COMMUNITY ACCESS NATIONAL NETWORK

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March 13, 2024
Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715

Dear Members of the Maryland Prescription Drug Affordability Board,

About CANN: 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 supports for people living with HIV/AIDS and/or viral hepatitis through advocacy, education, and networking.

We write today, deeply concerned with the Board's suggestion to begin a "cost-review study" of the antiretroviral medications used for both treatment and prevention of HIV, Biktarvy. We wish to begin with recognizing that the naming a medication for "cost review study" does not necessarily indicate any final determination of "affordable" nor does it dictate any imposition of an "upper payment limit" or regulated rate setting by another name. However, we are concerned the Board lacks sufficient knowledge to make appropriate considerations regarding any antiretroviral, the public health programs served through 340B rebates, and the very carefully constructed fashion in which public health is funded. The long and short of our concern is imposing an arbitrary reimbursement rate will necessarily divest from health equity efforts and harm efforts to achieve certain public health goals. We will explain in detail below and are grateful for your time in reviewing the information provided.

340B Entities Will Be Negatively Impacted by a UPL

Concerns related to 340B previously voiced have not been sufficiently addressed. Similar to the misleading testimony offered by a witness to the Vermont Senate in February, those 340B Grantee entities discussing concerns with Board have been told the equivalent of "a UPL will not effect 340B". This is not true.

340B finds its value in rebates which ultimately reduce acquisition costs for certain covered entities after reimbursements have been made. Straight forwardly, a reduction in allowable reimbursement rates necessarily reduces the rebate value realized by these covered entities. An upper payment limit below current reimbursements, therefore, reduces the realized savings and revenues which may be reinvested into public health programs, particularly among federal grantees (including but not limited to the state's AIDS Drug Assistance Program - ADAPs, STI Clinic Grantees – 318 Grantees, and Federally Qualified Health Centers – 330 Grantees).

In the instance of ADAPs, 318 Grantees, and 330 Grantees, 340B programmatic revenues are central to program design. Indeed, for many of these grantees, without 340B, these entities would not otherwise qualify for their grantee status due to a lower likelihood of sustainability. Each grantee is required to provide planning of sustainable programmatic revenues in order to qualify for the federal grant.

Let us describe how these dollars are reinvested and why imposing a UPL is a threat to health equity and public health programming in specificity.

ADAP: Maryland's AIDS Drug Assistance Program received about $24 million from the federal government in 2021 according to the most recent program monitoring report from the National Association of State and Territorial AIDS Directors (NASTAD). Maryland, however, did not provide detailed budgetary reporting to NASTAD. Instead, we must look at reporting from similarly situated states. Few states actually provide any state matching dollars to their ADAP and when they do, those dollars are often less than 10% of the federal award. However, rebate revenues generated from the program tend to exceed 16% (often times, quite a bit more) additional value in sustaining the program. In another state that received about the same amount as Maryland did in federal award, the ADAP also generated about $10 million in rebate revenues – a near 50% additional value. That value is reinvested in providing no-cost to patient antiretroviral medications to patients *or* used to pay for approved plan premiums to further overall access to care for recipients in Maryland living at or below 400% of the Federal Poverty Level but above Medicaid qualifying income levels. Revenues generated from 340B via the state's ADAP means the ADAP is sustainable, serves half again as many patients as it would otherwise, and helps move the state to achieving its health equity and public health goals.

Imposing an upper payment limit would reduce the value of those rebates, thus reducing how many patients the ADAP might be able to serve. Remember, ADAP serves severely patients who would not otherwise be able to afford or access their HIV medications.

STI Clinic Grantees and Subgrantees: 318 Grants are awarded to state and local health departments which then subcontract out to local clinics with expertise in delivering services. These grants are often relatively small compared to ADAPs, with awards often barely reaching some hundreds of thousands of dollars rather than millions. These subgrantees are some of the largest public providers of pre-exposure prophylaxis (PrEP) in the country. For some clarity as to exactly how well these programs work, while many subrecipients receive some financial support for their programming, some of the subgrantees only qualify for 340B because of in-kind agreements – which might just be HIV rapid test kits. In turn, these subgrantees are so efficient at delivering HIV screening and enrolling appropriately identified patients into PrEP services that their entire program model is based off realizing 340B savings.

A UPL would have even more of a dramatic effect on 318 subgrantees than it would on the ADAP.

Federally Qualified Health Centers: 330 grantees have a dedicated mission to serve impoverished communities "regardless of ability to pay". 330 grantees are required to offer healthcare services with sliding fee scales, limited to no collection practices, and are a key gateway for patients who need the most help. Some FQHCs utilize their 340B savings to offer food assistance, transportation, even housing in some situations. Others use their 340B savings to expand programming to include mental health and substance use services, particularly when state dollars are not readily available to support these non-profit healthcare providers. Each site is specifically selected due to the nature of the area necessarily being "underserved" – to be direct FQHCs serve communities that are more Black, more Brown, more Woman, and more Queer than their hospital counterparts. And they do so, at times, using those same rebates to provide patients with no-cost medication. Indeed, FQHCs are some of the best stewards of the program.

