COMMUNITY ACCESS NATIONAL NETWORK

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Maryland General Assembly
Legislative Services Building
90 State Circle
Annapolis, MD 21401

RE: OPPOSE: Proposed UPL Action Plan

Honorable Members of the Maryland Legislative Policy 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.

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.

Today, we write with comments regarding the proposed Upper Payment Limit Action Plan.

The Cost-Benefit of a UPL Does Not Serve Maryland Patients

The Oregon Prescription Drug Advisory Board recently contracted with Myers and Stauffer, independent consultants, to analyze the potential cost savings of implementing a UPL. While Maryland and Oregon are two different states, both have large numbers of citizens dependent upon Medicaid and safety net entities.

The consultants noted a few concerns that are particularly important to under-served and marginalized communities highly impacted by health disparities. The most noted is that the imposition of a UPL on a best-case basis may produce less than half a million dollars in “savings” to Oregon’s Medicaid program due to reductions in rebate values applied to the program. The UPL does not consider the negative fiscal impact of potentially reducing federal matching dollars (FMAP) in assisting the state of Oregon in meeting its Medicaid population’s needs. This mirrors the concern we further detailed in this letter regarding Maryland’s Medicaid shortfalls.

Moreover, their report indicated that Medicaid rebate reductions as a result of a UPL would be mirrored by a similar reduction in 340B discount values. For 340B covered entities serving marginalized populations and otherwise operating as safety net entities, such a reduction would likely prove damaging to patient affordability and access and harmful to the financial sustainability of these entities, particularly federally qualified health centers.

Simply put, a UPL does not serve either the "health system" as a whole or patients living in Maryland. CANN continues to urge the Maryland Legislature and the PDAB to weigh the potential of minor benefits relative to significant concerns in these regards.

Should the Board or Legislature seek to impose a UPL, the Legislature must be prepared to seek additional appropriations to support the state's Medicaid program, AIDS Drugs Assistance Program, and safety net providers, like FQHC's, or risk reducing meaningful access to care for the state's most vulnerable populations.

Draft Plan Lacks Specificity of Definitions, Stakeholders, and Goals

The first page of the document states that the Board may conduct cost review studies to determine whether the use of a medication "has led or will lead to affordability challenges for the State health care system or high out-of-pocket costs for patients ("affordability challenges"). There is further explanation that if a medication is deemed to pose an "affordability challenge", the Board can use remedies such as a UPL in response to the challenge.

Our concern with the opening sentiments is we do not perceive that the Board currently has a definition of what is or is not "affordable". With a lack of consensus on what defines "affordability", one cannot feasibly go one step further and delineate a drug as presenting an "affordability challenge". This is a matter of defining goals and endpoints of what will be achieved by enacting something such as an "upper payment limit" (UPL, alternatively "reimbursement cap"). Without having a consensus on what affordability looks like for various stakeholders and why the subsequently selected parameters of affordability best meet all parties' needs, one cannot move forward.

Similarly, the Draft Plan does not specify to which stakeholders a UPL should be "benefiting". Lacking a definition of "affordability" also means lacking a definition of "affordability for whom?" – Failing to specify these definitions, several states, including Maryland, already engaged in PDAB work have quite readily conflated "patient affordability" with "PBM profitability", which results in perverse incentives and perspectives, usurping any potential patient impacts with the priorities of for-profit companies. If the goal of a UPL is to serve patient-consumer needs, a reimbursement cap may not directly affect a patient-consumer's premium payments, co-pays, or other plan design concerns. If the goal of a UPL is meant to serve the plan sponsor's budgetary concerns, fiduciary duty requires the Board to consider potential unintended consequences relative to state-based payor programs like Medicaid, AIDS Drug Assistance Programs, and broader funding considerations for public health partners like hospitals and federally qualified health centers.

We detail these concerns with more specificity below.

Medication Shortages

On page two, the draft document states: "A UPL may not be applied to a prescription drug product that is on the federal Food and Drug Administration prescription drug shortage list. HG § 21-2C-13(c)(1). The Board shall

also "[m]onitor the availability of any prescription drug product for which it sets an upper payment limit," and "[i]f there becomes a shortage of the prescription drug product in the State, reconsider or suspend the upper payment limit."

As of the time of this letter, certain formulations of two of the Board's selected medications are in "shortage", according to the FDA.

- Dulaglutide, injection (3mg/0.5ml and 4.5mg/0.5ml), representing two (2) of four (4) dose formulations.

- Semaglutide injection (0.25mg/0.5ml), representing one (1) of eight (8) dose formulations.

