Maryland Prescription Drug Affordability Board
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As an advocacy coalition comprised of HealthHIV, Community Access National Network (CANN), and the AIDS Institute (TAI), we are dedicated to the well-being of people living with HIV and improving access to care for people living with HIV. Through this lens, we are writing to express our deep concerns and provide an HIV ecosystems analysis regarding the Maryland Prescription Drug Affordability Board's (PDAB) Cost Review Study Process—as well as the evolving landscape of Medicare Part D and the impact of the Inflation Reduction Act (IRA) on HIV treatment accessibility and affordability, in relation to the MD PDAB.

While a PDAB *could* contribute positively to the broader goal of making prescription drugs more affordable, its role and effectiveness in specifically addressing the challenges associated with employer-sponsored and high-deductible health plans are more complex and may have limitations that lead to unintended HIV ecosystems challenges. Direct interventions or regulations that specifically target the formulary and cost-sharing policies of these plans would be more appropriately necessary to effectively address the issues of limited drug formularies and high coinsurance rates impacting HIV medication adherence as opposed to targeting reimbursement rates of selected medications. Keeping in mind there are no "cookie-cutter" treatments for most chronic diseases and utilization management reviews have already been put in place in by insurers before non-generics are prescribed.

Maryland's PDAB aims to enhance the affordability of prescription drugs for state residents. Its primary objectives include reviewing drug list prices to identify unjustifiably high costs, setting upper payment limits for certain expensive drugs, and analyzing trends in the prescription drug market. The PDAB also has the power and responsibility to make policy recommendations to the state legislature, engage with stakeholders for input, and focus on transparency by reporting its findings. Additionally, it plays an educational role in informing the public and policymakers about drug pricing and its impact on healthcare affordability. This initiative reflects Maryland's commitment to tackling the challenge of rising drug costs and improving healthcare accessibility for its residents.

There are several considerations and potential limitations of a PDAB in this context:

1. **Scope and Authority Limitations**: Maryland's PDAB focus on monitoring and controlling drug prices at a broader level may not have the direct influence over the specific formulary decisions and cost-sharing structures of private insurance plans, including employer-sponsored and high-deductible plans. And while MD's PDAB is meant to work

towards reducing overall drug prices, it may have limited capacity or insufficient statutory power to address the specific issue of limited formularies and high coinsurance rates that are characteristic of these plans.

Regulatory agencies responsible for overseeing health insurance plans operating in Maryland, such as the Maryland Insurance Administration, will play a crucial role in enforcing compliance with the mandate. So too, does the Maryland Department of Health (MDH). Involving the MDH in PDAB conversations at an intra-agency level is necessary to ensure alignment with existing healthcare policies and regulations, especially those included in the Statewide Coordinated Statement of Need. Furthermore, MDH houses particular subject matter expertise and insights which may not afforded otherwise; including but not limited to access to patients readily engaged in public policy setting processes, knowledge of rebate generation and utilization in public payer programs, and insights on intended and unintended consequences of particular policy decisions affecting the access to care.

As such, the PDAB, in consultation with MDH and appropriate health insurance regulators and stakeholders, should develop comprehensive Cost Review Study Process guidelines outlining the requirements for the inclusion of FDA-approved and HHS treatment guideline drug formularies across all health insurance plans. The PDAB and MDH may need to allocate additional staff or hire consultants with expertise in drug formulary regulations and policy development. Implementing and monitoring QI/QA compliance with any PDAB policy may necessitate the development or enhancement of information systems to track formulary changes and ensure transparency. To date, this is not yet discussed.

2. **Complexities in Negotiating Drug Prices**: MD's PDAB aims to make drugs more affordable by negotiating or recommending lower prices. However, this process can be complex and may not immediately translate to lower out-of-pocket costs for patients, especially in the short term. Insurance companies and pharmacy benefit managers, who play a key role in determining formularies and setting coinsurance rates, might not always align these changes with MD's PDAB recommendations or negotiations. For example, statutory limitations may not require "pass through" of savings and no such limitations exist on payor retention of savings (or rebates). Ultimately, we ask for consideration that certain actions could actually have a negative impact on lifesaving medication access for patients.
3. **Variability in Employer-Sponsored Plans**: Employer-sponsored plans can vary significantly in their coverage and cost-sharing mechanisms. MD's PDAB actions might not uniformly impact all such plans, leading to continued disparities in drug accessibility and affordability for different groups of employees.

