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Dear Members of the Prescription Drug Affordability Stakeholder Council,

As background, **HealthHIV** is a national non-profit working with healthcare organizations, communities, and providers to advance effective HIV, HCV, STI, and LGBTQI+ health care, harm reduction, and health equity through education and training, technical assistance and capacity building, advocacy, communications, and health services research and evaluation.

And our work is purposefully connected to the broader HIV ecosystem—a network that supports not only clinical care but also the comprehensive well-being of individuals living with HIV.

The discussion regarding Biktarvy's affordability review and the potential imposition of an upper payment limit (UPL) is of genuine concern. We understand the Council's intent to make medications more affordable; however, we also recognize that the structure of such policies must carefully consider their broader impact—particularly on systems like the 340B program that are central to our public health response.

**Impact on the 340B Program and the HIV Ecosystem**

The 340B program is crucial for enabling covered entities, including Federally Qualified Health Centers and community-based supportive services agencies, to leverage 340B rebates and provide necessary services and medications to underserved populations. Although AIDS Drug Assistance Programs (ADAPs) are part of the ecosystem, they operate separately with their own funding mechanisms. The program's structure allows these entities to use savings from medication rebates to fund various health services—thus playing a pivotal role in our public health HIV ecosystem.

1. **Reduction in Rebate Value:**
   A UPL below current reimbursement rates could reduce the rebate values covered entities realize. This reduction directly impacts the savings and revenues these entities rely on to reinvest in public health programs. For Maryland's ADAP, which received approximately $24.494 million in state special funds FY 2022, these rebates add significant value, enabling the program to serve more patients and enhance overall access to care for individuals living below 500% of the Federal Poverty Level.

2. **Threat to Health Equity and Program Sustainability:**
   The potential reduction in rebate value due to a UPL could jeopardize the ability of programs like MD's ADAP to serve patients who critically depend on these services. For many grantees, the sustainability of their programs hinges on the 340B revenues. Any decline in these revenues threatens the very foundation of their operations and their mission to support health equity.

3. **Broader Implications for Public Health Programming:**
   Implementing a UPL could also have disproportionate effects on smaller subgrantees, such as those supported by 318 Grants, which are essential in delivering services like HIV screening and pre-exposure prophylaxis (PrEP). These entities are incredibly efficient, and their funding model is primarily based on

realizing 340B savings. This reliance on the rebate system emerged from a non-governmental response at the beginning of the epidemic. Reducing these savings could lead to significant service cuts, adversely affecting public health outcomes and undoing an ecosystem that has contributed to fewer new infections.

**Enhance Understanding of HIV Treatment Affordability: Key Considerations**

To fully understand the implications of a UPL on patient access to medications like Biktarvy, it is crucial to establish comprehensive access monitoring. This approach recognizes that affordability is just one dimension of access. Affordable medication that cannot be accessed by patients due to other barriers, such as delays in treatment initiation or administrative hurdles, does not truly serve public health needs.

**Potential Unintended Consequences:**

While Maryland has not detailed how a UPL might be implemented, it is clear that such a policy could lead to unintended consequences, including delays and interruptions in treatment. These disruptions can have far-reaching impacts—particularly for those relying on medications like Biktarvy for their HIV treatment.

If a UPL were set near the cost of multi-tablet regimens (MTRs) or even other DSHS single-tablet regimens (STRs), states and insurers might favor these less expensive regimens to contain costs. This could force patients, especially those who are stable on an STR, to switch to an MTR or a therapeutic alternative — alternatives that may not be suited, preferred, or part of the shared decision-making process. While the cost savings might look beneficial—or attractive to the payer on paper—this switch could disrupt treatment for patients who are well-managed on an STR, leading to potential adherence issues and negatively affecting viral suppression rates. *Remember this is a communicable disease.*

The economic implications of switching from STR to MTR under an UPL are highlighted by the pricing data in Table 22b of the DSHS Antiretroviral Treatment Guidelines [Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Department of Health and Human Services.] And while STRs like Biktarvy are priced at $3,795 monthly, generic components of a comparable MTR are significantly cheaper, even cumulatively. If a UPL encourages the use of these cheaper MTRs, patients, especially those stable on STRs, may be forced to switch, potentially disrupting their treatment and adherence leading to poorer health outcomes.

