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

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Maryland Prescription Drug Affordability Stakeholder Council
6900 Science Drive, Suite 112-114
Bowie, MD 20715

Dear Members of the Maryland Prescription Drug Affordability Stakeholder Council,

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.

On behalf of the patients CANN serves across the nation and, in particular, Marylanders living with HIV, we write today with great concern regarding the selection of medications for "affordability review", particularly Biktarvy – an antiretroviral (ARV) medication utilized for both the treatment and prevention of HIV.

ARVs Are Not Interchangeable

Due to the nature of HIV, antiretroviral medications are not interchangeable. Non-medical switching is ill-advised and potentially detrimental to both individual patient outcomes and the health of the community. When a person is diagnosed with HIV, the process for identifying the most clinically appropriate medication is two-fold: 1) genotype-specific testing is done to ensure the medication used is effective and ARV resistance to that particular medication does not already exist and 2) patient tolerability is sufficient. Providers and counselors "walk" a patient through the necessities associated with either a daily, single tablet regimen or an every-other-month injectable medication. Should a patient experience adherence barriers, regardless if those barrier originate within their personal lives or as a by-product of payor barriers (like prior authorization), the potential developing ARV resistance manifests. Once a patient develops resistance to a particular ARV, that **ENTIRE** class, regardless of brand, is now no longer a viable treatment for that patient.

It is inappropriate and defeatist to public health goals and individual patient success to risk imposing any barrier to care, including payor prioritization based upon reimbursement rates or, more specifically, payor profitability per medication.

Patient and System "Affordability" Rests with PBM and Formulary Design, NOT Reimbursement Rates

Underappreciated under the lens of "capping reimbursement rates", are particular problems associated with for-profit Pharmacy Benefit Managers (PBMs) and their role in "extracting value" from the public health funding stream and within the entire ecosystem of both patient affordability and, more broadly, access to care.

PBMs, not manufacturers or even wholesalers, determine the charges and costs associated, formulary positioning, and administrative process which amount to burden for individual patients. This design has already had an adverse impact in relation to the drug pricing provisions of the Inflation Reduction Act (IRA). This is evidenced by Novo Nordisk's recently announced withdrawal of Levemir, an insulin product, from the United States' marketplace. In announcing the withdrawal, the manufacturer announced "significant formulary losses impacting patient access" – or more directly, PBMs withdrawing coverage of the medication because it was no longer profitable to the payor after a reduction in list price.

Imposition of an "upper payment limit" may have similar effects, regardless of particular therapy. If the Maryland PDAB or PDASC are to consider any study of "cost" or "affordability", they must first consider adverse actions already affecting patient and system affordability and how those may be compounded without more sufficient guardrails in pharmacy benefit designs.

APCD Data is Incomplete and Questionable

All Payor Claims Databases (APCD) are not a complete picture of the patient experience or costs to systems. Rather, those data are merely what payor present as justification for charges to patients. The credibility of these data, or lack thereof, is worth noting as the federal Congress and several states are currently or have historically investigated the self-dealing nature of PBMs. Indeed, AG David Yost of Ohio has lead the way in the nation on this issue and, as recently as two years ago, then-AG Jeff Landry of Louisiana investigation one of the largest PBMs and their relationship with the primary carrier for self-dealing and inflated pricing to avoid the Affordable Care Act's Medical Loss Ratio rule.

Further, these data do not sufficiently capture the provider or patient costs (both tangible and intangible) associated with prior authorizations or step therapy. These costs, while not captured by APCD data, are meaningful and considered from the patient and system lens. While challenging to capture the costs associated for patients, the American Medical Association has invested in measuring the "system" cost to providers associated with punitive pharmacy benefit design via its Prior Authorization Physician Survey. Data contained therein found that prior authorization resulted in the potential or even likelihood of treatment abandonment 80% of the time. Similarly, physician offices reported an average of nearly two full days of staff and labor per week dedicated to managing prior authorizations. This is, again, a very tangible "cost to system" which may be even more adversely affected by instituting an upper reimbursement limit.