4. **Challenges in High-Deductible Plans**: High-deductible plans are designed to have lower premiums but higher out-of-pocket costs until the deductible is met. Even if the MD PDAB successfully lowers healthcare associated treatment and drug prices (*something we can all agree on*), patients in high-deductible plans may still face significant upfront costs for HIV medications, which could continue to impact adherence and health outcomes.

5. **Potential for Indirect Consequences**: Efforts by the MD PDAB to reduce drug prices might lead to unintended consequences, such as scaling back on research and development of new drugs, including HIV medications which treat a **communicable disease state**—as well as rare and orphan disease. This could potentially impact the availability of innovative treatments in the future. Additionally, other unintended consequences include potentially reducing rebate revenues which are used to extend necessary support services and sustain publicly funded service providers. Reduction of rebate revenues may negatively impact the ecosystem of care patients have come to rely upon.

6. **Time Lag in Impact**: The processes and negotiations undertaken by the MD PDAB to reduce drug prices take time. The immediate needs of individuals relying on HIV medications might not be quickly met, especially in scenarios where timely access to medications is critical for health and preventing transmission.

Expanded Context of Concern:

1. **Impact of MD's PDAB Cost Review Process on HIV Treatment Accessibility:**

    - **Potential Targeting of HIV Medications:** The selection criteria for cost review, focusing on total gross spending and WAC increases, may inadvertently prioritize HIV medications. This can lead to restricted access or negative pricing alterations, impacting the continuum of care for individuals relying on these medications.

    - **Implications for Innovation in HIV Therapy:** The emphasis on cost containment might deter investments in innovative HIV therapies. This is concerning given the critical role of advancements in transforming HIV from a terminal to a manageable chronic condition.

2. **Disparities in Healthcare Entry Points and Utilization Management:**

    The Maryland PDAB's mandate to review and potentially regulate drug prices plays a crucial role in shaping the overall pharmaceutical market. Its decisions can significantly influence the pricing strategies of pharmaceutical companies, which in turn affects how employer-sponsored health plans cover various medications, including those for HIV.

    The interplay between PDAB's actions, pharmaceutical pricing strategies, and the complex dynamics of employer-sponsored health plans underscores the need for careful consideration to ensure that efforts to control drug costs do not inadvertently restrict timely access to essential HIV treatments and prevention.

Disparate Healthcare Access Points and Out-of-Pocket Costs for HIV Patients Across Various Platforms:

The landscape of healthcare access for HIV patients in the United States is marked by considerable variability across different platforms, each presenting unique challenges in terms of out-of-pocket (OOP) costs and medication accessibility. For instance, Medicare beneficiaries, particularly those without low-income subsidies, often grapple with high OOP costs due to the program's design, which includes deductibles and co-insurance. Despite the Six Protected Classes policy ensuring coverage for most HIV medications, the financial burden remains significant for many. Medicaid, another critical source of coverage for HIV patients, especially for those with limited financial resources, typically provides broad coverage for HIV medications. However, state-implemented utilization management (UM) techniques like prior authorization and step therapy can delay access to necessary treatments, potentially increasing indirect OOP expenses such as transportation costs. These "cost-containment" strategies may be exacerbated under government limited reimbursement rates and can and do have the effect of prioritizing "older" medications, including multi-pill regimens. Employer-sponsored plans, while offering coverage, often come with preferred drug formularies and high coinsurance rates, leading to substantial OOP costs for HIV medications. This scenario may cause patients to delay or skip doses due to financial constraints, adversely affecting their health outcomes. On the other hand, programs like the Ryan White HIV/AIDS Program provide crucial support by offering medication assistance and covering costs not met by other payers, playing a vital role in ensuring access to HIV medications for low-income patients and those with no other coverage options.