While CANN has no means of estimating the market share of these dose formulations, the Board must make a diligent effort to understand the dynamics of these shortages, including the role and danger of "compounding" and other counterfeit drugs currently being marketed to patients who would benefit from semaglutide. Counterfeits pose an exceptional threat to patient-consumer safety and the United States drug supply chain. Specifically, the Board should consider consulting expertise on how a UPL might further counterfeit medication sales by creating an artificial and unsustainable business model for retail pharmacies. Maryland patients deserve to enjoy the supply chain security the rest of the country experiences, and this Board must also consider how its actions may undermine that security.

Additionally, we want to highlight that this emphasis on shortages as described in the Draft Action Plan, in itself, is an acknowledgment that instituting a UPL can potentially cause access problems for patients. While a UPL may not create a nationwide "shortage" as would be identified by the FDA's shortage database, insufficient reimbursement can create "medication deserts" by harming the sustainability of retail pharmacies as a business.

At this point, most of the Board's deliberations and energies seem to be focused on arriving at UPLs without equal consideration for the exploration of other options or consideration of confounding, factual information which might lead the Board to alternative conclusions. The Board must not decide on actions and then seek to justify them; instead, they should identify appropriate information prior to determining any particular action.

Criteria for a UPL do not Address Patient Experiences and are Insufficient

On page 3, under the section, 'Criteria for Setting an Upper Payment Limit,' several bullet points deserve consideration.

Bullet two: The Board shall determine that an upper payment limit is an appropriate tool to address the driver(s) of the affordability challenge identified for the prescription drug product

This bullet directly mirrors our concern that presently, without consensus on affordability or affordability challenges, it is not possible to conclude that a UPL is an appropriate solution.

Bullet five: The Board shall prioritize drugs with a high proportion of out-of-pocket costs compared to the net cost of the drug.

Out-of-pocket costs to patients are controlled by plan design, which includes formulary placements and cost share. A proposed UPL will not necessarily benefit patients' out-of-pocket costs, particularly for patient-

consumers participating in Medicaid, as most medications utilized by Medicaid beneficiaries do not have any out-of-pocket cost in which to consider Moreover, the assumption that a UPL may help with system costs is also not guaranteed, given the opaque nature of pricing in the drug supply chain. Furthermore, should the imposition of a reimbursement cap manifest in "medication deserts" or otherwise harm tangible access to these medications, "system" costs will increase as patients experience poorer health outcomes commonly associated with lack of access to medications.

Coincidentally, a UPL could increase Maryland' s state out of pocket costs by adversely affecting its Medicaid spending. More than one-quarter of the state's population is enrolled in Medicaid. Recent reporting indicates that Maryland is facing almost one billion dollars in projected budget deficits, with an estimated eight hundred million dollars of that as projected Medicaid shortfalls. The amount of federal dollars allocated to the state to help pay for Medicaid services is based on Federal Medical Assistance Percentages (FMAPs). FMAPs determine the matching federal funds based on the state expenditure. If UPLs drastically affect Medicaid expenditures, Maryland would receive fewer federal matching dollars, thus requiring increased state spending on Medicaid services. Conversely, instead of increasing state spending, a response to less funding could be cutting Medicaid services which would be deleterious to the health outcomes of the 1.7 million Maryland residents who depend on Medicaid.

Prior to any action by the Board, the Board must appropriately inquire with Maryland's Medicaid program to better understand any unintended budgetary consequences of imposing a UPL. The Board must consider Maryland's fiduciary duty to Medicaid and its intended beneficiaries as part of information gathering.

Cost Review Study Process is Opaque and otherwise Unspecified

Under the section labeled 'Cost Review Study Process,' the draft document states a cost review study involves: **"Board staff compiling and analyzing quantitative data, qualitative data, and public input for the Board to consider and determine whether use of the drug has led or will lead to affordability challenges. This study process informs subsequent policy action."**

Presently, we do not perceive much qualitative data gathering pursued or any robust pursuit of patient input or engagement. If the Board's purpose is to address patient-consumer experiences and concerns, the Board and its staff must take more meaningful action to engage patients. Failure to do so proves the unfortunate concern that the Board has already determined a conclusion and is merely seeking to justify that pre-determined conclusion rather than engaging in a good-faith exploration of data and experiences.

The section also specifies that **"the Board may request that manufacturers submit documents explaining the relationship between the price of a prescription drug product and the cost of development and therapeutic benefit…".** We inquire as to how comparing a manufacturer's price of a drug to what they spent on the research and development costs of the drug affects the Board's determination of the affordability of a drug for patients and the system and how a UPL factors into the results of said comparison. Furthermore, manufacturers, not the FDA, are largely tasked with continuous monitoring of drug supply chain safety and security, dedicating whole teams of employees and contractors to manage, investigate, and address bad actors exploiting the lack of government involvement in supply chain security. These are continuous costs which must be considered as equally important as current costs of manufacturing and development.