A UPL would necessarily reduce the rebate values realized by FQHCs and reduce those entities' ability to serve the most marginalized of Marylanders.

The Board Must First Establish Access Monitoring Prior to Beginning Any "Cost Review Study"
In order to appropriately appreciate the patient experience with regard to the issue of "affordability", the Board must first understand that "affordability" is but one arm of "access". An "affordable" medication means nothing if a patient cannot access that medication.

The Board has previously expressed concern regarding maintaining access – a comprehensive view of the patient experience. However, the Board has not established any definition of access nor has the Board meaningfully engaged in access monitoring deliberations. This must be done prior to proceeding with any additional steps, including "cost review study" or imposing rate setting. "Cost" cannot be sufficiently explored without distinguishing between particular cost burdens and the drivers of those burdens. For example, is "cost" comprehensive of transportation concerns in rural areas which may be prohibitive of any cost-sharing a patient might face at a pharmacy counter? Is "cost" comprehensive of an under reimbursement a pharmacy may face, resulting in not being able to fill a patient's needed prescription? Does "cost" include the necessary diagnostics or the even the provider visit required to get a prescription in the first place? How does the Board intend to differentiate throughout any "study"? What entities will the Board employ to ensure access is not harmed under a UPL? Is "cost" assessed to include those savings realized by diverted hospitalizations? Will "cost" consider the burden patients may face if additional utilization management is imposed to prefer a particular medication selected by the Board for UPL? Will the Board consider the accessibility of manufacturer patient assistance programs in determining "cost" to patients?

These questions deserve clear, precise answers prior to beginning any "cost review study".

Lessons From Colorado
As an organization lending our expertise and voice to people living with HIV across the nation, CANN was deeply involved in the "affordability review" process of Genvoya in Colorado. Genvoya is similarly situated to Biktarvy is some ways – to be clear, Genvoya may not be prescribed for PrEP and is no longer "first line treatment". Biktarvy, however, can be prescribed as PrEP and is considered "first line" for the treatment of HIV. Colorado's Board spent more than 50 hours across a few short months, in a deeply flawed process. Patient impact surveys suffered from design bias, asking leading questions, were not well distributed, and were open – initially – for a mere 21 days. To put this into context, Ryan White needs assessment surveys take the better part of a year to fully grasp program impact. In addition to this, Colorado engaged in "small group meetings" of patients, caregivers, providers, and manufacturers throughout the review data gathering process.

It was, in a word, **traumatic** for patients desperately concerned about losing access to their medications. Hours upon hours were spent explaining that sufficient systems exist to blunt out-of-pocket expenditures for patients through a variety of ways, including public programs like the AIDS Drug Assistance Program.

All of this to arrive to the decision that Genvoya was "not unaffordable" to patients in Colorado and, indeed, imposing a UPL would potentially harm public health programming dependent upon 340B savings generation.

Conclusions
CANN appreciates the very noble goal of reducing patient cost burdens. We recognize "affordability" is an essential arm of "access" and, ultimately, access to care for people living with HIV is our greatest priority. We share this goal with the Board. The unfortunate reality is that Board was not empowered by the legislature with an appropriate tool to address issues of access. Addressing discriminatory plan design, PBM abuses, under

reimbursement already harming non-chain, independent pharmacies, curbing utilization management practices that delay and deny care – all of these would better serve Marylanders than the process before you.

We wish to be one hundred percent clear: a "cost review study" is harmful to patients on an emotional level. People living with HIV are disproportionately Black and Queer. We already face discrimination elsewhere in our lives, struggles to access care, and harmful policies and practices which hurt our ability to trust institutions of power, including the healthcare system writ large. Including this very Board. Engaging in a process which will ultimately ask the question "Are you worth our dollars?" is not going to improve that situation.

Even the thought of imposing a UPL is a "threat" to our access to care through the ADAP, STI Clinics, and FQHCs because of mechanisms of funding outside of this Board's purview. Reducing the value of 340B by imposing a UPL necessarily divests from marginalized communities.

It is with a very sincere shared interest we ask this Board to halt the "cost review study" process, any determination of medications for review, particularly Biktarvy, and consider the content laid above.

- Establish access monitoring metrics
- Establish access monitoring processes
- Study the potential impacts to 340B served programs and entities
- Ensure "cost review study" content is appropriately designed and unbiased
- Ensure "cost review study" processes will not disadvantage, deprioritize, or otherwise harm patients

There is good work to be done by this Board but it won't be found with a "cost review study" as currently described or a UPL.

CANN looks forward to working with the Board and we are readily available to staff to discuss our concerns and find collaborative solutions.

Ever in your service,

Jen laws
President & CEO
Community Access National network