Potential Impact of a Prescription Drug Affordability Board (PDAB) on the HIV Healthcare Ecosystem:

The introduction of a PDAB in this already complex and fragmented healthcare landscape for HIV patients could have mixed implications. While the primary intent of such a board is to regulate and reduce drug prices, its actions could inadvertently disrupt the delicate balance within the HIV healthcare ecosystem. For example, if PDAB's pricing regulations lead to reduced profitability for certain HIV medications, pharmaceutical companies might respond by scaling back on research and development of new treatments or limiting the distribution of existing ones. This could particularly impact innovative and next-generation HIV therapies, slowing down the progress in HIV treatment advancements. Additionally, PDAB's price controls could affect the reimbursement rates within Medicare and Medicaid, potentially leading to changes in formulary placements and UM practices. This might result in restricted access to certain HIV drugs, forcing patients to switch to less

preferred treatments or other disruptions in care. In employer-sponsored plans, PDAB's influence might lead to changes in formulary designs, potentially narrowing the range of available HIV medications and impacting patients' ability to continue with their existing, effective treatment regimens. These actions are coined as "non-medical switching"; such switching is anecdotally associated with poorer retention in care and lower patient satisfaction. Moreover, such regulatory interventions could also influence the funding and operational dynamics of programs like the Ryan White HIV/AIDS Program, which might need to adapt its assistance offerings in response to the shifting drug pricing landscape. Thus, while PDAB's efforts could lead to overall cost reductions in some moderate term, the potential unintended consequences on the HIV treatment accessibility and the broader public health goal of managing HIV effectively need to be carefully considered and addressed as harm to this space may produce *increased* systems costs in the future.

Potential Unintended Impact Could Result in:

1. **Negative Influence on Pharmaceutical Pricing**: PDAB's reviews and potential price regulations may compel pharmaceutical companies to adjust their pricing strategies. While this could lead to lower list prices for HIV medications, there is a possibility that companies might offset these regulations by altering rebate structures or shifting costs in other ways. This could inadvertently impact the cost-sharing mechanisms in employer-sponsored plans, which often base patient out-of-pocket costs on the list price of medications.
2. **Impact on Formulary Design**: Employer-sponsored plans rely on formularies to manage drug costs. PDAB's pricing recommendations may influence which HIV medications are included in these formularies. If PDAB's actions lead to significant price reductions for certain HIV drugs, these medications might become more favorable to formulary committees due to their lower cost, potentially improving accessibility for patients. Keeping in mind that HIV treatment is not one size fits all due to resistant mutations. Conversely, if price controls lead to a perceived reduction in value or rebate agreements for certain drugs, this might result in limited formulary placement, reducing patient access to these medications.
3. **Negotiation Dynamics**: Employer-sponsored plans often engage in negotiations with pharmaceutical companies and pharmacy benefit managers (PBMs) to determine coverage and pricing. PDAB's activities might alter the dynamics of these negotiations, potentially benefiting patients through lower prices or, alternatively, limiting bargaining power and leading to reduced coverage options for certain HIV medications.
4. **Cost-Sharing and Affordability**: Even if MD's PDAB actions do lead to lower list prices for HIV medications (and the research is not yet definitive), the structure of employer-sponsored plans, particularly those with high deductibles, may still result in significant out-of-pocket expenses for patients. The actual impact on affordability for individuals depends

on how these plans adjust their cost-sharing mechanisms in response to PDAB's pricing interventions.

5. **Access to Innovative Treatments**: MD's PDAB focus on cost containment might also influence how new, potentially more effective HIV treatments are priced and covered by employer-sponsored plans. If PDAB's price controls are perceived as too restrictive, it might discourage pharmaceutical companies from introducing innovative treatments into the Maryland market, affecting patients' access to the latest HIV therapies.

Potential Implications of the Prescription Drug Affordability Board (PDAB) Actions in Relation to Medicare Part D and the Inflation Reduction Act (IRA) on HIV Medication Accessibility:

1. **Changes in Medicare Part D Prescription Drug Plans (PDPs):** The consolidation and reduction in the number of PDP options pose significant challenges, particularly for older individuals living with HIV. These changes can lead to restricted availability of essential HIV medications and force patients into navigating complex plans with potentially less favorable cost-sharing terms. This scenario might disproportionately affect those who rely on specific HIV treatments not widely covered across different plans.

