the commercial market has additional layers of complexity and potential patient and system harm.

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Senator Hershey also expressed concern that UPLs would only result in savings for the insurance plans and reduced spending of state taxpayer dollars instead of relieving patient costs.

Senator Ellis raised concerns about the effects of the Board's activity on the 340 B program in the state. Director York explained that a thorough analysis of that vein of reporting is not due to the General Assembly until 2026. At this juncture, no expansion of authority should be granted without a detailed understanding of the intricacies of 340 B funding mechanisms.

Program Metric Monitoring is Fundamental

HB 424 appears to remove the requirement of monitoring program impacts. Tracking the impact of decisions made is the cornerstone of evaluating program implementation. This is exceptionally important when considering expanding authority to the entire state. It is imperative to assess if changes made effectively result in positive fiscal outcomes, remedying the problems of affordability the Board desires to solve. Proper monitoring also identifies adverse patient outcomes regarding access, medical effects of potential changes to drugs prescribed because of a UPL or other cost containment measures, and the financial viability of the complex payor-provider-patient ecosystem. Program monitoring provides the opportunity to identify problems as they develop instead of being discovered after they become crises.

HB 424 Does Not Consider Potential Fiscal Shortfalls

Recent data indicates that instituting an "Upper Payment Limit" (UPL) will not result in savings worth the risk of enforcing it. The Oregon Prescription Drug Advisory Board (PDAB) utilized the consulting firm Myers and Stauffer to examine the costs and benefits of imposing a UPL in Oregon. The <u>resulting report</u> indicated that a UPL would result in limited financial savings and possibly adverse fiscal effects, particularly as it relates to the state's Medicaid program and 340B safety net providers via reduced values of rebates, **necessitating additional appropriations to make programs and providers whole.**

Utilizing several theoretical UPL price points, the analysis showed that in the best-case scenario, the imposition of a UPL would produce less than half a million dollars in "savings" to Oregon's Medicaid program due to reductions in rebate values applied to the program. Additionally, there would potentially be a reduction of federal matching dollars (FMAP) or program-sustaining revenues from the Medicaid Drug Rebate Program (MDRP), weakening the Medicaid program's ability to meet vulnerable populations' needs.

In 2024, Maryland approved \$148.3 million in state spending reductions to balance the budget while also having to direct more money to pay for Medicaid. This was due to the larger-than-anticipated retention of Medicaid participants.

The potential harm to the 340B safety program was also recently highlighted in a recent New York Times article. The article discussed how a significant insulin cost cap harmed access to care and affordability of medications for patients and generated additional sustainability concerns for public health providers, particularly Federally Qualified Health Centers, due to negative impacts on 340B revenue generation. A

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reduction in 340B revenues would also harm Maryland's AIDS Drug Assistance Program (ADAP). The vulnerable populations served by Maryland's ADAP would be negatively affected by anything that adds instability to an already fragile ecosystem.

Maryland would require additional appropriations to make up for funding losses. Programs and services harmed by reduced funds would need to be made whole.

The current discourse is based on faulty reasoning

The current paradigm of the Board views cost control issues in a manner that does not reflect mechanisms that truly affect drug pricing. One of the main selection criteria for drugs selected for affordability review is the wholesale acquisition cost (WAC). This is an exemplary example of how list price does not directly correlate with affordability. The recent administrative complaint filed by the <u>Federal Trade Commission</u> gives evidence that PBMs predatorily manipulate the WACs of medications for their own profit. When manufacturers offer lower WAC medications that are clinically identical to the high WAC versions, PBMs categorically assign the high WAC versions to their formularies marketed to health plans to the exclusion of low WAC options.

Another Federal Trade Commission report explains the egregious extent to which PBMs inflate the prices of drugs in the generic market and manipulate distribution and pharmacy networks for profit to the detriment of patients and pharmacies. UPLs or other cost containment caps do not address these issues.

There Is Currently No 'Proof Of Concept'

HB 424 seeks to expand the current authority of the Board to set upper payment limits for all purchases and payor reimbursements of prescription drug products in the state. From the passing of the legislation that created the Board in 2019 up to the present, no action has been taken to improve drug affordability for Marylanders. There are unresolved issues and concerns that have not been remedied, particularly regarding fiscal impact study and ensuring Marylanders maintain access to life-saving medications. Despite detailed questions from the public on these issues - the Board and staff remain unresponsive.

For example, although board discourse has expressed a need, there is no current plan for robust patient input and engagement. There are also no contingency plans in place for possible unintended adverse effects on patient populations. There are only "concepts of a plan" regarding the enforcement of a UPL on payors. As will be discussed later in this letter, there has been no serious consideration of additional appropriations that may be needed to make up for losses and threats to financial stability for pharmacists and safety net providers because of enacting upper payment limits.

At this juncture, there are too many unanswered questions, a paucity of contingency planning, and well-intentioned discourse with no tangible proof of success. It is imprudent to extend the authority of the Board because doing so would also broaden the scope of potential damage that could be caused to Marylanders.

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Conclusion

Presently, there are too many unknowns for the Board to proceed effectively with its current authority. Accordingly, there is no acceptable preparation to grant additional authority. Bestowing expanded powers would be akin to riding a bicycle without training wheels before one is ready. Falling and scraping knees or experiencing a head injury would be akin to multi-faceted patient harm, which would be harmful to the well-being of Marylanders.

Additionally, board operations, potential enforcement, and cost-control monitoring are significant fiscal expenditures. The Board is supported entirely through a Special Fund based on fee assessments to health insurance carriers, pharmacy benefit managers, prescription drug manufacturers, and wholesale distributors. The appropriation and allowance for FY2023 and FY2024 were over \$1.4 million each year. Additional funding and human resources would be required to implement UPLs. As the Oregon independent consulting analysis indicates, the meager potential savings could be overshadowed by the program's costs after adjusting for resulting financial losses.

While CANN is primarily focused on policy matters affecting access to care for people living with and affected by HIV, we stand in firm support of all people living with chronic and rare diseases and recognize the very reality of those living with multiple health conditions and the necessity of timely, personalized care for every one of those health conditions. State Prescription Drug Affordability Boards are of profound importance to our community.

Ultimately, CANN respects the work and effort the Maryland Legislature is trying to achieve. We understand that you care about your constituents, neighbors, and even your families. And we know you want to address the complexities of our healthcare system, which leaves far too many patients behind. In these issues, we agree.

Presently, the Boards' activity is not actionable to achieve that goal; thus, expanding that authority is premature. We are readily available to answer any questions you may have and look forward to future discussion on improving access to care for Marylanders. Jen Laws, CEO, and I can be reached respectively at Jen@tiicann.org and Ranier@tiicann.org.

Respectfully submitted,

Rames Li

Ranier Simons

Director of State Policy, PDABs

Community Access National Network (CANN)

On behalf of

Jen Laws

President & CEO

Community Access National Network (CANN)