Methodologies for Establishing a UPL Open the Door to Discriminatory Selection

We have multiple concerns regarding the section discussing possible methodologies to be used to establish a UPL on pages nine and ten.

Cost Effective Analysis – This section, in essence, describes the theory of utilizing QALYs. QALY theory and practice puts a price tag on the value of a year of life. QALYs arbitrarily define a monetary value on what is defined as a full year of life in perfect health. Any drug whose utilization does not offer a full year of life or provides less than a full quality of life is considered less of a priority for usage or reimbursement and is scored lower.

The entire QALY methodology (i.e., Cost Effective Analysis) is built upon subjective value judgments. It is detrimental to public health to arbitrarily attribute a value to a perfect year of health and use that for universal efficacy cost comparisons.

QALYs disadvantage people with disabilities as well as those with chronic health conditions because these populations will never be able to achieve what is defined as the "highest quality of life." Drugs treating these populations would be considered of lower priority and value because their potential of returning patients to perfect health is much lower than the potential of ideal health offered by medications utilized by younger people and those in better health states.

Moreover, Congress has already banned the use of QALY theory in cost effectiveness reviews in the Medicare program. The following link directs to a study from the Pioneer Institute discussing the need for extreme caution in this line of cost-effective analysis. (LINK)

Therapeutic Class Reference Upper Payment Limit – This section discusses limiting drugs within the same therapeutic class to be included in reference baskets for setting UPLs by therapeutic class. We urge caution in any therapeutic equivalency comparative effectiveness dialogue as many nuanced factors are involved. Two crucial factors are the differences in the way different patients respond to the same drug as well as the potential to undermine the doctor-patient relationship by possibly interfering with the physician's recommended treatment priority.

Domestic Reference Upper Payment Limit – We urge caution in making decisions based on prices paid by other purchasers. Due to the opacity of the drug supply chain and pricing process, it isn't possible to gain robust details on how a particular purchaser arrived at their net price. Using another payer's situation could have unforeseen negative consequences on the best interests of the Maryland system.

International Reference Upper Payment Limit – Drug prices paid in other countries should not be considered. Seeking drug pricing information from other countries would be comparing apples to oranges, providing no translatable correlation. Other countries' markets are very different from those in the U.S., including those with a single-payer system and vastly different means of price control. Additionally, other countries' pricing methodologies include QALYs and other discriminatory designs. Thus, utilizing drug pricing information from other countries is a 'backdooring' of prohibited metrics.

Conflict of Interests in Consultants Must be Addressed

The Board must consider conflicts of interests in pursuing any consulting agreements for data analysis. Particularly, the Board should consider those entities funded by the same funding interests that presented authorizing legislation as necessarily conflicted and prohibit any contracting with those entities. Similarly,

Board members with these same conflicts should be prohibited from serving; at this time, at least one Board member has received exceptional funding from Arnold Ventures, the fiduciary sponsor of NASHP's model PDAB legislation.

Policy Conclusions are Nonspecific

Under the Final Policy Action section on page 12, the draft document states: "The policy review process culminates in the adoption of: (1) other (non-UPL) policy recommendations; (2) proposed regulations setting the UPL at the specified amount; or (3) both.

Our concern is that this section and other places throughout the draft document allude to the possible utilization of non-UPL policy recommendations. Yet, there is no high-level nor detailed discussion of what those are or how they are being investigated. Additionally, potential non-UPL policy recommendations may require the Board to seek and obtain additional legislative authority to enable enforcement. The draft document does not indicate how this possibility would manifest and be executed. Nor does it specify how such a process would fit into and alter policy implementation timelines, including the necessary feedback from all stakeholders, including patients.

Continuous Monitoring for Patient Access is Unaddressed

The PDAB's enabling statute requires the Board to monitor impacts on patient access to care upon imposition of a UPL. However, the Draft Action Plan does not offer any specificity of establishing a monitoring system *prior* to establishing a UPL – failing it statutory obligation. A UPL must not be imposed prior to establishing both a monitoring system and baseline data.

We thank you for the opportunity to provide feedback on the proposed Upper Payment Limit Action Plan. We respectfully ask that you consider all the concerns raised.

Respectfully submitted,

Sincerely,

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Director of State Policy
Community Access National Network (CANN)

On behalf of
Jen Laws
President & CEO
Community Access National Network