2. **Rising Costs in PDPs vs. MA-PD Shifts:** As premiums for PDPs increase, the contrasting rise in Medicare Advantage Drug Plans (MA-PDs) offering lower premiums presents a nuanced challenge. While ostensibly beneficial, these MA-PDs might impose network restrictions that could limit access to preferred HIV treatment providers and medications. This shift could place a financial strain on patients who might have to choose between affordable plans and those that offer comprehensive HIV medication coverage.

3. **Implications of the Inflation Reduction Act (IRA):** The IRA introduces crucial measures like out-of-pocket spending caps and manufacturer discounts, which are intended to alleviate financial burdens for patients. However, the direct impact of these measures on the cost and availability of HIV drugs remains uncertain and warrants close monitoring. It's essential to assess whether these IRA provisions translate into tangible benefits for HIV patients, particularly in terms of reducing their out-of-pocket expenses for critical medications.

4. **High Costs and Complexities in Medicare:** The out-of-pocket expenses under Medicare's structure, especially for beneficiaries without low-income subsidies, remain a significant barrier. These high costs can be challenging for HIV patients, impacting their ability to afford necessary treatments and maintain consistent medication adherence.

Utilization Management (UM) in Medicaid: The impact of Utilization Management (UM) in Medicaid, especially on individuals who are dual eligible (qualified for both Medicare and Medicaid) and may experience "churning" between coverage plans, is a complex issue with several critical implications:

1. **Disruption in Medication Continuity**: Dual eligible individuals, particularly those who churn between different coverage plans, can face significant disruptions in their medication continuity. This is particularly problematic for HIV patients, where consistent medication adherence is crucial. When transitioning between Medicare and Medicaid, the differences in formulary coverage and UM requirements (like prior authorization or step therapy) can lead to gaps in medication access. This can result in periods where patients are unable to take their HIV medications as prescribed, potentially leading to health deterioration, increased morbidity and mortality as well as increased risk of HIV transmission.

2. **Navigational Challenges**: Dual eligible individuals often have to navigate two complex systems with different rules and coverage details. This can be particularly challenging for those without adequate case management support, such as individuals not enrolled in Ryan White programs or lacking targeted case management from Title XIX. The need to frequently adjust to different UM requirements, formularies, and cost-sharing structures can be overwhelming and lead to lapses in treatment adherence.

3. **Increased Administrative Burden**: The process of obtaining prior authorizations or fulfilling step therapy requirements can be more burdensome for dual eligible individuals. They may need to go through these processes multiple times as they churn between Medicare and Medicaid, leading to delays in getting the necessary HIV medications and increased administrative workload for healthcare providers.

4. **Financial Implications**: While dual eligible individuals are typically protected from high out-of-pocket costs, the churning between plans can lead to temporary financial burdens. For example, they might face unexpected costs due to differences in coverage between Medicare and Medicaid, or during the transition phases, especially if there are delays in re-establishing their Medicaid eligibility.

5. **Impact on Health Outcomes**: The inconsistency in medication access due to churning and UM barriers can have serious health implications for HIV patients. Interruptions in HIV treatment can lead to viral rebound, development of drug resistance, and overall poorer health outcomes. This is particularly concerning given the public health goal of maintaining viral suppression in HIV patients to improve health and reduce transmission. Again, in these situations, system costs are increased in the longer-term due to intensive "salvage" therapies necessary to stabilize patients.

6. **Need for Streamlined Processes**: There is a critical need for more streamlined and coordinated processes between Medicare and Medicaid to minimize the challenges faced by dual eligible individuals. This includes ensuring continuity of medication coverage, simplifying UM processes, and providing robust case management support to navigate the complexities of dual eligibility.

