COMMUNITY ACCESS NATIONAL NETWORK

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Maryland Prescription Drug Affordability Board
169000 Science Drive, Suite 112-114
Bowie, MD 20715

RE: Ongoing Affordability Discussions

Dear Honorable Members of the Maryland Prescription Drug Affordability Board,

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.

Affordability Challenge Remains Unclear

Just like Farxiga and Jardiance, Ozempic and Trulicity have been preliminarily found to pose "affordability challenges" because staff research indicated their Wholesale Acquisition Costs (WAC) increased faster than inflation. Additionally, it was found that total gross prescription drug spend for state and local governments exceeds 2.27% of gross prescription drug spend for Trulicity and 4.87% of gross prescription drug spend for Ozempic.

However, these data points do not define "affordability challenge". They simply state the status quo of spending. There has been **no** identification of what an acceptable percentage of gross spend is, nor an analysis of how something like a UPL will achieve that percentage once it is identified, ***if*** it is identified. Moreover, in this vein, the focus on affordability is through the lens of "system" costs and prices, and it remains unclear how patients or even government payors would directly benefit.

WAC does not directly translate into affordability for patients or government payors, despite it being one of the metrics statutorily used for potential drug selection. **Patient out-of-pocket costs, such as co-payments, are directly determined by plan design.** While it has been implied that a percentage of WAC is how plan co-insurance payments are determined, it is not a simplistic direct causal relationship. As staff has explained in the past, transparency on

pricing mechanisms based on the relationship between PBMs and plans is opaque. Thus, pursuing a policy to disincentivize WAC increases requires much more informed data to prove that it is a worthwhile endeavor.

Essential Baseline Data is Lacking

Staff reporting indicates that important data is missing, which raises questions about how effectively patient and system affordability can be reliably analyzed using the presented metrics. Repeatedly, staff have indicated that they have not been able to obtain data to assess cost impacts on public budgets for state and local governments. Additionally, a specific amount of spending cannot be deemed "too high" if it's simply a result of high utilization of an effective drug, because a large swath of Marylanders gain significant benefits from it. There has been no data presented describing the implications of contrasting differences between the specific drug utilization of Marylanders and the national population utilization.

Without a thorough background analysis, such as, but not limited to, addressing the aforementioned missing data, it is unclear how the analysis can conclude that a UPL is the remedy to a heretofore non-specific "affordability challenge". It is further unclear how using the "maximum fair price" as a benchmark for UPL is a bona fide solution, given the lack of clarity about public budget impacts or market adjustment in benefit design by PBMs upon imposition of a UPL.

Solution Development Efforts Appear Skewed

It has been presented that the development of non-UPL affordability solutions would run "in parallel" with UPL development. However, based upon Board and staff discussion, that intent does not appear to be represented as a meaningful consideration. Several non-UPL affordability solutions, without the potential for patient harm, appear to be more timely in terms of patient and system cost relief, but also less expensive for state budgets. Various aspects of PBM reform, including prohibitions on predatory plan tiering and copay caps, for example, are a means to directly regulate within the current abilities of the legislature and the way insurance is regulated without imposing a UPL, and more directly, addressing patient affordability needs.

Moreover, there hasn't been a discussion of a suggested policy for issues such as how to protect patients from readily foreseeable unintended consequences and ensure that a drug with an applied UPL cannot be removed from a formulary as a result of the UPL being set. "Monitoring" has been hinted at; however, it is unclear what is being done *now* and what will be done in the future, along with the actions to be taken based on information gleaned from said monitoring. The basic principles of program and policy monitoring require both a "baseline" and specified plans for evaluating the same data across change implementation. Thus far, neither the Board nor staff have committed to or sought out establishment of "baseline" benefit designs, pharmacy acquisition and availability of named medications, or even impact on the state's Medicaid Drug Rebate Program revenues of named medications. No meaningful effort to assess the current state of access has been made.

Furthermore, Director York has made repeated mention of imposition of a UPL "on the backend". What he means by this is entirely unclear and should be defined in explicit detail to the public and the Board so as to understand the impact of a UPL on any variety of supply chain actors and what patients should be expecting in the instance of imposing a UPL. If the Director is suggesting a post-reimbursement fee capture, similarly

structured to direct and indirect remuneration fees, that needs to be explained, as implementing this design would be particularly harmful to pharmacies.

Additionally, no effort has been made to explain how 340B claims will be identified and excluded from the imposition of a UPL, as mandated by Maryland law. This process needs to be explained and properly understood, with information from the public as to anticipated impacts, for the Board to make an informed decision.

With the present mandate to help patients and the state regarding public health plans, and the desire to further affect the commercial market, it appears there is too much left unanswered, unexamined, and unarticulated to continue on the present path. **Moving forward without the above information betrays the public trust and the stated legislative intent of the very law enacting this very Board.**

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.

Respectfully submitted,

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Community Access National Network (CANN)

On behalf of
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Community Access National Network