Additionally, APCD data does not sufficiently capture denials of coverage. ADPC data does not capture rebate data and even rebate data presented by manufacturers will not capture which, how much, or if any rebates are passed onto patients or employers, absorbed as profit for PBMs, or how those rebates are used to influence formulary position and thus cost-sharing. APCD data will not capture manufacturer patient assistance program design or sufficiently tell the story of how manufacturers, government programs, or private charitable entities

cover costs and reduce burden for patients. And without extraordinary outreach to patients, the cost review process will not capture this experience in a sufficiently quantifiable way, as we saw in Colorado.

A UPL Will Harm Public Health Funding and Thus Exacerbate Health Disparities

Because of how public health is funded, both by the 340B Drug Discount Program and by Medicaid rebates (including those Federal matching dollars), singularly focused action on reimbursement rates **ONLY** threaten to harm patients and the healthcare ecosystem writ large. The value of these rebates and the quantifiable federal matching dollars which allow reinvestment into marginalized communities are realized on dollars already spent. There is NO ability to recoup these funds "after the fact", once a reimbursement rate is reduced.

Necessarily, this means, that an upper payment limit will reduce available dollars to 340B funded entities and the state's Medicaid program.

More directly, a reduction in reimbursement rate alone, rather than a comprehensive address of pharmacy benefit design, will divest from the most marginalized and most vulnerable patients, families, and communities in Maryland. Imposing an upper payment limit will harm programs funded by these mechanisms by reducing dollars available to reinvest in these programs, including but not limited to free pop-up clinics, health awareness programs, and direct service programs like those found within Federally Qualified Health Centers, and, in particular, the state's AIDS Drug Assistance Program.

Maryland's PDAB and PDASC Must Pivot to Assessing the Honest Barriers Patients Face

Because of the complex mechanisms of public health funding, the nature of counterintuitive unintended consequences associated with healthcare and public health funding, and because, ultimately, the idea of a PDAB was sold on improving access to care for Marylanders – which a UPL will not do – the PDAB and PDASC should consider requesting a broader authority, without a prescribed mechanism of action, to more sufficiently study the nature of cost drivers for patients, the healthcare ecosystem, and the state itself prior to taking ANY additional action.

Failing to "pause" will harm patients on a personal level. We've already seen this in Colorado. Indeed, despite being told for more than a year to ask the question of "what happens if the UPL is set below acquisition cost?", the Colorado PDAB failed to do so – until this month. At which in point in time, patient concerns regarding continued accessibility were only finally starting to be heard. This after more than 50 hours of meetings and testimony and tears and honest fear for the lives and well-being of their families, were Colorado patients only beginning to be heard. Marylanders deserve better than this process.

Similarly, after nearly two years of the same healthcare and public health funding concerns, the Oregon PDAB is being faced with having to answer regarding system costs associated with reduced rebate funding necessary to run public programs. Some stakeholders are attempting to negotiate additional state funding for the state's AIDS Drug Assistance Program but the concerns relative to FQHCs are yet to be addressed and they are becoming loud and clear.

It is incumbent of the Maryland PDAB to heed these warnings sooner rather than later and not repeat the failures of other states attempting the same process. These concerns are not ill-borne nor are they over-inflated,

rather they reflect the reality of the landscape as it is today. Far too much of the posturing from certain voices on your board seek to wave off the concerns associated with drug shortages or to inaccurately and over-simplify our healthcare funding process by, rather offensively, relating life-saving medications to "bread". This is dismissive of legitimate concerns and, frankly, should be its own warning to the PDAB and PDASC as to insufficient nature of the expertise currently influencing the posture of PDAB and PDASC.

You well know these things are not as simple as "bread". Patient lives are on the line.

The intentions of the PDAB and PDASC are noble. Those intentions should be respected. Patients and providers, especially those with policy expertise, deserve the same respect as we ring pertinent alarm bells or, for your benefit, share our experiences from other states engaging in the same process.

CANN looks forward tow working with the PDAB and PDASC, sharing our experiences from other state regarding PDABs, and ensuring patient experiences and voices are the highest priority of Maryland's PDAB.

Ever yours in service,

Jen Laws
President & CEO
Community Access National Network