7. **Restrictions in Employer-Sponsored and High-Deductible Plans:** The limited drug formularies and high coinsurance rates characteristic of many employer-sponsored and high-deductible health plans can lead to

elevated out-of-pocket costs for HIV medications. These financial barriers can significantly affect medication adherence and overall health outcomes, especially for those who cannot afford the high upfront costs or who find their prescribed HIV medications not included in their plan's formulary.

MD's Potential Impact on HIV Treatment Accessibility and Innovation in Therapy:

1. **Risks of Cost Review Process:** The criteria for drug selection based on total gross spending, patient out-of-pocket costs, and Wholesale Acquisition Cost (WAC) increases risk inadvertently targeting HIV medications. This could lead to restricted access or significant alterations in pricing structures, negatively impacting patients reliant on these life-saving drugs.

"Stifling of Innovation": The focus on cost containment could dissuade pharmaceutical companies from investing in the development of new HIV treatments or improving existing ones, potentially stifling innovation in a field where advancements have been pivotal.

The concern about stifling innovation in HIV treatments due to cost containment efforts is a nuanced issue that involves multiple stakeholders. While pharmaceutical companies are central to innovation, it's not solely their responsibility.

State PDABs, as part of the broader healthcare ecosystem, can contribute to striking a balance between cost containment and innovation. Their role in ensuring reasonable drug pricing can improve access to treatments, incentivize value-based innovation, and create an environment where pharmaceutical companies can thrive while addressing public health needs.

Collaboration among all stakeholders is key to achieving this delicate balance. This involves:

1. **Shared Responsibility for Innovation**: Innovation in the field of HIV treatments is a shared responsibility involving multiple stakeholders, including pharmaceutical companies, government agencies, research institutions, and patient advocacy groups. While pharmaceutical companies are integral to drug development, government bodies like the state PDABs also play a role in shaping the environment in which innovation occurs. By focusing only on cost containment, PDABs can inadvertently impact the incentives for pharmaceutical companies to invest in HIV treatments. Therefore, it's a collective responsibility to strike a balance between cost containment and fostering innovation.
2. **Market Incentives**: Pharmaceutical companies are profit-driven entities, and market incentives heavily influence their decisions to invest in research and development. High prices for medications can be a significant driver of profitability. However, it's crucial to ensure that profit incentives align with public health goals. PDABs can contribute to this alignment by ensuring that drug prices are reasonable and justifiable, which can promote a sustainable market for HIV treatments without compromising innovation. However, to

affect this type of change, PDABs must have the power to ensure any "savings" are passed back to sponsors and patients.

3. **Balancing Access and Innovation**: Access to HIV medications is a fundamental public health concern. High drug prices can create barriers to access, leading to adverse health outcomes and increased transmission rates. PDABs, by addressing drug pricing concerns, can improve access to existing treatments. This, in turn, can reduce the need for costly hospitalizations and other healthcare interventions associated with uncontrolled HIV, potentially offsetting the financial impact on pharmaceutical companies.
4. **Incentivizing Value-Based Innovation**: PDABs can encourage pharmaceutical companies to focus on value-based innovation rather than incremental changes in drug formulations. By linking drug prices to demonstrated clinical benefits and outcomes, PDABs can incentivize pharmaceutical companies to invest in treatments that genuinely improve patients' lives. This approach aligns innovation with the goal of improving healthcare outcomes and managing costs effectively.
5. **Research Funding**: Government bodies and research institutions can also play a pivotal role in advancing HIV treatment innovation. Public funding for research and development can mitigate some of the risks associated with pharmaceutical companies' reluctance to invest in niche or less profitable areas of healthcare. PDABs can advocate for increased research funding and partnerships to support innovation.

