COMMUNITY ACCESS NATIONAL NETWORK

Mailing Address:

Attn: Jen Laws
PO Box 3009
Slidell, LA 70459

Chief Executive Officer:

Jen Laws
Phone: (313) 333-8534
Fax: (646) 786-3825
Email: jen@tiicann.org

November 8, 2024

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

RE: Comment on Proposed Regulations

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.

Today, we write with exceptional concern regarding proposed rulemaking and the Board's and staff's failure to meet statutory obligations, recognize existing data, and the current failure to meaningfully involve patients.

Process and Proposed Rules Inhibit Patient Engagement; No "Emergency" Exists

Prior to discussing the content of the proposed rulemaking, CANN must first point out that the process of the proposed rules has left patient communities and other stakeholders less than 10 calendar days (fewer than 6 business days) in which to engage with proposed "emergency" rulemaking without clearly establishing what "emergency" the Board and staff are seeking to address. Such actions necessarily degrade public trust in the institution of the Board and staff.

We urge the Board to reconsider proposed rulemaking wholesale and work to meaningfully engage the public. We are also gravely concerned that any good work to come from the Board may be washed away in an administrative procedure challenge due to failure to meaningfully engage the public.

Statutory Obligations Remain Unmet

Maryland's enacting statute *requires* the Board and staff to sufficiently establish monitoring metrics for any imposed "upper payment limit" (UPL). To date, the Board has failed to clearly and specifically establish such monitoring metrics. The Board's UPL "action plan" makes only a passing reference to such monitoring metrics, without even establishing "concepts of a plan".

Directly, the failure to establish such monitoring *prior* to establishing or imposing a UPL similarly means no "baseline" data will exist and any outcomes of a monitoring program will be fatally flawed.

In specificity, the following related sections of proposed regulation raise great concern:

> *Section .02(B-3)*: **The Board shall: (3) Set an upper payment limit in a way to minimize adverse outcomes and minimize the risk of unintended consequences;**
> Minimizing adverse outcomes and unintended consequences is an important goal. However, previous Board deliberations highlighted a concern that it is difficult to predict the future, and the only means to evaluate outcomes is waiting to observe the consequences of instituting a UPL. In light of this, what mechanisms are being set forth to preemptively minimize adverse effects?
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> *Section .02(C1)*: **The Board shall not set an upper payment limit if: (1) Utilization of the prescription drug product by Eligible Governmental Entities is minimal**
> This verbiage would imply that drugs, such as those for rare diseases would be exempt from a UPL given the low numbers of people utilizing them in comparison to many other drugs. Will the Board set definitive criteria establishing "minimal utilization"?
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> *Section .08(A-4)*: **The Board shall provide for the automatic suspension of the UPL for the time that the prescription drug product is on the federal Food and Drug Administration prescription drug shortage list by regulation.**
> We suggest that the criteria for automatic suspension be expanded to include other lists. In the last meeting, the Board discussion highlighted the issue that state pharmacists maintain a larger drug shortage list than that of the FDA and that hospitals also have shortage lists specific to the state hospitals.

"Preliminary Affordability Determinations" Usurp Patient Engagement and Display Board Bias
In addition to the Board's failure to establish access monitoring metrics, the Board's consideration of "preliminary affordability determinations" similarly displays the Board's predetermined bias. The nature of "preliminary determinations" as described in the proposed rules excludes patient engagement of any kind. Such an action, if adopted and taken, undermines the Board and staff's stated interest in involving patients and the public writ large, again, opening the door to bias and administrative challenges.

Regarding patient engagement, the draft contains multiple references to information gathering and stakeholder feedback. Additionally, during meeting deliberations members of the Board have continuously expressed a desire for more feedback from stakeholders and patient input. Presently, we feel the current structure and timelines set for comment do not display a meaningful desire for a robust inclusion of patient input. We suggest looking at ways other states have sought to solicit meaningful input. This would include meaningfully constructed surveys disseminated to patients to solicit information that is not captured by APCD data, such as drug costs by those who are uninsured transportation and familial costs related to prescription drug access.

Additionally, with proper outreach, patients can give feedback about affordability concerns for medications the Board has not identified with their current criteria, resulting in an analysis of the costs of drugs ***patients*** define as their real-world drug affordability challenges. Staff could conduct patient forums that permit dialogue about patient concerns in an environment more conducive to candid discussion than a legislative hearing.

In specificity, the following related sections of proposed regulation raise great concern:

> *Section .02(B -1)*: **The Board shall: (1) Consider the cost of administering the drug and delivering the drug to consumers, as well as other relevant administrative costs;**
> We encourage the Board to thoroughly consider costs that have not previously come up during public meeting deliberations. There are important costs to consider that are not as conveniently documented in the manner that costs such as pharmacy dispensing fees are. One example is physician and staff time. A UPL could drive a PBM to institute utilization management requirements such as prior authorization for a drug. Prior authorization would add to physician and staff time due to the required clinical documentation necessary. Additionally, prior authorization can cost patients time in the form of delays associated with prior authorization denial.

> *Section .03(B-1)*: **The purpose of the policy review process is to: (1) Based on the best available information…**
> Previous Board deliberations have highlighted concerns with the quality of available information. There have been questions concerning the age of data, desired data points that haven't been previously included, and concerns about necessary data that may be very difficult, if not impossible, to obtain. We inquire as to what standards will be set to define "best." Additionally, if the parameters of the defined "best" are not met, what will be the course of action?