**Example**

In WA state, for example, setting the 340B argument partially aside, the real-world impacts of adherence are already evident in Washington State. The *HIV antivirals annual report* [Clinical Quality and Care Transformation. (2023). HIV antivirals annual report. Engrossed Substitute Senate Bill 5187; Section 211(46); Chapter 475; Laws of 2023. Health Care Authority. December 1, 2023] indicates a trend where a switch from MTR to STR might not just be a matter of convenience but also a factor in treatment effectiveness. The report shows a 7% higher viral suppression rate among patients on STRs than those on MTRs—93% versus 86% [Clinical Quality and Care Transformation, 2023]. This difference is not merely statistical but translates into real-world patient health impacts.

To put this into perspective, based on the report's data:

- 3,848 clients were diagnosed with HIV and had at least one prescription drug claim in 2021.
- Of these, 93% on STR would mean approximately 3,579 patients achieving viral suppression.
- In contrast, 86% on MTR would translate to about 3,309 patients being virally suppressed.

This means the 7% gap accounts for about 270 patients (3,579 - 3,309) who might not achieve viral suppression due to being on MTRs instead of STRs. Implementing a UPL that could push patients from STRs to MTRs risks complicating the treatment regimen and potentially increasing the number of patients not virally suppressed by hundreds, depending on the total population size. This shift could lead to more frequent medical needs/visits, higher medical case management (and non-medical) needs, and increased overall healthcare costs—effectively setting back efforts to manage HIV more effectively and considerably in terms of people's quality of life. The report underscores the importance of considering these clinical outcomes when setting policies that affect drug payment structures. Until real-world impact considerations are monitored by this Council and PDAB, these concerns remain significant and warrant careful attention.

It must be pointed out that there are many reasons for the 7% difference: resistance issues, preference, stability, fewer side effects, shared decision-making, etc. *To be clear*, we (this Council, the PDAB) do not know the specific reasons for the 7% difference in viral suppression rates between STRs and MTRs, as stated by the Health Care Authority, but it represents a real and impactful difference nonetheless. And that warrants more review, dialogue, and transparency before any affordability review imposing a UPL is undertaken on the most widely used STR.

**Weigh the Practical and Systemic Implications on Patient Care and System Efficiency**
In light of the potential challenges a UPL introduces, it is crucial to prioritize patients—*particularly* those with high-acuity health issues, to prevent any disruption in their continuum of care.

The introduction of a UPL could necessitate increased involvement from non-medical and medical case managers and multidisciplinary teams to address these patients' heightened needs effectively.

*This approach involves maintaining consistent patient care and managing the additional costs these supports impose on the healthcare system.*

Transitioning patients from one medication to another—especially under the constraints of a UPL requires careful planning and coordination to ensure continuity of care and system efficiency. For high-acuity patients, this might mean enhanced engagement with medical case management beyond the typical scope of services provided by programs like Ryan White. These patients often need additional support to manage the transition, including more frequent consultations, personalized adherence strategies, and direct intervention by healthcare professionals to mitigate any risks associated with changing treatments.

If these 340B savings diminish due to a UPL, there could be a gap in funding for essential services and medications. The state might then face pressure to "backfill" or compensate for these financial shortfalls to ensure PWH continues to receive necessary care without disruption—disruption that, if adherence issues arise from these decisions, further

carries potential criminal liability on patients through COMAR § 18-601.1 (whereas the penalty "**subject to a fine not exceeding $2,500 or imprisonment not exceeding 3 years or both")**.

Furthermore, logistical hurdles such as ensuring the availability of new medication at local pharmacies, adjusting pickup times, and handling formulary replacements need meticulous attention to minimize disruptions to patient care. Each step, from managing the inventory of the old medication to smoothly integrating the new one, needs to be strategically planned to avoid treatment gaps, unnecessary waste, and additional strain on our healthcare resources.

These necessary adjustments and the associated costs underscore the importance of a thoughtful approach when considering the implementation of a UPL. It's about more than just the direct cost of medication; it's about ensuring a seamless transition that maintains the quality of care and life for all patients—particularly those most vulnerable. Remember, each PWH's situation is unique, and changes should be made carefully to ensure continuity of care and avoid any negative impacts on treatment outcomes.

**Conclusion:**

As you continue your deliberations, we urge the Council to consider the full scope of implications that a UPL on Biktarvy could have on the HIV ecosystem and the broader public health landscape in Maryland. A thoughtful approach that includes a preliminary study of access and the potential impacts on covered entities is essential.

We appreciate the opportunity to share our perspectives and look forward to engaging further with the Council on this critical issue. Thank you for considering our views as you work towards policies that balance patient protections and affordability together with the need to maintain robust and equitable public health programming.