Recommendations for MD's PDAB Policy Improvement:

1. **Advocacy for Patient-Centric Healthcare Plans**: Develop plans that emphasize comprehensive coverage for HIV medications, focusing on reducing out-of-pocket costs and enhancing access.
2. **Transparent Pharmaceutical Pricing and Rethinking UM Practices**: Push for transparent pricing strategies for HIV medications and advocate for the reevaluation of UM practices that delay access to essential treatments. Insurers and PBM's should not be interfering with the patient-provider relationship, medication choice, steering patients to their preferred (and PBM-owned or associated) pharmacies, or otherwise negatively affecting patient access to timely, individualized care.
3. **Inclusive Representation in Policy Making**: Include representatives from the HIV patient community in bodies like the Stakeholder Council to ensure policies reflect the lived experiences and needs of those impacted. This has been a particular issue in other states' PDABs. Patients seeking involvement have returned to their legislatures feelings unheard and not meaningfully considered in process or decisions.
4. **Fostering Innovation in HIV Treatment**: Support policies that encourage ongoing research and development in HIV therapies, which are vital for the continued advancement of treatment options.
5. **Uniformity in Coverage Across Healthcare Platforms**: Call for harmonized coverage policies across Medicare, Medicaid, and private insurance to guarantee equitable access to HIV medications.

6. **Incorporation of Research into Policy Decisions**: Use real-world and peer-reviewed research and findings from studies like "*Nonadherence to Any Prescribed Medication Due to Costs Among Adults with HIV Infection*" (United States, 2016–2017 Linda Beer, PhD, corresponding authors: Yunfeng Tie, PhD, John Weiser, MD, and R. Luke Shouse, MD) to help contextualize and inform policy decisions, emphasizing the impact of financial barriers on medication adherence.
7. **Targeted Subsidy Programs for HIV Medications**: PDAB could advocate for and facilitate the establishment of targeted subsidy programs specifically for HIV medications. These programs would aim to reduce the out-of-pocket costs for HIV patients, especially those under high-deductible health plans or employer-sponsored insurance lacking comprehensive HIV medication coverage. By providing direct financial assistance or negotiating with pharmaceutical companies for lower prices for these critical drugs, these subsidy programs could ensure that financial barriers do not hinder access to essential HIV treatments. This approach would also alleviate the pressure on patients navigating the complexities of Medicare and Medicaid, ensuring more uniform access across different healthcare platforms.
8. **Mandatory Inclusion of Comprehensive HIV Drug Formularies in All Health Plans**: Another significant action could be the implementation of policies mandating the inclusion of comprehensive HIV drug formularies in all health insurance plans, including employer-sponsored and high-deductible plans. This policy would ensure that a wide range of HIV medications, especially newer and more effective treatments, are available to patients irrespective of their insurance type. PDAB, in collaboration with healthcare regulators, could develop guidelines for these formularies, ensuring they meet the diverse needs of HIV patients and keep pace with advancements in HIV therapy.
9. **Incentivizing Research and Development of HIV Medications**: To counter potential negative impacts on pharmaceutical innovation due to pricing regulations, PDAB and other regulatory bodies could propose incentives for the research and development of new HIV medications. These incentives could take the form of tax credits, expedited review processes for HIV drug approvals, or extended patent protections for breakthrough therapies. Such measures would encourage pharmaceutical companies to continue investing in the development of innovative HIV treatments, ensuring the sustained progress of HIV therapy research. Additionally, these incentives could be tied to agreements ensuring reasonable pricing and broad accessibility of these new medications upon their release, balancing the need for innovation with the imperative of affordability.

Conclusion:

Addressing these multifaceted issues requires a comprehensive and informed approach. Our advocacy emphasizes the development of healthcare policies that balance affordability with the need for robust and innovative HIV treatment options while not sacrificing access to treatment and medications. We advocate for a collaborative approach to ensure the best outcomes for individuals living with HIV, grounded in a deep understanding of the unique challenges they face.

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We appreciate your attention to these critical issues and remain committed to engaging constructively with the Board and other stakeholders to improve the lives of those affected by HIV.

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About Community Access National Network:

The Community Access National Network (CANN) is a 501(c)(3) national nonprofit organization (formerly incorporated under the "Ryan White CARE Act Title II Community AIDS National Network") working 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. These services must be affordable to the people who need them regardless of insurance status, income, or geographic location.

About HealthHIV:

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

About The AIDS Institute:

The AIDS Institute began as a grass roots community mobilization effort in 1985. Over the years, The AIDS Institute has expanded its vision to become a respected national leader dedicated to supporting and protecting health care access for people living with HIV/AIDS, Hepatitis, and patients living with chronic diseases.

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