> *Section .06(B-2)*: **Therapeutic Class Reference Upper Payment Limit**
> Drugs may be in the same therapeutic class, but they all do not have the same efficacy or demand. Thus, their prices should be and are different. Therefore, setting a price based on the lowest net cost among all competitor products in the same therapeutic class is problematic.

> *Section .06(B-2a)*: **Under this methodology, a UPL value may be set as the initial price at which the drug was first marketed (launch price) adjusted for inflation.**
> This methodology does not consider factors other than inflation that affect a drug's pricing over time.

Proposed Rules Include Existing State Government Data, Which the Board has Already Refused to Consider

We do wish to acknowledge the proposed rules include several beneficial aspects while still being problematic in process. Namely, proposed rules include consideration of other state data regarding UPLs and affects on patient accessibility. However, the Board has *already* been presented with data from Oregon's PDAB regarding potential impacts to their state's Medicaid program and safety net provider network.

In summary, Oregon's PDAB requested an assessment from the state's Medicaid program, in which consultants Stauffer & Meyer presented findings. Those findings include an unknown but largely anticipated impact of reduced rebate values for both the Medicaid program and 340B, safety net providers. The most measurable anticipated outcome noticed by Stauffer & Meyer includes a less than half a million dollar "savings" in the state's $36 billion Medicaid program due singularly to rebate value reductions. Stauffer & Meyer encouraged Oregon's PDAB to request information from safety net provider entities as to 340B value reduction impacts on services and scope of program reach as such financial changes would be significant.

While Board Member Anderson and Director York have dismissed these concerns, they remain unanswered in any meaningful way. The risk that comes from this lack of direct answer is cutting off Maryland's most vulnerable populations from provider services and harming the stability of the state's Medicaid program with no appreciable benefit for patients or the state's budget. Indeed, such dramatic changes in the financial stability of the drug supply chain will very likely require the state of Maryland to appropriate additional dollars in order to stabilize both the Medicaid program and safety net providers.

Plainly put, while Board Member Anderson has stated that he views reduced values in 340B rebates as a provider consideration, it is not limited to provider entities as an impact. If patients from highly marginalized and disproportionately affected communities cannot get the services we need and see our providers due to lack of sufficient funding, we cannot get either the diagnoses or prescriptions we need to live and thrive. And to be as precise as possible in our concerns, CANN wishes to highlight that such negative impacts will absolutely prove most harmful to patients already struggling to have our healthcare needs met.

> *Section .06(B-5)*: **Domestic Reference Upper Payment Limit**
> It is problematic to set limits 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.

The Board's Consideration of QALYs or International Pricing Data Dependent upon QALYs Violates Federal Non-discrimination Rules

Earlier this year, the federal Department of Health and Human Services and Centers for Medicare and Medicaid Services finalized federal rules recognizing "quality adjusted life years" and similarly situated metrics as necessarily discriminatory toward persons with chronic health conditions and older patients. Those same rules, integrating protections under the Americans with Disability Act and Section 504 are directly addressed in terms of "cost containment" efforts as detailed below from 89 FR 4006, *Nondiscrimination on the Basis of Disability In Programs or Activities Receiving Federal Assistance* (Section: *Value Assessments [84.57]*);

> *Comment:*
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> *The Department requested comment on how value assessment tools and methods may provide unequal opportunities to individuals with disabilities. Numerous commenters indicated that value assessment methods could limit people with disabilities' access to health care goods and services, including pharmaceutical interventions, and expressed concern that the use of the QALY unfairly limited access to emerging pharmaceutical interventions that could extend the lives of people with disabilities.*
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> *Response:*
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> *While the nondiscriminatory use of value assessment is an important tool for health care cost containment, the Department agrees that discriminatory usages of value assessment harm people with disabilities and provide unequal opportunities.*
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> *Comment:*
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> *One commenter argued that the use of the QALYs and other methods of value assessment that frequently entail discounting the value of life extension on the basis of disability are not discriminatory because they are "only one step" in a process of decision-making, noting that policymakers also take into account other factors in their ultimate decision-making.*

Response:

Although recipients may make use of multiple factors to influence their decision-making, the use of a measure of value that assigns lower value to extending the lives of people with disabilities to determine eligibility, referral, or provision or withdrawal of an aid, benefit, or service can be nonetheless discriminatory.

These federal rules apply specifically to state Medicaid programs as recipients of federal assistance dollars. The Board *must* acknowledge these rules or risk running affront of federal authority on the issue.

> *Section .06(B-6)*: **International Reference Upper Payment Limit**
> We would like to reiterate previous concerns about this methodology. Drug prices paid in other countries should not be considered. 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, utilizing this data presents a potential backdoor insertion of QALY methodology which is prohibited.

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.

CANN recognizes the above issues are uncomfortable to consider and meaningfully integrating our feedback would require dramatic adjustments both to the Board's process and its current operation. However, the good-faith effort of the Board to improve access to and affordability of care for Marylanders is in dramatic risk because of the Board's and staff's failure to address these issues as previously raised by the public and, specifically, patient communities. We do not wish to see the public's trust or the legislative intent of the Board undermined because the Board is rushing headlong with pre-determined biases rather than an objective, systematic, and unbiased approach to the issues patients and the state of Maryland are facing. Codifying the current proposed rules as drafted, however, will not only result in a completely foreseeable cause of action for litigation, but it will destroy the last shreds of objectivity, cooperation with the public, and priority for patients the Board was tasked with meeting.

We urge the Board to reject both the process of these proposed rules and the problematic sections of the proposed rules as outlined above for the sake of Maryland's budget and patients.

Respectfully submitted,

Ranier Simons
Director of State Policy
Community Access National Network

On behalf of

Jen Laws
President & CEO
Community Access National Network